# Patient and Public Involvement and Engagement in Research

### Guidance for researchers applying to access Imperial Health Knowledge Bank (IHKB) participants/data in relation to expectations regarding public involvement and engagement in research plans

**Background**

All applications to access IHKB participants/data are made to a data access committee which includes public contributors who review the following sections of the application:

* Lay summary
* Public benefit question
* Public involvement and engagement plans

**What is Patient and Public Involvement and Engagement**

We use the National Institute of Health and Care Research (NIHR) definitions) which are as follows:

* **Public Involvement:** Where members of the public are actively involved in research projects and in research organisations and research is carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them
* **Public Engagement:** Where information and knowledge about research is provided and disseminated
* **Public Participation:**Where people take part in a research study

When using the term ‘public’ NIHR include patients, potential patients, carers and people who use health and social care services as well as people from specific communities and from organisations that represent people who use services. Also included are people with lived experience of one or more health conditions, whether they’re current patients or not.

You will note that the IHKB application form asks the following question:

“What plans do you have to involve and engage with members of the public as part of this research project proposal?”

We have set out below guidance relating to answering this question: From 1 December 2023, the Health Research Authority (HRA) launched new [Quality Standards and Design and Review Principles](https://www.hra.nhs.uk/about-us/news-updates/frequently-asked-questions-quality-standards-and-design-and-review-principles/) to improve information for people invited to take part in research. Therefore, in order to receive HRA ethics approval, research is required to adhere to these principles.

**Mapping for Guidance to follow with your application.**



##### Guidance1: Applications which received HRA Ethics Approval prior to 1 December 2023

##### Where HRA approval for your study was received prior to 1 December 2023, you will hopefully have already been involving the ‘public’ (see definition above) in your research to date as is expected by most funders and good practice. However, if for some reason you have not, you will be expected to include your plans for public involvement and engagement for the remainder of your study in the IHKB application form. We suggest you include in the response to this question: “The trial/study is nearly completed to recruitment, we have not undertaken any patient involvement and engagement to date, however we are going to commit to… [include what will be done in future – see below for guidance]”

For example:

* What are your plans to involve the public in developing lay summaries of results of the study?
	+ You could ask a patient living the condition/issue being researched who is known to a clinician with whom you are linked/ charity/patient group to assist with this (ethics approval is not required for this) to review a draft summary to ensure it is appropriate for those most affected by your research
* What are your plans for dissemination of study results to:
	+ study participants. Do you have approval to recontact participants with the summarised results of the study? If not, can you commit to:
		- identifying a way to provide the summarised results to participants?
		- provide a lay summary of the results to IHKB to include in their newsletter to all IHKB participants within 3 months of the study ending?
	+ those impacted by the study i.e. patients living with the condition/issue (apart from study participants) and their carers/family or charities/patient groups supporting those patients (consider translation of results into different languages of those most affected by the condition/issue; different mediums through which to share the results e.g. infographic, video etc)
	+ the public (more generally) who may also be interested in the results. Will the results be included in a media article, at a science festival, shared at community events and schools? Please note that scientific publications do not count as dissemination to the public as these are not in lay language and often behind paywalls.

##### Guidance 2: Applications which received HRA Ethics Approval on or after 1 December 2023

We would expect that you have at least involved the public in the review of the participant information sheet and informed consent (as this is required by the HRA). Please confirm who you involved in this review, how many people you involved, and how their input changed the document. Please also explain what other public involvement you have undertaken or planned for the study.

Have you asked the public, and what did they tell you about the following:

* + whether this research was relevant and important to them
	+ whether the research process was ethical and acceptable to them
	+ the design of the research including:
* the outcome measures (were additional outcome measures included as a result of public involvement feedback (even as secondary or exploratory outcome measures)
* the inclusion/exclusion criteria (whether these were appropriate)
* the recruitment plan is acceptable to those who would take part (and would maximise retention)
* the participant’s study visit schedule including the tests required and their frequency (to maximise retention)
* the recruitment strategy and materials (were these clear, appropriate, in relevant languages and understandable)
* whether appropriate expenses are being paid to study participants e.g. travel, refreshments, accommodation
* whether appropriate support is provided where needed to study participants e.g. psychological support
* whether participant facing materials are clear and understandable e.g. interview or survey questions, post study experience survey, quality of life measures
* if the dissemination plan of results is appropriate

