NHS
Health Research Authority

Proportionate Review

Information and Guidance for Applicants

Contents

1. What is Proportionate Review?

The Proportionate Review Service (PRS) provides an accelerated, proportionate review of research studies which raise no material ethical issues. Studies which have no material ethical issues have minimal risk, burden or intrusion for research participants.

Under the PRS, new applications are reviewed via email correspondence, teleconference or at a face to face meeting by a sub-committee (comprised of experienced expert and lay members) rather than at a full meeting of a REC. The final decision is notified to the applicant by email within 21 calendar days of receipt of a valid application.

A PRS review is as rigorous as a full REC review and will not affect the opinion you are given.

If the Proportionate Review Sub- Committee has any questions during the 21 day review period it may call or email the study contact for clarification or further information.

2. Proportionate Review Suitability: Roles and Responsibilities

It is not a requirement that applicants know their application's Proportionate Review suitability prior to booking it for review.

The Central Booking Service operators ask a number of questions to establish if an application should be booked to a Full or Proportionate Review meeting.

Upon receipt the REC Manager undertakes a thorough pre- screen of the application to gauge its PR suitability.

The Proportionate Review sub-committee also give consideration to the applications suitability for PR when the application is sent for review.

3. Applications which are not suitable for Proportionate Review

- Clinical Trials of Investigational Medicinal Products (CTIMPs)
- Clinical investigations of medical devices prior to CE marking
- Research involving adults lacking capacity to consent and subject to the MCA (Eng/Wales) /AWI (Scot)
- Research involving exposure to ionising radiation which is additional to that received in routine clinical care for any participant
- Research Tissue Bank
- Research Database
- Applications requiring review by CAG
- Research involving prisoners
- Studies funded by the US Department for Health and Human Services
- Research involving residents or information about residents in Residential Care homes in Northern Ireland

- Research involving patients or information about patients in Nursing Homes or Independent Health Care Clinics in Northern Ireland

4. Applications which are usually suitable for Proportionate Review

1. Research using prospectively collected data or tissue that is anonymous to the researcher
2. Research using existing tissue samples which are not anonymous and already taken with consent for research
3. Research using 'surplus or extra tissue' with consent (e.g. further blood taken at time of routine sampling, tissue taken during a 'clinically directed' procedure or non invasive or minimally invasive procedure in non vulnerable groups)
4. Questionnaire research that does NOT include highly sensitive areas or where accidental disclosure would NOT have serious consequence *(sensitive questionnaires which are validated for use in the proposed population and used by experienced practitioners are acceptable for PR)*
5. Research interview / focus group that does not include highly sensitive areas or where accidental disclosure would NOT have serious consequence
6. Research surveying the safety or efficacy of established non drug treatments, involving limited intervention and NO change to the patient's treatment.
7. Minimally invasive basic science studies involving healthy volunteers or patients (e.g. which involve the taking of a single blood sample or other similar minimally invasive intervention)
8. Studies which do not fit categories 1-7 but do not have any 'Material Ethical Issues'

N.B. Link anonymised data, where the researcher can identify the participant, does not fit category I.

N.B: Research involving children may be considered for Proportionate Review where it does not have any 'material ethical issues'.

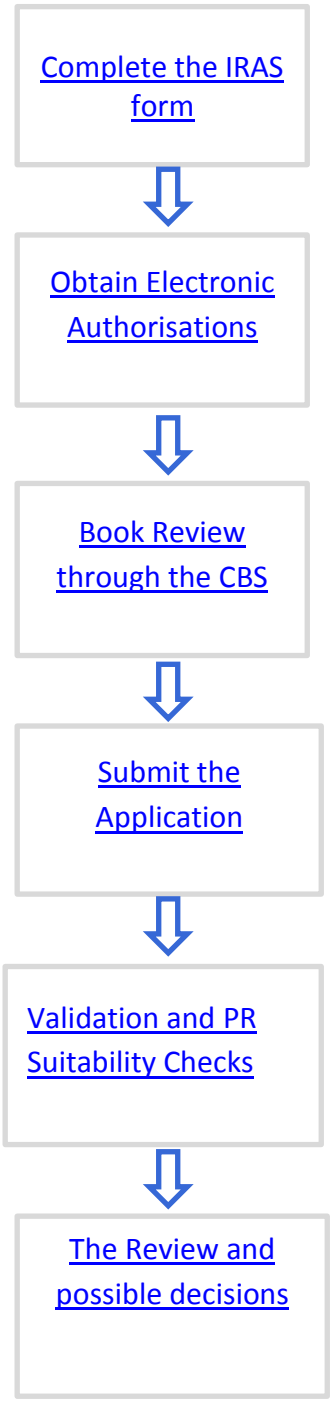
5. Other Factors considered by REC staff and REC members when gauging PR suitability

There are additional factors which are considered by the REC Manager and Committee when assessing if an application is suitable for Proportionate Review. The below list provides examples but is not exhaustive.

