Project ethics and governance review process

Introduction

This project ethics and governance review process ensures that appropriate arrangements exist for RCOT knowledge-gathering projects and research undertaken by its staff, UK branches and individuals or organisations we have commissioned, where RCOT has the role of a project sponsor.

Generally, market research and social media activities such as web polls and tweet chats, evaluation of member events, resources or training days don't need to follow the review process.

Projects involving only RCOT staff do not normally need to follow the review process unless sensitive topics or concerns are being explored that might need an ethics or governance review. This should be discussed with the Director of People and Culture. RCOT R&D officers can offer advice on projects if there are any concerns.

Additional documents which should be reviewed are:

- Research governance and project ethics policy [PE1-22]
- Personal data retention and destruction policy - March 2022.docx

The majority of projects carried out by RCOT or its UK branches don't have significant ethical issues, but projects need to be reviewed to ensure that there is:

- a robust approach to planning and deciding the best way to gather the knowledge or information
- an ethical approach, considering and protecting the rights and welfare of the individuals and organisations that are involved
- compliance with General Data Protection and Data Protection Act 2018 legislation compliance with other relevant legislation (e.g., UK Research Governance Frameworks, Mental Capacity, Health and Safety).

The level of review will depend on the type of project. There are two categories of project review. Most projects undertaken by RCOT will fall into **category A or B.**

Category A includes:

- service evaluation or service development activities (including member surveys, focus groups, interviews)
- audit activities
- RCOT consultation (depending on the aim, level and method of consultation needed and who needs to be consulted)
- commissioned projects/consultation.

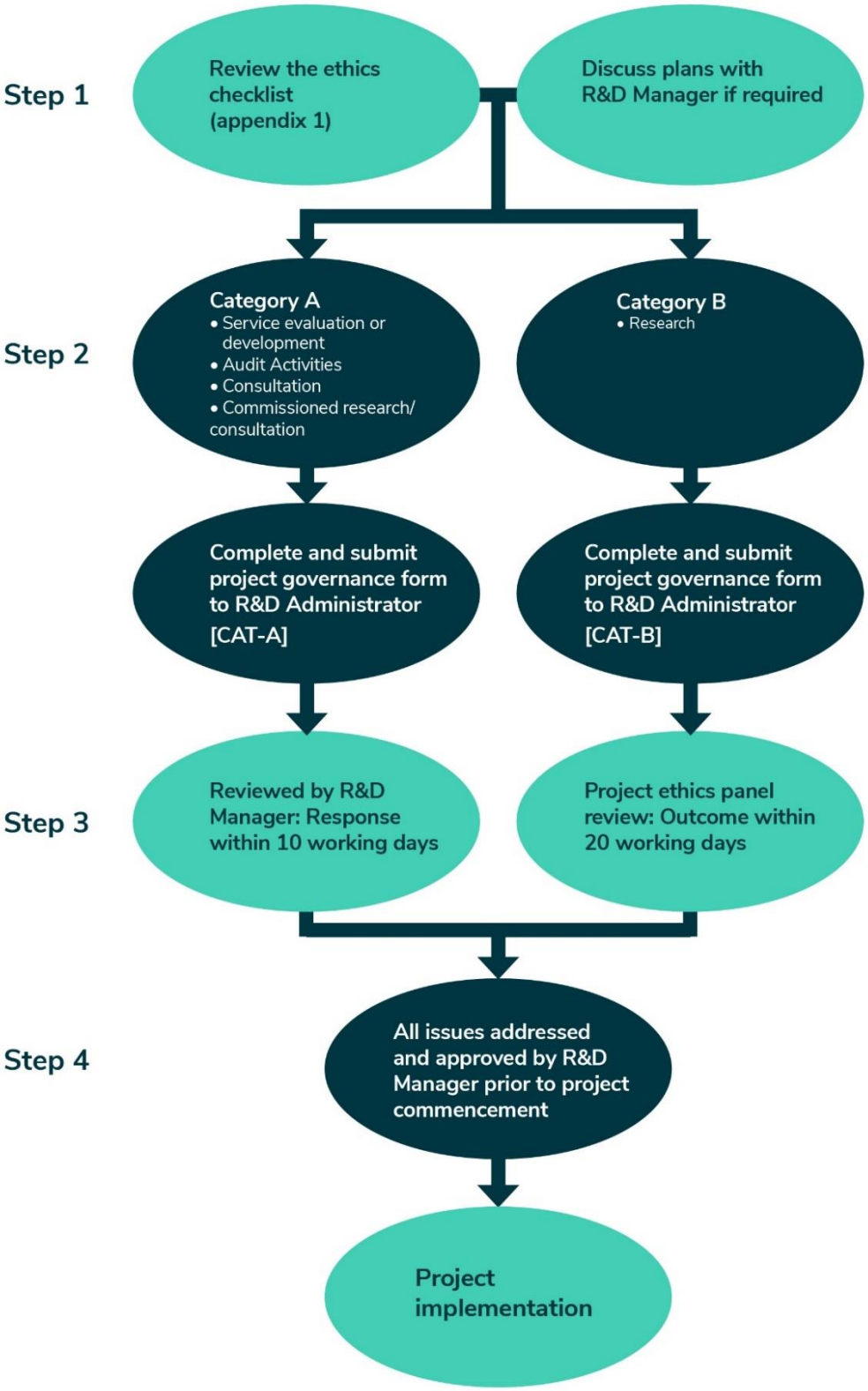
Category B includes Research:

