

HRA Strategy for Public Involvement

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Contents

1. About the Health Research Authority	3
2. Who is this public involvement strategy for?	3
3. Where are we now?	3
4. What are the aims of this public involvement strategy?	5
5. What are the objectives of this public involvement strategy?	6
6. How will we know this public involvement strategy is successful – outcomes and benefits?	9
7. How will we monitor this public involvement strategy?	9
8. Roles and responsibilities	10
 Appendices	
A. What do we mean by public involvement in health research?	12
B. Why is public involvement in health research important to the HRA and more widely?	14
C. What are our principles and standards for public involvement?	15

1. About the Health Research Authority

1.1 The purpose of the Health Research Authority (HRA) is to protect and promote the interests of patients and the public in health research. We do this by making sure there are strong and effective systems in place to ensure that health research is well managed and meets high quality and ethical standards. We do not conduct or fund health research itself, our responsibilities are to support the funding and conduct of health research by others. More information is available on our web site at www.hra.nhs.uk.

2. Who is this public involvement strategy for?

2.1 This strategy is aimed at:

- **Patients and the public** – those who may take part in health research studies or become actively involved in the design, conduct or management of health research studies
- **External users of our service** - researchers who put in applications for ethical review and research governance approvals
- **Partner organisations** who fund, approve, manage and regulate health research such as the Medicines and Healthcare Products Regulatory Agency (MHRA) and the National Institute for Health Research (NIHR)
- **HRA staff, Board and committees** – all those who work with or for the HRA and may be affected by the services we develop and how we operate them

3. Where are we now?

3.1 When the HRA was set¹ up we made a strong commitment to involve patients and the public. Over the last 18 months we developed this strategy through a working group and workshops with a range of partners.

3.2 We have developed a clear definition of what we mean by public involvement, which is at Appendix A.

3.3 By way of background to the strategy we have set out why public involvement in health research is important to us and our work and more widely in health research, and this is at Appendix B.

3.4 We have also developed a set of principles and standards for public involvement, both for how we will involve patients and the public and for how we think patients and the public should be involved in health research more widely, and these are at Appendix C.

¹ The HRA was set up on 1 December 2011

3.5 We have invited patients and the public to take part in many of our workshops and other events related to our wider agenda. However, so far we have only involved patients and the public in a small part of our core business.

3.6 We know we can do much more to involve patients and the public in our work and we will learn from organisations that do this well such as the National Institute for Health Research (NIHR) and its equivalent organisations in Wales, Scotland and Northern Ireland, the National Institute for Health and Care Excellence (NICE) and a number of health research charities.

3.7 We know we have some areas of strength in involving patients and the public, and we are determined to build on this. The ethical review process for health research has a history of public involvement in the form of:

3.7.1 A long running commitment that a third of the members of Research Ethics Committees² must be lay. They are appointed through open advertisement, which means that they attract a wide range of people, many of whom have a service user or carer perspective. The lay role is one of the most important components of a high quality ethical review service.

3.7.2 Consideration of the nature and effectiveness of the involvement of patients and the public in the design of health research studies including, but not limited to, the content of patient information sheets.

3.8 More recently we have involved patients and the public in other areas of our work and looked more widely at public involvement in health research, for example:

3.8.1 The most up-to-date guidance being developed for applicants for ethical review on writing Patient Information Sheets has been informed by workshops with our partners including patients.

3.8.2 Conducting a joint project in 2011 with INVOLVE³ to analyse the extent and nature of the public involvement reported in applications for ethical review. This showed that patients and the public were involved in about a fifth of the applications submitted in 2010 and forms a baseline from which we will be able to measure changes⁴.

² There are 69 Research Ethics Committees with between 7 and 18 members each amounting to over 1,000 members of whom a third are lay

³ INVOLVE is the national advisory group on involving patients and the public in health research and is funded by the National Institute for Health Research in England – see www.invo.org.uk

⁴ Tarpey M., (2011) Public involvement in research applications to the National Research Ethics Service, INVOLVE, Eastleigh

4. What are the aims of this public involvement strategy?

4.1 This Public Involvement Strategy sets out the HRA's approach to how we will:

- Involve patients and the public directly in our own work, and
- Use our influence to support and enable those who conduct, fund and manage health research to involve patients and the public more in their work

4.2 The aims of the strategy are to:

- Improve the quality of decision making in the HRA through listening to patient and public voices
- Improve the quality of research the HRA approves by ensuring that more of it involves patients and the public where it will add value in terms of its relevance to what is important to patients and the public, and the likelihood of improving people's health and wellbeing

4.3 The objectives we will pursue to achieve this strategy, which are described in detail below in Section 5, are to:

1. Develop the HRA into an effective "involving" organisation.
2. Embed public involvement into the core business of the HRA
3. Develop the role of the HRA with its partners to support the spread of public involvement in health research

4.4 We will be clear about the aspects of our work where we will involve patients and the public and those where we will not.

