

Proportionate Review- Frequently Asked Questions

This document has been kept concise for ease of reference and contains general information only. Therefore the list of Proportionate Review Service (PRS) eligibility criteria mentioned is not exhaustive. Studies booked for Proportionate Review will be reassessed and pertaining ethical issues will be analysed in the context of each study by Research Ethics Service staff.

The Research Ethics Service reserves rights to withdraw applications from the PRS and arrange for an alternative review should the application not meet the PRS assessment criteria.

What is proportionate review?

The Proportionate Review Service (PRS) provides for a proportionate review of research studies which raise no material ethical issues. Under the PRS, new applications are reviewed by a Proportionate Review sub-committee rather than at a full meeting of a REC, with the aim of notifying the final decision to the applicant within 14 calendar days of receipt of a valid application.

What are “no material ethical issues”?

Non material ethical issues have minimal risk, burden or intrusion for research participants. These include anonymous tissue studies and non-sensitive questionnaire and interview studies. Guidance on what constitutes non material ethical issues is published at

<http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-proportionate-review-service/>

This provides a “No Material Ethical Issues Tool (NMEIT)”, a document which serves as a screening tool for the PRS applications.

What is a No Material Ethical Issues Tool?

As well as a table with categories of studies usually suitable for the PRS, there is a list of study types which always require a full REC review.

Criteria for determining whether a study is suitable for review through the PRS are developed by NRES in consultation with the National Research Ethics Advisory Panel and published on the NRES website and in IRAS. The criteria are kept under review in the light of developments in policy and guidance, feedback from researchers and sponsors and opinion within the Research Ethics Service.

For details of how to use the tool please refer to STEP 2 in section ‘How can I check if my application is suitable for the PRS?’

What is anonymous data or tissue referred to in the NMEIT?

‘Anonymous’ means that a researcher would not have any access to patient identifiable data during any of the stages of research including:

- Identification of participants
- Approaching participants with study information
- Consenting research participants



- Allocation of a unique study number
- Data collection process
- Data analysis process
- Reporting and closure of the study

Link anonymised data, where the researcher can identify the participant, does not fit category I of the No Material Ethical Issues Tool.

More guidance on anonymised data can be accessed via the following link:

<http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/>

What are “highly sensitive areas” referred to in NMEIT?

The term “highly sensitive areas” refers to questions which may cause anxiety because of the nature of the question or of the population being asked. For example, questions about HIV status, sexual activity, recreational drug use, mental health etc. Assessment of a question’s sensitive nature might be influenced by whether the answers are to be anonymised.

What are “established non drug treatments” referred to in the NMEIT?

“Established non-drug treatments” include treatments other than medication, which are already in use and follow local (e.g. Trust) and national protocols.

What kind of medical devices can be reviewed by a PRS Sub-committee?

Category VI of NMEIT might include some non-invasive medical devices after CE marking used only for their intended purpose and involving no change to patient and their treatment.

Use of the medical device has to meet local (e.g. Trust) and national protocols.

Research applications involving invasive medical devices, including implantable medical devices and those containing medicinal substances are not suitable for the PRS and should be reviewed by a full REC flagged to review medical devices.

How can I check if my application is suitable for the PRS?

Please follow these three steps:

- **STEP1** *Does your research require NHS REC review*

Following changes to GAfREC made in September 2011 some research does not require NHS REC review. To check for your study type review requirements follow the link:

<http://www.hra.nhs.uk/resources/before-you-apply/is-nhs-rec-review-required/>

If your research requires NHS REC review, proceed to STEP2.

- **STEP2** *Check your study against the ‘No Material Ethical Issues Tool’ (NMEIT)* Using the NMEIT check your application against a list of study types located in the first part of the tool. If your application is any of these, your research is not suitable for the PRS and will require a full REC review.



Using the PR table in the NMEIT, check if your application fits any of the research types listed. If it fits more than one category, choose the one which most closely fits your study. If you cannot find a suitable category, your study requires full REC review.

- **STEP3** *Check your application against further eligibility criteria*

If your application meets the criteria in the NMEIT, check that your project fulfils further essential criteria listed below (see “What is involved in the PRS screening?” section), which your application will be assessed against by the REC office when you book in.