Activity that aims to generate transferable and generalisable new knowledge by addressing clearly defined research questions using systematic and rigorous methods. This may be primary or secondary research.

The project ethics checklist (appendix 1) will guide you through questions to think about before completing a **category A or B project governance form**. RCOT R&D Officers can offer further advice.

Royal College of Occupational Therapists

Project ethics flow chart



Step 1: Project planning - using the project ethics checklist

All projects must have clear aims, a convincing background or evidence-base and/or an identified business need

The **project ethics checklist** (appendix 1) will help you think through the various ethical or governance issues in relation to your proposed knowledge-gathering activity, not all will be relevant to every project. The checklist provides a useful framework that will assist you as Project Lead in completing a project governance form (CAT A or B).

Please contact the RCOT R&D Manager for advice during the planning stage of your project**.** A discussion can facilitate early identification of the type of project and review process. Initial discussion can mean that the overall process will be more streamlined, and any issues can be addressed before you complete project governance form/proposal.

Step 2: Complete and submit a project governance form

Once you are clear about the type of project and have considered all the questions in the checklist**,** a project governance form (category A or category B) must be completed.

Category A: Service evaluation or service development activities (including member surveys, focus groups, interviews); audit activities; RCOT consultation (depending on the aim, level and method of consultation needed and who needs to be consulted); commissioned projects/consultation.

The form [CAT-A] must be submitted together with the participant information and data collection tool (survey/interview questions or topic/focus group guide) where appropriate.

Category B: Research activity determined as primary or secondary research, aiming to generate transferable and generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods).

The form [CAT-B] for research studies must be submitted with along with a full research proposal and any other relevant additional information (e.g. online survey link; questionnaires; interview schedules; information for participants; consent form, etc.).

Authorisation: Once completed, the category A or category B should be authorised by the relevant RCOT Director or Chair of the UK branch (a scanned signature, e-signature or email trail to evidence authorisation is acceptable). The authorised form and all additional documents should be emailed to the RCOT R&D Administrator.

The RCOT R&D Administrator will acknowledge receipt and provide a unique reference number and project details will be logged ready for review by the R&D Manager (or other designated RCOT officer with relevant experience).

The form must be submitted, reviewed and approved before the project can start.

Step 3: R&D Manager reviews proposal

CAT-A: The R&D Manager (or other designated RCOT officer with relevant experience) will carry out a proportionate review/risk assessment within 10 days [using Form PE3], considering the following:

- project type
- likelihood of harm: such as the type of participants; nature of information being sought; researcher/ project lead experience; methodology; GDPR and data handling and any other external considerations.
- level of risk: this is assessed as being acceptable, not acceptable or more information may be required before a decision can be made.

Feedback will be provided to the project lead which should be addressed if required and the CAT-A form resubmitted to the R&D Administrator. A further review and approval are needed before the project can start.

CAT-B: The R&D Manager coordinates a review of the research proposal by an RCOT project ethics review panel consisting of one/two RCOT officers not involved with the project and a member with relevant expertise. The panel is chaired by the Chair of Council. Feedback will be provided to the researcher which should be addressed and if necessary, the CAT-B form resubmitted for approval before the research study can begin.

Note: An RCOT project ethics review panel may also be convened for other project categories when the project raises significant ethical concerns.

Step 4: Project implementation

Once the project has been approved you can begin your project as per your plan/proposal.

Please be aware of the following:

- **Project changes:** If you need to make changes to your project, you will need to amend your project approval to include these changes. Any significant proposed changes to the project must be notified to the R&D Administrator. This is essential for research projects where a project ethics review panel has given a favourable opinion based on the proposal:
    - Minor changes can be made by emailing the R&D Administrator for review by the R&D Manager.
    - Major changes may require a new CAT A or B form to be submitted; making clear what the changes are. Examples of major amendments includes substantial changes to the project aims or methodology, or any changes where the risks and ethical issues are vastly increased, for example carrying out in person interviews rather than telephone/online interviews.

  If you need to extend the length of time your project is running, you also need to request an extension to your project approval by emailing the R&D Administrator. Please note, that this needs to be submitted **before** the current approval expires.