4.5 This version of the strategy is being distributed for comment with our partners and anyone else interested in our work. The strategy will be reviewed at the beginning of 2014 in light of the comments and feedback received. We will review the strategy annually thereafter.

4.6 This public involvement strategy sits within a broader strategy for engagement with our partners, and an important part of that is clear communications as part of the HRA's communications strategy and plan. We will ensure that we use our full range of communications methods to support our public involvement and in promoting public involvement more widely.

5. What are the objectives of this public involvement strategy?

Objective 1: Develop the HRA into an effective “involving” organisation.

5.1 We will develop the HRA as an organisation that values public involvement, develops the capacity and capability of its staff to involve patients and the public in its own work and supports and promotes involvement more widely in health research.

We will do this by:

5.1.1 Publishing a statement of organisational commitment to public involvement based around clear definitions and principles for what we mean by this term. . An initial statement has been included in our first Annual Review and will be followed up on the HRA’s web site.

5.1.2 Providing basic level training for all staff and committee members to ensure they are aware of and understand the principles and benefits of public involvement in health research. We will build this training into the induction of new staff and committee members.

5.1.3 Providing additional training and support for those staff whose work could benefit from involving patients and the public. This will ensure that they have the confidence and skills to involve the public professionally to maximise the impact it will have on their work. We will look to a range of partner organisations to advise on and deliver the different levels of training we require, ensuring patients and the public are also involved in designing and delivering the training.

5.1.4 Developing our capacity to support public involvement in our work and ensuring there are adequate resources to deliver this. We will review the resource requirements we need to support the involvement of patients and the public in our own work and the work we do to promote public involvement more widely. We will build a team of staff to support this appropriate to our needs and the funding available.

5.1.5 Ensuring through our management structures that we apply our principles and standards for public involvement (Appendix C) as we start to involve patients and the public more in our work.

5.1.6 Identifying up to five areas of work or projects (see 5.2.1 below) in which we can involve patients and the public where we have not done so previously. We will identify these areas of involvement by the end of 2013 and take them forward during 2014, ensuring the outcomes and lessons learnt are shared across the organisation.

Objective 2: Embed public involvement into the core business of the HRA

5.2 We will build public involvement into our core business by:

5.2.1 Reviewing our business plan to identify all areas of our work where public involvement would add value and where public involvement can be promoted as part of our influencing work with research communities.

5.2.2 Building the inclusion of public involvement into the business planning cycle and guidance for HRA teams.

5.2.3 Building the consideration of whether and how to involve patients and the public and how well we have done it into our routine management and reporting.

5.2.4 Building up networks of contacts with patients, the public and representative organisations who have already contributed to our work so we can involve them further and get their help to find other people to involve. We will also identify and review approaches to identifying patients and the public more widely with a view to ensuring that we are able to find a wide and diverse range of people to contribute to our work.

5.2.5 Appraising the most effective ways to involve patients and the public in our work. We will do this in collaboration with our partners and consider different approaches that have been used successfully by a number of organisations who informed the development of this strategy. This will include looking at the merits of setting up a panel of patients and the public as a source of people to involve in our work, which has worked well for the National Institute for Health and Care Excellence (NICE) and the research coordinating centres of the National Institute for Health Research (NIHR).

5.2.6 Continuing to invite patients and the public to join our working groups and committees and to contribute to workshops and other events.

Objective 3: Develop the role of the HRA with its partners to support the spread of public involvement in health research

5.3 We will promote and support the spread of public involvement in health research with a view to this becoming the rule and not the exception. We will also work with our partners including the National Institute for Health Research (NIHR) to exert our influence on those who conduct, fund and manage health research to understand the benefits of public involvement for health research. We will ensure the actions we take to promote public involvement will not increase the regulatory burden on the research community.

We will play our part in supporting the spread of public involvement in health research by:

5.3.1 Contributing to collaborative work to develop and embed public involvement in health research and related debate including: seeking observer status with INVOLVE; networking with public involvement leads in organisations that fund and manage health research including the Life Sciences industries; attending and contributing to workshops and other events related to public involvement in health research.