What is involved in the PRS screening process?

The PRS screening process undertaken by Research Ethics Service staff includes:

- Assessment of the application for material ethical issues: risk, burden or intrusion for study participants. Only studies involving minimal risk, burden or intrusion can be accepted for the PRS.
- Assessment of access to patient records. Applications proposing accessing patient records by people outside the direct care team to identify patients or collect data without consent are not suitable for the PRS.
- Assessment of the quality of the application:
 - Project filter questions have to be completed correctly otherwise IRAS will not generate applicable sections and important information may therefore be missing.
 - The set of supporting documents listed in the IRAS checklist must be complete. Patient Information Leaflets and Consent Forms should be submitted as separate documents. All documentation to be used in research must be marked with version numbers and dates.
 - For more guidance on recruitment documents follow the link: <http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/>
 - For educational projects at non-doctoral level, the academic supervisor should normally be named as Chief Investigator while for doctoral level projects the student should be named as Chief Investigator (subject to University policy).
- An application has to fit at least one of the categories listed in the NMEIT (please refer to “How can I check if my application is suitable for the PRS?”)

What if I cannot decide if my study is suitable for the PRS?

Researchers undertaking research in the NHS are advised to contact their local Research and Development Department for further guidance.

Additionally we operate a queries line: hra.queries@nhs.net . Should you wish to use this service, please email your draft IRAS form and one of our advisers will be happy to provide some more guidance as to whether your study would be suitable for Proportionate Review.



How can I book my application for the PRS?

Once your application is ready to submit, including having all IRAS electronic authorisations in place, call the Central Booking Service (CBS) on 0161 625 7836.

What happens after I book my study for the PRS?

Once submitted, your application will be checked again for the PRS suitability by one of our experienced REC office staff. The REC Manager will check the study suitability for review against the current eligibility criteria as part of the validation process. Consideration will be given to any significant ethical issues described by the applicant in the application form.

How are the PRS meetings held?

The PRS meetings can take place face to face, via telephone conference or via email correspondence. Since the review is undertaken in a sub-committee the REC Manager will minute the discussion and inform the researcher within 14 days of receipt of a valid application by letter of the PRS decision. The researchers do not attend the meeting, but they may be contacted by one of the REC members if any clarification is required. This can be by phone or email, so it is important that researchers plan their availability before making the PRS booking.

Decisions available to the PRS sub-committee include:

- Favourable opinion
- Favourable opinion with conditions
- Provisional opinion
- Unfavourable opinion
- No opinion

What if my application is not suitable for the PRS?

If the application is valid, but unsuitable for proportionate review, the REC Manager will notify the applicant by telephone or email and explain the reasons. The application will be booked to a full REC meeting, in discussion with the applicant and taking account of their preferences for full REC meeting location.

If during the PRS review your application is found to contain material ethical issues, which PRS Members decide need a further discussion in a full meeting, you will receive a 'No Opinion' decision letter listing the ethical issues identified. At this point you are not required to respond to the issues raised. In parallel to your receiving the letter, we will contact you to arrange a transfer of your application for a full REC review. The application will be booked to a REC in your local area to enable you to attend the meeting. Following the transfer, the clock on application extends to a maximum of 60 days from the date the valid application was initially received. If the first available slot is rejected then the clock on the application will change to 60 days from the cut-off date for applications for the chosen full REC meeting.



What are the most common errors to avoid when applying for the PRS?

Complete the IRAS filter questions correctly and thoroughly to avoid delays or even an unfavourable opinion which can be issued for poor quality applications.

Remember that incorrectly completed filter questions generate an inadequate form. All applicants are encouraged to contact their local R&D for more advice and/or follow IRAS learning module for more guidance:

https://www.myresearchproject.org.uk/ELearning/IRAS_E_learning.htm

Participant recruitment documentation (Patient Information Leaflets, Informed Consent Forms etc.) should follow the guidance published by the Health Research Authority - for details follow the link:

<http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/>

Further Information

Please see the Standard Operating Procedures for Research ethics Committees in the United Kingdom for more details. Alternatively, please contact your local REC Centre for advice.

SOPs link: <http://www.hra.nhs.uk/resources/research-legislation-and-governance/standard-operating-procedures/>

