Standard Operating Procedure:

Peer Review

# Purpose

This standard operating procedure (SOP) explains the process of obtaining a peer review for clinical research conducted within the University of Birmingham (UoB).

# Scope

The SOP applies to all clinical research for which the University of Birmingham (UoB) takes on sponsorship duties for ensuring appropriate peer review is undertaken. This SOP also applies to clinical research approved by a UoB research ethics committee (REC) that is required to follow UoB-GCP-POL-001 UoB Principles of Good Clinical Practice (GCP) for Clinical Research. This SOP may be used as a guidance document in all other cases.

# Implementation plan

This SOP will be implemented directly after its effective date for any clinical study or trial that is in grant- application or set-up phase. For all other clinical research this SOP will be implemented, as far as possible, within three months of the effective date.

# Stakeholders

Where the UoB takes on the sponsor’s responsibility for peer review, the UoB will delegate the majority of these duties to the CI and/or to a clinical trials unit (CTU), who may delegate these duties further to their research team(s). All delegation of duties will be documented (e.g. using either the CI declaration and/or the UoB-CLN-CTM-002 Clinical Trials Task Delegation Log).

* CI: the CI may delegate activities to members of their team, although evidence of CI oversight and approval is still expected and may not be delegated where ‘no delegation allowed’ is indicated. The SOP will state where delegation is possible. For clinical research approved by a UoB REC, the role of CI may be referred to as the principal investigator (PI), or the supervisor for postgraduate research students.
* Clinical Trials Oversight Committee (CTOC)
* UKCRC-registered UoB CTU
* Research Governance Team (RGT)

# Background and rationale

Independent peer review of a clinical research project is essential to ensure that the research is of high quality. The [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) describes the need for appropriate independent expert (“peer”) review of any research project undertaken under the framework. The Department of Health (DoH) [Eligibility Criteria for NIHR Clinical Research Network (CRN) Support](https://www.nihr.ac.uk/documents/researchers/collaborations-services-and-support-for-your-research/run-your-study/Eligibility%20Criteria%20for%20NIHR%20Clinical%20Research%20Network%20Support.pdf) provides a standard for high-quality peer review of studies, whereby it must be independent, expert and proportionate. The UoB is committed to supporting high-quality research and expects peer review to be conducted accordingly across its clinical research portfolio. This SOP sets out the peer-review processes for clinical research.

# Process map



\* The chair of the CTOC (or delegate) can act as an independent reviewer where two other reviews are opposing.

# Procedure

Decide on the need for peer review.

1. During the project set-up, and before submitting the research for ethics review, the CI (no delegation allowed), or the CTU (for UoB CTU-managed projects) will review and determine the level needed for peer review of the proposed research. There are two possible outcome options as listed below.
* **Option 1 - no further peer review required**: this option applies to clinical research that has already been peer reviewed by major grant-giving bodies and/or similar organisations, to include UK Research Councils (including the Medical Research Council (MRC)); the National Institute for Health Research (NIHR); and members of the Association of Medical Charities (including the Wellcome Trust and a large number of specialist or disease-specific charities). For programme grants, the CI must be able to demonstrate that the relevant grant-giving body had conducted formal independent peer review of the proposed research. If, as part of the programme grant, the project has not been specifically considered by the grant-giving body, further peer review is required.
* **Option 2 – peer review by at least two suitable reviewers:** this option applies to all other clinical research projects**.** The peer review will be conducted by at least two suitable reviewers with in-the-field and methodological expertise who are not involved in the project. Note: for educational research, the CI will be a supervisor who may provide an appropriate level of review.