- **Data retention:** The RCOT Personal Data Retention & Destruction Policy - March 2022.docx should be followed in terms of storing project data and data should be destroyed according to the timescales in that policy.
    - Primary data generated by projects not classed as research should adhere to data protection requirements and normally be retained for a minimum of three years and then destroyed.

- Anonymised reports and fully anonymised data may be kept indefinitely or for as long as it is useful.
- Relevant documents/reports may be reviewed for potential archiving.

- **Research data retention**: In line with the UK Research Integrity Office (UKRIO) Code of Practice for Research: Promoting good practice and preventing misconduct. Data should be kept intact for any legally specified period and otherwise for a minimum of three years at least, subject to any legal, ethical or other requirements, from the end of the project. It should be kept in a form that would enable retrieval by a third party, subject to limitations imposed by legislation and general principles of confidentiality. (For specific research data guidance see appendix 2).

- **Project monitoring:** The RCOT Research and development team has no responsibility for monitoring the conduct of a project. This responsibility lies with the project lead/principal investigator and sponsor/employing organisation.

- **Ethical issues of concern arising:** The project lead/principal investigator must report any ethical issues or concerns that arise during the project to the R&D Administrator. These might include unexpected difficulties with recruitment or data collected, distressing situations for the project lead or participants that had not been anticipated.

- **Project completion:** Good ethics and project lead responsibilities do not stop after the project has been approved but are part of the project lifecycle. The R&D Administrator should be notified when the project is completed and provide a copy of the final report or a summary.

For further information or advice please contact:
R&D Administrator – kinza.ahmad@rcot.co.uk

Appendix 1: Project ethics checklist

This checklist will help you think through the various ethical and governance issues of your knowledge-gathering activity, not everything will be relevant to every project. The checklist provides a framework to help you as project lead to complete the project governance form (CAT-A or B).

1. Background and aims

- ☑ What are the main questions you wish to answer?
- ☑ How was the need for the project identified?
- ☑ How does the project link to the RCOT/your team business plan?
- ☑ What are the aims of the project?
- ☑ What are the proposed project start and finish dates?
- ☑ Is the timetable realistic? Is it influenced by external constraints or deadlines?

2. Organisational details

- ☑ Does the project have an agreed 'sponsor'? (The sponsor is the individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a project.) This will usually be RCOT for HQ and UK branches projects.
- ☑ Are you leading this project on your own or with others?
- ☑ Who else will be involved in the project? Are public contributors included in your project? What are their roles and responsibilities?
- ☑ Who will be funding this activity?
- ☑ What resources (e.g. budget, staff time) are needed to support the project? Has the allocation of these resources been agreed as part of budget setting?
- ☑ Are any resources expected to be supplied through any NHS or local government source (e.g. practitioner's work time to complete a questionnaire)? If so, has this been agreed by relevant managers?
- ☑ Have you determined whether the project should be reviewed by an NHS or other research ethics committee (i.e., community/social care, university)? If so, when will you apply for their ethical approval?
- ☑ How will your project be supervised and monitored and by whom?

How will you provide regular updates and progress reports and who will you provide them to?

3. Participants

- ☑ Who are you targeting in this project? Who will be your participants?
- ☑ Will any vulnerable groups be involved and how will you manage any specific needs?
- ☑ How will you include hard to reach and marginalised communities?
- ☑ What is the inclusion and exclusion criteria for identifying your participants?
- ☑ How many participants will be involved and how will you recruit them?
- ☑ Will you be providing an incentive to take part to your participants?

- ☑ Are the participants known to you? How could that affect the project (e.g., bias the results)? What arrangements will be put in place to avoid the possibility of coercion?
- ☑ Is there a chance participants could feel any distress, frustration or other discomfort as a result of participating? Are there any other potential risks involved, including to the investigator? How will you manage any identified risks? What support will you offer them?
- ☑ Will participants be clearly and fully informed of the purpose of the project? How will you do this?
- ☑ How will informed consent be obtained from participants?
- ☑ Where informed consent is unable to be provided, what will you do? (NB due account must be given to mental capacity legislation.)
- ☑ What follow-up support will be available to participants should they require it?

4. Methods and data

- ☑ What sort of data will you be collecting – quantitative (e.g., numbers), qualitative (e.g. interview or focus group transcripts) or a combination of the two?
- ☑ What is the main method you will use to collect the data (e.g., questionnaire, face-to-face interviews, telephone survey, online survey, focus groups etc.) and how will this happen?
- ☑ What steps will be taken to safeguard the confidentiality of participant data?
- ☑ How will you analyse the data you collect?
- ☑ What methods of analysis are you going to use?
- ☑ Will you be using any specific software (e.g. SPSS, NVivo, Excel, etc.) for data entry or analysis?
- ☑ How and where will the data be stored, for how long and how will it be disposed of?
- ☑ Who will have access to the data?
- ☑ How will you ensure confidentiality and anonymity of data?
- ☑ Who will have ultimate ownership of the data?
- ☑ How will you ensure compliance with data protection and GDPR legislation?
- ☑ Will the data be used for any purposes other than the project?