- The likelihood of the research procedures throwing up incidental findings of clinical importance.
- The research procedures when considered together overly arduous and/or burdensome.

- The vulnerability of the participant group at the time of approach to participate. For example- diagnosis of a serious condition taking place on the same day as the recruitment.
- The inclusion of genetic testing which could have wider implications for the participant.
- The overall sensitivity of the application and topics being covered combined with the potential for participant distress

6. Proportionate Review Application Process Flow



7. Completing the Integrated Research Application System (IRAS) Form

The IRAS is a single system for applying for the permissions and approvals for health and social care/community care research in the UK. It enables you to enter the information about your project once instead of duplicating information in separate application forms, uses filters to ensure that the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required.

IRAS captures the information needed for the relevant approvals from the following review bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Confidentiality Advisory Group (CAG)
- Gene Therapy Advisory Committee (GTAC)
- Health Research Authority (HRA) for projects seeking HRA Approval
- Medicines and Healthcare products Regulatory Agency (MHRA)
- NHS / HSC R&D offices
- NHS / HSC Research Ethics Committees
- National Offender Management Service (NOMS)
- Social Care Research Ethics Committee

The IRAS system can be accessed by following the below link:

https://www.myresearchproject.org.uk/signin.aspx

The IRAS training module can be accessed by following the below link:

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

8. Obtaining Electronic Authorisations

IRAS offers the facility for electronic authorisations. It is mandatory for the authorisations to be in place prior to booking the application for REC review. Ink signatures are no longer an accepted alternative.

The IRAS system works by means of a secure transfer between the project owner and the person giving the authorisation. Authorisations can be requested from the Chief Investigator and Sponsor representative by entering the REC form, navigating to the authorisations tab, selecting ‘request’, entering the appropriate contacts email address and selecting ‘send request’.

**Please note- the only data field that can be amended without invalidating the authorisations. If the form has been amended after it has been authorised but has not been

saved, the data change alert will only appear when save is pressed following completion of the REC details box. **

9. How to book your application for review

All applications can be booked through the Central Booking System.

Telephone: 0207 104 8000

Opening Hours- 9.00 to 16.30pm Monday- Friday

Email: nres.cbs@nhs.net

The Central Booking Team will check that the application is ready for submission by:

- Verbally checking that all of the authorisations are in place.
- Verbally checking that the application can be submitted on the same day.
- Verbally checking that the IRAS REC checklist has been completed.
- Verbally checking that the version numbers and dates detailed in the checklist match those on the supporting documents.

If the application is ready to be submitted the Central Booking Team will then:

- Ask a number of questions which are based on the content of the IRAS form in order to determine if the application requires a flagged Committee.
- Ask a number of further questions to establish if the application may be suitable for Proportionate Review.
- If the application is potentially suitable for Proportionate Review it will be booked to the next available meeting in the UK.
- If the application requires a Full REC Review the appropriate Committee options will be provided in order for applicants to make their selection.

10. Submitting the Application

Once an application has been booked it is a requirement to submit the application on the same day.

Submission steps:

- The REC details given by CBS and held within the confirmation email are to be entered onto the Project Title page of the REC form situated in the box just before Part A.

**Please note- this is the only part of the data field that can be amended without invalidating the authorisations. If the form has been amended after it has been authorised but has not been saved, the data change alert will only appear when save is pressed following completion of the REC details box. **

- Complete a final check that all of the documents are uploaded to the IRAS REC checklist. A disk symbol appears when a document is uploaded.
- The application can then be submitted by returning to the E-submission tab and pressing E-submit.

Once submitted the IRAS form and documents uploaded to the IRAS REC checklist are viewable by the REC Manager. It is not possible for the booking staff or REC staff to view any part of the IRAS form until E-submit has been selected.

11. REC Manager Processes- Validation and Suitability Checks

On receipt of the application there are several processes that the Committee REC Manager goes through to ensure the application is valid, suitable and ready to be reviewed by the PR committee.

1. The REC Manager will use the **checklist** you have provided to ensure that all of the documents requiring review have been received.

2. The IRAS form will be checked to make sure that it is the **final version** and that the DRAFT watermark is not on the form.

3. The REC Manager will check that all of the declarations have been completed and that the correct **electronic authorisations** have been obtained. The Chief Investigator must be based in the UK and cannot be the same person as the Sponsor's Contact.

4. The **submission code** on the bottom right hand corner of the form will be checked as this needs to be the same on every page.