## Organise peer review

1. If further peer review is required, the CI (or delegate) will be responsible for commissioning the peer review. Support for commissioning the peer review may be obtained through the RGT.
* For UKCRC-registered UoB CTUs, the UoB CTUs will be responsible for commissioning the peer review through their internal process.
1. The CI (or delegate) will make available to the individual arranging the peer review the latest information on the project. This will include the background and rationale, the risk profile of the clinical research to the participant, recruitment strategy, methodology, power calculations (as applicable), and key staff involved both within and outside of the UoB.
2. The CI (or delegate) will recommend at least two suitable peer reviewers to the individual arranging the peer review and will consider the need for more reviewers depending on the risks associated with, or complexity of, the research.
3. The individual arranging the peer review will select at least two suitable peer reviewers.
* For clinical research managed outside a UoB CTU, the CI (or delegate) will notify the RGT of the intended reviewers. The RGT will assess the suitability of the proposed reviewers and either accept the reviewers, and/or identify further reviewers.
* Where the CI (or delegate) has recommended external reviewers, the individual arranging the review should consider using external sources e.g. PubMed.
1. The individual arranging the peer review will contact the peer reviewer(s) to request a peer review of the research proposal that is documented in a written report (see UoB-PRV-QCD-001 Peer Review Letter and Report Template). The report will address the questions listed below.
* Does the clinical research address a clear research question?
* Does the background information adequately justify the clinical research?
* Is the methodology appropriate for the clinical research?
* Is the proposed sample size sufficient to answer the research question?
* Where appropriate, is the importance to the NHS and service users clear?
* Are the risks associated with the clinical research justified by the potential benefit?
* Given the current proposal, is the clinical research feasible and achievable (able to answer the research question)?
* Have risks to participants been appropriately identified and managed within the proposed clinical research?
* Any other comments?

## Follow up on peer review

1. Upon receipt of the peer-review report from the reviewer, the individual arranging the peer review will share the report with the CI/CTU, highlighting any points within the report that require further action.
2. The CI (or delegate) will appropriately act upon the action points and will confirm to the individual arranging the peer review the actions that have been taken.
3. The individual arranging the peer review will ensure any outstanding action points are appropriately addressed and will confirm this to the CI in writing (where applicable).
4. Where there are opposing peer reviews and a mutual decision cannot be determined, the individual arranging the peer review will request a further review by the chair of the CTOC (or delegate). The chair of the CTOC (or delegate) will act as a mediator and provide a final decision on the review.
5. The CI (or delegate) will ensure that the following are filed in the study/trial master file (S/TMF) and made available upon request:
* peer-review report
* confirmation from the individual arranging the peer review that action points have been appropriately addressed (where applicable)
* any other key information relating to the peer review.

# List of expected outputs

* Where appropriate, evidence of confirmation from the RGT on the reviewer(s) suitability.
* Peer-review reports from the individuals performing the peer review (where applicable).
* Evidence of a review and decision by the chair of the CTOC (or delegate) acting as a mediator (if required).
* A written statement from the individual arranging the peer review confirming that action points identified during the peer review have been appropriately addressed (where applicable).

# Related documents

* UoB-CLN-CTM-002 Clinical Trials Task Delegation Log
* UoB-GCP-POL-001 UoB Principles of Good Clinical Practice (GCP) for Clinical Research
* UoB-PRV-QCD-001 Peer Review Letter and Report Template

Note the UoB QMS documents can be found on the [Clinical Research Compliance Team (CRCT) website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT (crct@contacts.bham.ac.uk) and/or from the RGT (researchgovernance@contacts.bham.ac.uk).

# References and frameworks

* Department of Health Eligibility Criteria for NIHR Clinical Research Network Support: <https://www.nihr.ac.uk/documents/researchers/collaborations-services-and-support-for-your-research/run-your-study/Eligibility%20Criteria%20for%20NIHR%20Clinical%20Research%20Network%20Support.pdf>
* HRA Peer / Scientific review of research and the role of NRES Research Ethics Committees (RECs): <https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/scientific-review-and-recs.pdf>
* RGT mailbox: researchgovernance@contacts.bham.ac.uk
* UK Policy Framework for Health and Social Care Research: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>

# Abbreviations and definitions:

| Term | Description |
| --- | --- |
| CI  | Chief investigator |
| CRN | Clinical Research Network |
| CTOC | Clinical Trials Oversight Committee |
| CTU | Clinical Trials Unit |
| DoH | Department of Health |
| GP | General practitioner |
| HRA | Health Regulatory Authority |
| MRC | Medical Research Council |
| NHS | National Health Service |
| NIHR | National Institute for Health Research |
| Peer review | The evaluation of research by fellow scientists, academics and/or professionals to assess its suitability |
| REC | Research ethics committee |
| RGT | Research Governance Team |
| SOP | Standard operating procedure |
| S/TMF | Study/trial master file |
| UKCRC | UK Clinical Research Collaboration |
| UoB | University of Birmingham |

See also the [Glossary of Terms](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/Glossary-of-Terms.aspx).