In addition:

* will research participants be informed of the overall study results in a timely manner and in a way which is accessible to them?
* is there a patient on the trial management/steering committee (to bring a patient/public perspective to the progress/challenges of the study)?
* do you have a patient advisory group who meet throughout the study to bring their perspectives/advice to:
* changes to the protocol and consent documentation
* difficulties with recruitment
* review of results/trends identified/gaps in results
* sharing the results in appropriate formats and to appropriate groups
* co-authoring papers
* co-presenting results
* implementing results
* evaluating the impact of the public involvement

For support before submitting an application, please contact us to discuss your study, email at imperial.healthknowledgebank@nhs.net.

**Links for further information regarding NHS HRA Requirements for Involving Patients in HRA Ethical Approval**

[Frequently Asked Questions: Quality Standards and Design and Review Principles - Health Research Authority](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hra.nhs.uk%2Fabout-us%2Fnews-updates%2Ffrequently-asked-questions-quality-standards-and-design-and-review-principles%2F%23%3A~%3Atext%3DWe%25E2%2580%2599ve%2520launched%2520new%2520Quality%2520Standards%2520and%2520Design%2520and%2Cand%2520will%2520become%2520mandatory%2520from%25201%2520December%25202023.&data=05%7C02%7Csarah.stimpson%40nhs.net%7C3645ec5dd1e9403079a508dd2e4b3013%7C37c354b285b047f5b22207b48d774ee3%7C0%7C1%7C638717622666927617%7CUnknown%7CTWFpbGZsb3d8eyJFbXB0eU1hcGkiOnRydWUsIlYiOiIwLjAuMDAwMCIsIlAiOiJXaW4zMiIsIkFOIjoiTWFpbCIsIldUIjoyfQ%3D%3D%7C0%7C%7C%7C&sdata=gzXOHGQ%2Fzr4Gwurt9ChTWtpByC1%2FN2sMJQEN%2Fv%2F%2FLXg%3D&reserved=0)

[Participant Information Quality Standards - Health Research Authority](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hra.nhs.uk%2Fplanning-and-improving-research%2Fresearch-planning%2Fparticipant-information-quality-standards%2F&data=05%7C02%7Csarah.stimpson%40nhs.net%7C3645ec5dd1e9403079a508dd2e4b3013%7C37c354b285b047f5b22207b48d774ee3%7C0%7C1%7C638717622666959309%7CUnknown%7CTWFpbGZsb3d8eyJFbXB0eU1hcGkiOnRydWUsIlYiOiIwLjAuMDAwMCIsIlAiOiJXaW4zMiIsIkFOIjoiTWFpbCIsIldUIjoyfQ%3D%3D%7C0%7C%7C%7C&sdata=pCUWGNvHZEjCL7nJAEpLBZlrnyCIB55oFdyBHIza91Q%3D&reserved=0)

[Participant Information Design and Review Principles - Health Research Authority](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hra.nhs.uk%2Fplanning-and-improving-research%2Fresearch-planning%2Fparticipant-information-design-and-review-principles%2F&data=05%7C02%7Csarah.stimpson%40nhs.net%7C3645ec5dd1e9403079a508dd2e4b3013%7C37c354b285b047f5b22207b48d774ee3%7C0%7C1%7C638717622666976159%7CUnknown%7CTWFpbGZsb3d8eyJFbXB0eU1hcGkiOnRydWUsIlYiOiIwLjAuMDAwMCIsIlAiOiJXaW4zMiIsIkFOIjoiTWFpbCIsIldUIjoyfQ%3D%3D%7C0%7C%7C%7C&sdata=UctoHVxMpOARSkQCwQzJQxV4pF93RWI1h9u4CEkLpE8%3D&reserved=0)

**Links for further guidance on involving patients in research**

Imperial Patient Experience Research Centre Public Involvement Research Hub: [Public Involvement Resource Hub | Faculty of Medicine | Imperial College London](https://www.imperial.ac.uk/patient-experience-research-centre/ppi/ppi-resource-hub/)

If you are an Imperial Biomedical Research Centre linked researcher, please contact the Imperial Patient Experience Research Centre on: publicinvolvement@imperial.ac.uk