5.3.2 Signposting resources on our web site and through our other communications channels to: organisations who have helpful approaches and resources; key contacts for advice and guidance and; helpful documents and web sites.

5.3.3 Continuing the mapping work that we have been doing on public involvement in health research to look for examples of good practice as an on-going development resource for the HRA's web site.

5.3.4 Repeating the joint project we did with INVOLVE in 2011 (see paragraph 3.8.2 above) with applications made in 2012 to see whether the extent and nature of public involvement in applications for ethical review has changed since 2010.

5.3.5 Evaluating whether and how we can gather the evidence to support the development of a simple good practice guide on how public involvement can make a difference to securing research and ethics approvals.

5.3.6 Supporting collaborative work to develop minimum standards for public involvement in health research studies.

5.3.7 Developing better ways of capturing information on public involvement in applications for ethical and governance review. We will improve the questions on public involvement in the replacement for the Integrated Research Application System (IRAS) form and related guidance and training for researchers.

5.3.8 Requiring researchers to describe how patients and the public have been involved in the development of their studies for inclusion in the Patient Information Sheet, developing the guidance for writing these accordingly.

5.3.9 Developing guidance and training for Research Ethics Committee members to assess whether the public involvement reported for studies in applications is appropriate and proportionate.

6 How will we know this public involvement strategy is successful – outcomes and benefits?

6.1 Applicants for ethical review and governance approvals involve patients and the public in their work where it is appropriate and will add value, and will understand and can explain how public involvement can help them to secure ethical and governance approvals more quickly and without problems.

6.2 Applicants for ethical review provide details of whether, and if so how, they have involved patients and the public in the development of their research.

6.3 The health research community views the HRA as an authority on public involvement and acts on our advice and guidance to involve patients and the public more in health research.

6.4 The proportion of applications for ethical review that are given a favourable opinion without changes will increase because applicants have involved patients and the public in the development of their research.

6.5 Patients and the public inform the development of our policies and guidance such as: guidance for researchers on writing Patient Information Sheets for health research studies; or the development of guidance for researchers on how they should inform study participants of the results.

6.6 Patients and organisations that represent patient interests in research understand and can explain the contribution the HRA makes to protecting and promoting the interests of patients and the public in health research, and view the HRA as an organisation that listens to patients and understands and takes account of their views.

7. How will we monitor this public involvement strategy?

7.1 While this strategy is out for comment and feedback from our partners we will start some of the work necessary to deliver the strategy such as planning the training for our staff and committees, reviewing our business plan, putting resources on our web site and networking. We will involve patients and the public in this work where it is appropriate and will add value.

7.2 We will use the comments and feedback we receive to review the strategy and develop an action plan to put it fully into action. The plan will initially cover the 12 months following the period for comment and feedback and be developed into a longer term plan thereafter. The strategy will also be reviewed by our Executive Management Team and Board once the comments and feedback have been incorporated.

7.3 The action plan will be reviewed and updated annually by our Executive Management Team and Board as part of annual progress reviews of our business plan, team plans and individual objectives. This will measure both the success of the strategy itself and the impact it has had on our work overall.

7.4 We will work with our partners to explore ways in which we can measure the impact this strategy has had.

8. Roles and responsibilities

8.1 The HRA is responsible for this Public Involvement Strategy and it has been approved by our Executive Management Team and Board at the different stages of its development. Our Public Involvement Lead will be responsible for leading the further development and implementation of the strategy, including the period for comment and feedback from our partners. We will establish a clear framework for accountability to ensure that we deliver the strategy and monitor and assess its effectiveness.

8.2 Our **Chief Executive** has overall accountability for our public involvement activities covering both our delivery and influencing agendas. Responsibility for delivering this strategy has been delegated to the Director of Business Support, working closely with the Director of Communications. Our Chief Executive will ensure that public involvement remains a priority across the organisation.

8.3 The **HRA Board** has approved this public involvement strategy and takes responsibility for: monitoring and reviewing overall implementation of the strategy; reviewing and responding to the way the HRA responds to input from the public; assuring itself the organisation is properly equipped for public involvement; and keeping abreast of public involvement policy, practice and procedure.

8.4 The **Executive Management Team and its Management Groups** will be responsible for: assuring itself and the Board that we are properly equipped for public involvement; monitoring and reviewing the detailed implementation of the strategy; following up issues which arise from public involvement, ensuring any resultant actions or decisions are taken; and showing leadership by example to the rest of the organisation.

