

Proportionate Review summary for researchers

Overview

This leaflet provides an overview of the proportionate review (PR) service for researchers applying for REC approval.

What is proportionate review?

Where a study contains 'no material ethical issues' (i.e. there is minimal risk, burden or intrusion for the participants), it can be reviewed and approved by a proportionate review sub-committee on behalf of the REC. The aim of PR is for studies which present minimal risk or burden for participants to be reviewed within 14 days of receipt of a valid application.

What studies are eligible?

Please see the [No Material Ethical Issues Tool \(NMEIT\)](#) which describes the types of studies eligible to be reviewed via PR. Eligible studies include certain research studies using tissue which may be anonymous or which may already have consent to be used for research purposes and also questionnaire research that does not include highly sensitive areas. The NMEIT highlights those studies which always require review at a full REC meeting, such as clinical trials of investigational medicinal products (CTIMP's) and research involving adults lacking capacity. Researchers should use this tool to help decide if their study may be suitable for PR.

What are the benefits of proportionate review?

- Offers an ethical review in proportion to the risks and ethical issues involved in the research.
- Enables NRES to provide a more efficient and responsive service.
- Allows researchers undertaking projects raising no material ethical issues to receive an ethical opinion more promptly and reduce project timelines.
- Makes better use of the time of REC members, allowing full REC meetings to concentrate on research raising more significant ethical issues.

How and where to apply for proportionate review

PR is a service available to all researchers in England. There is a limited service in Wales and Scotland. At present, not all REC centres hold Proportionate review sub-committee (PRSC) meetings however PR studies can be reviewed by any of the PRSC meeting across the country. The researcher should complete the NRES application form via the IRAS website and Question A6-3 should be completed; this confirms the study is suitable for PR. Researchers should contact their local REC which will find the next available PRSC meeting in the country. If this is not in the local area, the LAS operator will take the researcher's details and arrange for the REC with the next available PRSC to contact the researcher directly to book in.

The Local Allocation System (LAS) operator will run through some questions to check the application is ready to be submitted and suitable for PR. If the application is suitable, the application will be allocated to the next PRSC and a REC reference number given. The researcher should send their application to the REC office and the eligibility for PR will again be checked. If the study is suitable, the application will then be sent to the PRSC members. If, however, the coordinator is of the opinion that the study is not suitable for PR, the application would be transferred with your agreement either to the next available full REC meeting or a REC in your local area and reviewed within the normal 60 days.

How are proportionate review meetings held?

PRSC meetings can take place face to face, via telephone conference or via email correspondence. The quorum requirement for PRSC is a minimum of three REC members, one of whom must be a

chair, vice-chair or alternate vice-chair. There also must be at least one lay member and one expert member in attendance.

Do researchers need to attend the PRSC meeting?

No. Researchers are not required to attend the meeting; however they may be contacted by one of the REC members if any clarification is required. This can take place by phone or email and a time and date will be detailed on the validation letter from the REC office.

