Eye research applications to United Kingdom research ethics committees: insights from 2022-2024

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Background

Ophthalmology research in the UK involving patients must be approved by an **NHS Research Ethics Committee (REC)** prior to commencement. RECs evaluate each proposal around the **nine 'ethics domains'** using a publicly accessible ethics review form.

Scan the QR code to learn about the 9 ethics domains. [NHS HRA website]

Research approval is frequently delayed

- often due to recurring issues identified in documentation submitted to RECs.

Aims & Objectives

- **Explore the issues most frequently identified** by NHS RECs when reviewing ophthalmology applications
- **Examine the type and amount of ophthalmology-related research taking place in the UK** and how it is funded, to build a picture of the current landscape

Methods

Health Research Authority (HRA) Assessment Review Portal (HARP) database was searched, using search terms (ophthalmic diagnoses) derived from the International Classification of Diseases 11th Revision (ICD-11), to identify ophthalmology-related research applications submitted to an NHS REC within a **two-year period** (Jan 2022 to Jan 2024).

Of the 150 applications retrieved, **100 fulfilled the criteria for inclusion** and were analysed.

A mixed-methods approach was used, incorporating both quantitative and qualitative techniques.

Results

Ophthalmology accounted for 1.8% of all UK health research applications during the review period.

The **most common search terms** within the applications were:

- age-related macular degeneration (27%),
- cataract (21%),
- and glaucoma (11%).

Sponsors of ophthalmology-related studies included NHS organisations (32%), academic institutions (27%), pharmaceutical companies (20%), and medical device manufacturers (14%).

The **mean time to an ethics decision was 31 days**.
Of the applications

- 78% received a provisional ethics opinion from the REC; meaning that changes to the application were needed prior to approval.
- 22% of applications received a favourable ethics opinion meaning that there were no changes, or only very minor changes required.

A total of **696 ethics issues were identified**.

- The **majority** (n= 438, 63%) concerned the **informed consent process and adequacy of participant information**; particularly issues relating to accessibility and readability of information for visually impaired participants, communication of data protection arrangements, and the provision of more toned down information about potential benefits. (Table 1a)
- **Second** most common (n= 93, 13%) ethics issues related to the **care and protection of research participants** including: reimbursement processes, participant welfare safeguards, and ensuring that participants were given sufficient time to make a decision about whether to take part in the study. (Table 1b)

All studies ultimately secured a favourable ethics opinion following amendment.

Table 1: Themes derived from the 2 most frequently cited ethics domains

1a: Domain: Informed consent process and the adequacy and completeness of research participant information

Themes within the Domain	Examples of Ethics Issues Raised by RECs
Limits of confidentiality	*'It should state in the patient information sheet (PIS) that new cases of hepatitis/HIV found in the study will be reported to healthcare authorities.'*
Visually impaired research participants and an independent witness	*'If participants are visually impaired then an independent witness should be involved to read the PIS as well as sign that they have done this...'* *'The PIS and consent form should be made available in large print for those who are visually impaired.'*
Patients given adequate time to make an informed decision	*'Please clarify in the documentation that consent will be taken at the initial site visit instead of the same day participants receive the study information.'* *'The Committee agreed it was important for potential participants to be given adequate time to think about participating in the study after they discuss it with the researchers'*
Named contact on PIS	*'The PIS should include details on who a participant can contact if they have concerns or complaints about the study.'*
Improving young persons' information sheet	*'Please reduce the length - seven pages is too long.'* *'Please ensure that the language is appropriate for this age group as readability scoring (SMOG scale) indicates that the current text is for 10-11 year olds'* *'Please ensure that the images used reflect a diverse society.'*
Toning down the benefits	*'Ensure that the expected benefits are explained more modestly throughout the PIS. It is important that the potential benefits of the study are not overstated as the research is yet to be carried out.'*
Improving pregnant partner information sheet	*Review the language used in the Pregnant Partner PIS, specifically where the word 'must' is used, as the document ought to be encouraging participants to report these.* *In the "What are your choices about how your information is used?" section, remove all reference to samples since only data will be collected from pregnant partners.*
PIS - Lay language and provision of summary PIS	*'Although it is appropriate, the PIS is very lengthy. To aid ease of understanding and readability please provide a summary sheet.'*
Continued access to study intervention	*'Please add a statement in the PIS to confirm to participants that the drug will no longer be made available to them following the conclusion of the trial phase, even if it was proving beneficial to participants whilst in the study'*

1b: Domain: Care & protection of research participants; respect for potential and enrolled research participants' welfare & dignity

Themes within the Domain	Examples of Ethics Issues Raised by RECs
Data protection	*'It is noted that IRAS section A36 indicates that personal data will be stored on laptops.* *a) Please clarify whether they will be personal laptops or University laptops.* *b) If personal laptops, please confirm whether they adhere to the Sponsor's confidentiality policies.'*
Patient/Public involvement	*'Please provide further information about the nature of the Patient and Public Involvement (PPI) that has been undertaken'*
Transparency of data analysis & storage/use or data transparency	*'A statement should be added to the Protocol and PIS to explain that anonymised, imaging data will be sent abroad [and] retinal images will be stored there with a company in Boston – even though the research itself would be carried out in the UK.'*
Reimbursement for travel	*'Please clarify whether the maximum £30 travel expenses payable is per visit or in total. Please also update this information in the PIS so it is clear to participants'* *'Make it clear in the PIS documents that participants' expenses will not be renumerated.'*
Informing GPs of participant involement	*'...GPs of the participants should be informed about their participation through a brief GP letter.'*

Conclusion

First study to systematically analyse ethics review outcomes for UK ophthalmic research.

We have **identified recurring shortcomings in applications** submitted to RECs, and **present practical strategies** to enable researchers to anticipate and address these ahead of submission to REC review (Table 2)

Table 2: Top tips when submitting an ophthalmology research application

Ensure the participant information meets the Health Research Authority's **Quality Standards**
Adapt for patient group: Ensure the participant information is adapted to the participant group. For example, consider the font size or providing information electronically if potential participants might have a visual impairment. Provide adapted versions of the participant information for children and their parents or guardians (if applicable), and consider how assistance with reading or viewing the participant information might need to be provided by an independent witness for those visual impairments.
Readability & plain language: Ensure the study is explained in plain language. Avoid overcomplicated or scientific terms, and explain acronyms or abbreviations the first time they are used. Keep sentences short (8 - 10 words) and paragraphs concise (3 to 5 sentences) to help with the readability.
Public involvement: involve patients or people with relevant lived experience to contribute to designing the research and participant information. The Health Research Authority has a checklist for researchers which can be used to help explain how people have been involved to the REC.
Ethical issues: use the application to the REC as an opportunity to describe how potential ethical issues have already been identified and mitigated.

Scan the QR code. Participant Information Quality Standards [NHS HRA website]

Scan the QR code. Participant Information Design & Review principles [NHS HRA website]

Scan the QR code. Best practice principles in public Involvement [NHS HRA website]

Embedding ethics early in study design will streamline the review process, and reduce delays in the delivery of impactful research in ophthalmology.

Key Words

REC	Research Ethics Committee
HRA	Health Research Authority
HARP	Health Research Authority Assessment Review Portal
PIS	Patient Information Sheet