5. The REC Manager will check that the **filter page** to ensure it has been completed correctly. If it has not the sections relevant for your project type may not have been generated, making the application invalid.

6. If the participant is to be given less than **24 hours to consent**, the REC Manager will check that question **A31** has been completed.

7. Unless the research involves qualitative methods only, the REC Manager will check that **A56** has been completed.

8. The REC Manager will check that the **Lead Sponsor** and **Sponsor Contact** have been detailed in sections **A64 and A4**. We will check that the Sponsor Contact is an authorised signatory for the institution.

9. **Insurance and indemnity** arrangements need to be detailed in question **A76** and insurance documents need to be included with the submission package for non NHS sponsored studies.

10. The REC Manager will check that the **Chief Investigators CV** has been included. If this is an educational programme, the **Student** and **Academic Supervisor's CV** will also need to be included in the application.

11. If any of the collaborators detailed in **A63** are members of the REC the Committee Manager will arrange for the application to be sent to a different REC.

12. The REC Manager will also check application **suitability for proportionate review** against the criteria specified in points 3, 4 and 5**.**

Applicants will hear from the REC manager in the 5 days following submission either to confirm that the application is valid or to request further documentation or clarifications.

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.

12. The Review

The Proportionate Review Sub-Committee has a quorum of at least three members with at least 6 months of service on a REC. It is a requirement that the PR Sub- Committee includes a Committee officer, at least on expert member and at least one lay or lay plus member.

The Proportionate Review meetings are generally held by correspondence so there is not an option for applicants to attend. The reviewers may contact the Chief Investigator by phone or email prior or during their review to seek any further information, clarification or assurances that may help the sub-committee to reach their decision.

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.

13. Decisions Available

The below information provides information about the possible outcomes of a Proportionate Review Meeting. The decisions are the same as those that can be given following a Full REC review with one addition- the 'No Opinion'.

Favourable Opinion- If the PR Sub-Committee issues a favourable opinion the study can start subject to the management permission or approval obtained from each host organisation for each study site. Sponsors are not required to notify the PR Sub- Committee of approvals from host organisations.

Favourable Opinion with Conditions- When giving a Favourable Opinion, the REC may specify certain conditions that must be met *prior to the start of the study* (or the start at each site). In this case, the Favourable Opinion is valid only when the conditions are met. It is the responsibility of the sponsor to ensure that the specified conditions are met prior to the study start.

Provisional Opinion- The PR Sub-Committee may decide that a final opinion cannot be issued until further information or clarification is received from the applicant, or until changes or omissions are made to study documentation. Any altered documents will need to be approved by the PR Sub-Committee before a Favourable Opinion can be issued.

Unfavourable Opinion- Where the final opinion is Unfavourable, the applicant will be given a full explanation of the REC's reasons including options for further review.

No Opinion- If the application is found to contain material ethical issues it will need to be transferred to a full REC meeting for further review. A 'No Opinion' decision letter listing the identified ethical issues will be issued. The letter will contain an indication of the further information or changes likely to be required so that the applicant can begin to address these issues. However, the further information should not be formally submitted at this point as the application will have to be forwarded to full REC unchanged. In parallel to receiving the letter, the REC will contact the applicant to discuss availability to attend a full REC meeting in the researchers' region. If the first available slot in their region is accepted by the applicant (advisable), the 60 day clock (relevant for applications reviewed in a full REC meeting) will start from the date the valid application was initially received extending the existing clock. If the first available slot cannot be accepted by applicant, the clock on the application will start from the beginning from the cut- off date for the chosen meeting.

14. Glossary

Anonymous- Where the researcher (or anyone outside the direct care team) does not intend to access any patient identifiable data during any of the stages of research. The researcher would not have 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

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

Highly sensitive- This refers to questions which may cause anxiety because of the nature of the question or of the population being asked. Assessment of a question's sensitive nature might be influenced by whether the answers are to be anonymised. Examples of

topics often considered highly sensitive include HIV status, sexual activity, recreational drug use and mental health.

Ionising Radiation- Ionising radiation is radiation that carries enough energy to free electrons from atoms or molecules, thereby ionising them. Examples of ionising radiation include X-rays, CT scanning, DXA scans, Radiotherapy and Radionuclide imaging.

Minimally invasive- A minimally invasive medical procedure is defined as one that is carried out by entering the body through the skin or through a body cavity or anatomical opening, but with the smallest damage possible to these structures. Examples of procedures considered minimally invasive in research include prick test, swabs and taking a small amount of blood. Some procedures which are considered to be minimally invasive in a medical setting but would not be for research purposes. If the procedure is more invasive than the above example or if it involves a sensitive area of the body for example smear or rectal examination, the procedures would be considered invasive.