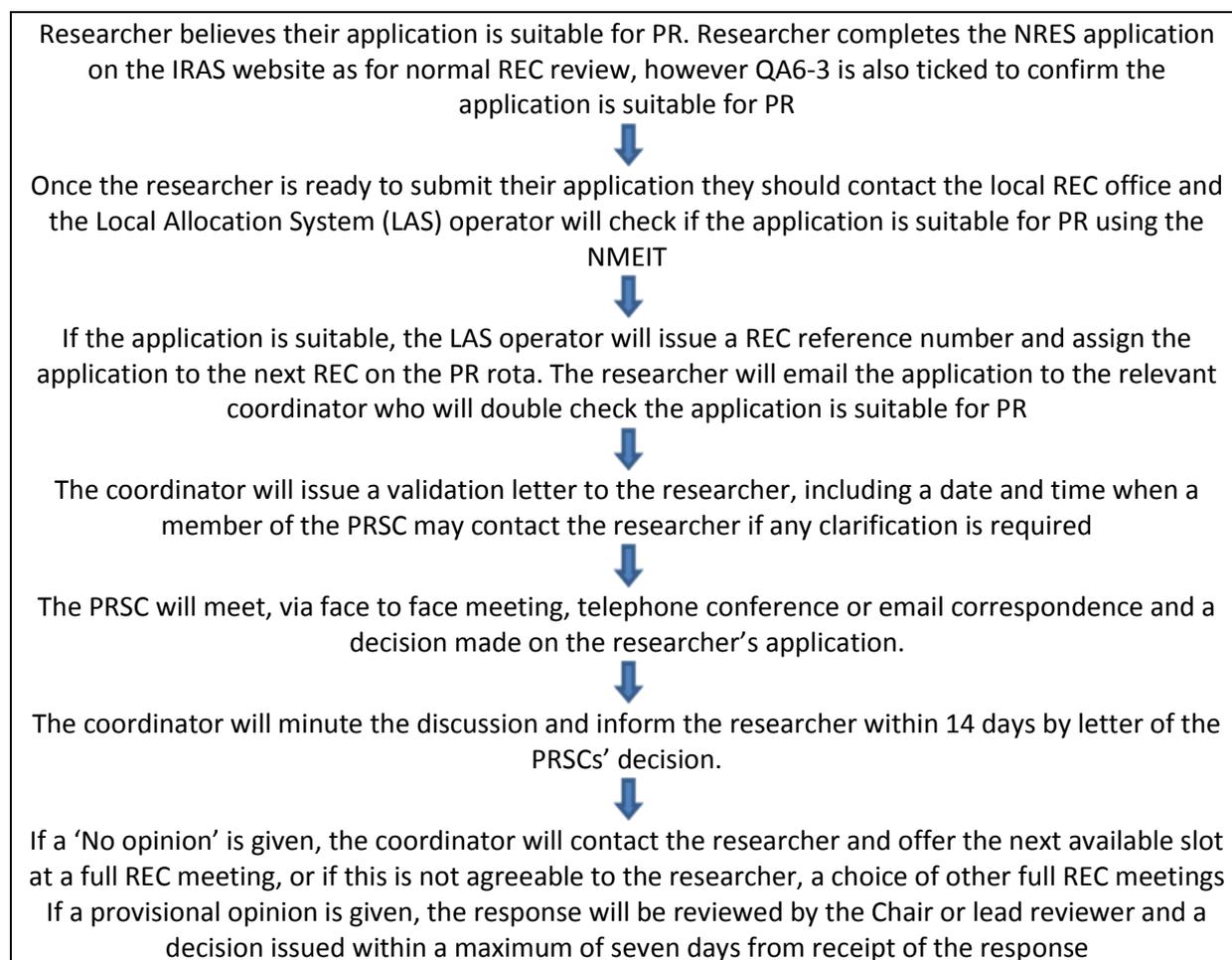
What decisions can be given at a proportionate review meeting?

The PRSC can give the following decisions:

1. Favourable opinion (same as full REC review)
2. Favourable opinion with conditions (same as full REC review)
3. Provisional opinion (same as full REC review)
4. Unfavourable opinion (for any studies which are unlikely to be approved at full committee)
5. No Opinion (study contains material ethical issues and needs to be reviewed by a full REC)

If a 'No Opinion' is given, the application must be reviewed at a full REC meeting. The researcher will be informed of the reasons for the decision and offered the next available full REC meeting. If the researcher accepts this meeting slot, the application will be reviewed within the mandatory 60 days (with the 60 days starting from the date of receipt of the valid PR application). If the researcher decides against the first available meeting slot, the clock will stop and the 60 day clock will begin from the cut-off date of the meeting chosen by the researcher.

Timeline



Further information

Please see the [Proportionate review service flowchart](#), the [No Material Ethical Issues Tool](#) and the [Standard Operating Procedures for Research Ethics Committees in the United Kingdom v5.0](#) for more information on proportionate review. Alternatively, please contact your local REC centre for advice.