Helping to ensure public involvement informs ethical review.
Guidance for public contributors

Background

The current question on the application form for ethical review about patient and public involvement (question A14-1 on the Integrated Research Application System [IRAS] form) does not usually lead to applicants providing information that helps reassure Research Ethics Committees (RECs) about the issues they are typically concerned about. This is because the question does not make any explicit link between involvement and potential ethical concerns even though one of the main benefits of involving patients and the public is to help ensure that studies are ethical and acceptable to participants. The Health Research Authority (HRA) is currently working to address this gap but it may take a year or more to make changes to the application form and develop guidance and learning support for applicants and RECs.

In the meantime, and without prejudicing the work the HRA is doing, it should be possible for public contributors and researchers to work together to improve their applications for ethical review by making the information on how patients and the public have contributed to the design of studies more relevant to the issues that RECs are concerned about.

Action for public contributors

If you have worked with a researcher to help design a study you can also help them to complete their application for ethical review by following the guidance below about what sort of information to include in the answers to a number of questions on the IRAS form. The objective is to add information about the relevance of the experience and advice you and other patients and the public brought to the study, what you did to help and how the design of the study changed as a result. It can also include what you will be doing to help with the conduct and management of the study.

Question A14-1, the existing question on public involvement. Describe here [in the free text box] the people who have been involved in designing the study and in what ways. Include numbers involved and what they did when as well as what [lived] experience they brought to the study and why that is relevant. Also include information about what the people involved will do to help with the conduct and management of the study.

This is to explain to the REC the range of input and justify that as being appropriate to the study (and more valid than the views of REC members).

For the each of the questions below include in the answer you help the researcher to write how the people described in A14-1 (which may include yourself) have helped address the issues raised by the question and what changed in the design of the study as a result:

Question A6-2, which asks applicants to summarise the main ethical, legal, or management issues arising from their study and say how they have addressed them. RECs will be assured if they see evidence that potential participants think the study is relevant and acceptable to take part in.

Jim Elliott, Advocate for patients in research, jim@drakesyard.co.uk. October 2017

Question A13, which asks for a summary of the design and methods, making it clear exactly what will happen to the research participants, how many times and in what order. RECS will be assured to see evidence that potential participants think that what will happen to the participants will be understood and accepted by them.

Question A22, which asks applicants what the potential risks and burdens are for participants and how they will minimise them. RECs will be assured by being told that potential participants think the risks and burdens are acceptable to them and that the practicalities of the study are acceptable.

Question A30-1 about gaining informed consent. Most RECs think that relevant patients need to be involved in producing the Participant Information Sheet, consent form and any other patient-facing information so will be assured to see details to confirm it. This could also include how the consent process has been shaped by the involvement.

Question A51 about the dissemination of the results. RECs consider that making the results of studies widely available is an ethical issue and see a role for the public in doing this well, including producing versions that are accessible to multiple audiences.

Attending the REC meeting

You could also suggest to the researcher that you, or another person who was involved in designing the study, attend the REC meeting with them to help assure the REC that the study design is acceptable to the potential participants.

Measuring the difference this makes

This approach may increase the likelihood of an application being given an outright approval, or lead to fewer conditions being placed on a provisional approval. The time to the final decision may be shorter too.

Please ask the researcher to let you know the decision reached by the REC and how long that took (date of submission and decision) along with the IRAS number of the application.

Please let the HRA's Public Involvement team know that you have used this approach and advise them what the IRAS number is for the application. They will be measuring the impact of this approach across the UK. If the approach can be applied to all applications made by a research group / unit etc. it should be possible to measure the difference it makes compared to a period of time before it was introduced (i.e. a simple "before and after" study can be done). The HRA's Public Involvement team will be able to help you do this. You can contact them at: hrapublicinvolvement@nhs.net

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