5. Dissemination

- ☑ How will your findings be disseminated (publication, report, journal article etc.) and to whom (including participants and stakeholders)?
- ☑ What might the implications of your findings be?
- ☑ Is there any potential sensitivity associated with the topic, e.g., will the findings possibly lead to heightened media/political interest or a risk of misinterpretation?
- ☑ How could your findings be used to inform and improve services?

Appendix 2: Research data retention guidance

1. Introduction

Special procedures apply to the retention and storage of documentation and data which have been classified as 'Research' data:

Research documents are documents that record the planning and progress of the research project (for example project proposal, meeting agendas, project meeting minutes etc.) and the final project report.

Primary research data is any data that has been collected by the researcher (for example, completed surveys, recordings and transcriptions of interviews or focus groups). It also includes any related documents that contain personal information about study participants (for example signatures on consent forms or email/contact addresses).

The UK Research Integrity Office's (UKRIO) Code of Practice for Research Promoting good practice and preventing misconduct (2009 and 2021) is an essential reference tool to support researchers and organisations in the conduct of research of the highest quality and standards. This should be referred to where RCOT is acting as the research sponsor, that is where 'The organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project' (NHS Health Research Authority, 2022).

The UKRIO Code of Practice for Research section 3 on collection and retention of data states:

> Section 3.12.1 Organisations and researchers should comply with all legal, ethical, funding body and organisational requirements for the collection, use and storage of data, especially personal data, where particular attention should be paid to the requirements of data protection legislation. They should also maintain confidentiality where undertakings have been made to third parties or to protect intellectual property rights. Organisations and researchers should ensure that research data relating to publications is available for discussion with other researchers, subject to any existing agreements on confidentiality.
>
> Section 3.12.2 Data should be kept intact for any legally specified period and otherwise for three years at least, subject to any legal, ethical or other requirements, from the end of the project. It should be kept in a form that would enable retrieval by a third party, subject to limitations imposed by legislation and general principles of confidentiality.
>
> Section 3.12.3 Organisations and researchers should comply with any subject-specific requirements for the retention of data; for example, certain disciplines, such as health and biomedicine, may require research data to be retained for a considerably longer period.
>
> Section 3.12.4 If research data is to be deleted or destroyed, either because its agreed period of retention has expired or for legal or ethical reasons, it should be done so in accordance with all legal, ethical, research funder and organisational requirements and with particular concern for confidentiality and security.

2. RCOT research activity

The RCOT and its branches may be involved with one of two types of research activity:

2.1 Research projects undertaken directly by RCOT staff and/or its UK branches

Research projects may be undertaken by staff at RCOT headquarters or by its UK branches (e.g., specialist section or regional group members) on behalf of RCOT. This will normally be as part of their role as an employee of RCOT, or role as a UK branch member.

It is possible to distinguish RCOT's research activity from other types of activity (e.g., audit and service evaluation), as research activity will have required review by an RCOT project ethics review panel. If there is any uncertainty about whether a project is considered research, please contact the RCOT R&D Manager for advice.

The project lead should ensure that all members of a project team are aware of the requirements for retention and storage of research documentation and data and may nominate one person to take responsibility for this activity.

On completion of the project, 'research documents' and 'primary research data' should be identified and prepared for retention for the required length of time. It is vital that the 'research documents' and 'primary research data' are separated and labelled correctly.

This is particularly important for primary research data to ensure that any personal information it contains is dealt with in accordance with the General Data Protection Regulations Data Protection Act (2018) and destroyed, rather than archived.

The project documentation should also be labelled with clear instructions that it be retained securely until the required date of destruction which should be clearly stated.

Post-study data retention period: When the required data retention period has expired, the documentation should be processed as follows:

- Research documents can be professionally archived.
- Primary research data can now be securely destroyed as confidential waste or permanently deleted from digital storeage.

2.2 Research projects that are commissioned by RCOT or its UK branches

Commissioned projects are those where RCOT contracts with another individual and/or organisation (e.g., a university or freelance individual), for them to undertake planned research activity on behalf of RCOT.

The commissioned individual and/or organisation is responsible for fulfilling the UKRIO guidelines and, therefore, appropriate clauses should be included within the contract to ensure that all the research data are retained, stored, and then eventually destroyed, in line with good research practice and any specific funder or research establishment (e.g., university) guidance is followed.

Individual contractors will normally be expected to deliver their study data, once the project is signed off, to the RCOT for retention.

RCOT should retain a record of the project (for example, the final project report) for professional archiving purposes. Contracts should be retained for six years after completion of the project/payment of the last invoice, whichever is the later.