8.5 Our **Senior Managers** will be responsible for ensuring that their teams have the awareness and skills necessary to involve patients and the public, build public involvement and the promotion of it into the planning and delivery of their work and monitor its effectiveness. Our Senior Managers will also lead by example to champion public involvement in their teams and across the organisation.

8.6 We have appointed a **Public Involvement Lead** to lead the development of this strategy and support the organisation to put it into action. We will assess the

resources we need to support public involvement across the organisation and 'cost out' a plan to ensure the objectives to do this can be achieved and are affordable.

8.7 **All our staff** will have a responsibility to ensure they understand and can explain the value and benefits of public involvement to the work of the organisation and to health research more widely. Some staff will involve patients and the public in their own work, where it will add value, and they will have a responsibility to; work with colleagues to develop and share good practice and monitor the effectiveness of what we do, and; promote public involvement in health research where their work presents an opportunity to do so.

Appendix A: What do we mean by public involvement in health research?

A1 By **public involvement** we mean a range of activities that enable patients and the public to have a say in decisions about the way health research is planned, designed, delivered, developed, evaluated, managed and regulated. It also means where patients and the public are actively involved in the conduct of research studies.

A2 **Public involvement** means that work is undertaken ‘with’ or ‘by’ patients and the public rather than ‘to’, ‘about’ or ‘for’ them.

A3 By **public involvement** we do not mean **participation**, where people are recruited to and take part in research studies as the subjects of the research, and contribute the information or data used to answer the question being addressed.

A4 We recognise that other people and organisations use a range of terms for what we refer to as **public involvement** in their own activities, including **public engagement** and **public participation**. However, we have decided to use the term **public involvement** for this to be consistent with the Department of Health, National Institute for Health Research (NIHR) and majority of organisations who fund and manage health research in the UK.


A5 We will use the term **public involvement** as a short-hand term for involving patients and the public in health research. When we use this term **public** means patients, potential patients or members of the public including those with known genetic dispositions, carers and people who use health and social care services as well as people from organisations that represent people who use health and social care services.

A6 Where necessary we will define what we mean by **public** depending on who is taking part in the involvement activity. For instance, there may be times when patients and the public are involved, or where what is needed is the general public and not patients, or other times where patients and carers are needed and not the general public.

A7 We will not use any abbreviations for public involvement, such as PPI (for Patient and Public Involvement). This is to ensure that it is always clear that we mean **involvement** and that it is about patients and the public. It will also help avoid developing a jargon term that is misused, for example “PPI people”, “PPI involvement”, “PPI-ing”.

A8 The way in which patients and the public can be involved in the work of organisations varies. Different methods need to be used appropriate to the circumstances and audiences, which can vary in depth, influence, and timescale.

A9 The range of involvement⁵ can be represented in the table below. Maximum involvement in health research studies extends partnership to “user-led” or “user-controlled” research, where patients and the public set up studies and in some situations conduct them.

Minimum involvement					Maximum involvement
Giving information	Getting information	Forums for debate	Working with	Working in partnership	
Exhibitions, leaflets and written documents.	Citizens' panels, interviews, patient diaries.	Focus groups, seminars, meetings with patients.	Membership of decision making bodies, Citizen's Juries, public dialogue	Part of or leading project teams to co-produce work.	
“We want to tell you about something that needs to change”	“As a user or carer, what was your experience of...?”	“We would like to discuss this issue with you”	“We want to work with you on this issue”	“We want you to be an equal member of our team”	

⁵ Based on Arnstein's “ladder of citizen participation”

Appendix B: Why is public involvement in health research important to the HRA and more widely?

B.1 Our Board is committed to involving patients and the public in our work because we feel this is fundamental to support our core purpose. We believe as an organisation that those who are affected by a decision have a right to be involved in the decision-making process. We also believe that involving patients and the public in our work will improve the quality of decision-making. Involvement will ensure that we have a full understanding of what the interests of patients and the public in research are and so fulfil our key purpose to protect them.

B.2 As well as our direct responsibilities at the HRA, we have an important role in influencing the behaviour of researchers and the organisations that fund and manage health research, who are dependent on our approval processes. We believe that involving patients and the public in health research will improve it by ensuring it is relevant to the needs of patients and more likely to have an impact on their health and wellbeing. Therefore, we want to use our influence to support and enable the spread of public involvement in health research.

B.3 In recent years, great emphasis has been placed on patient and public involvement and engagement in general in the health sector. This is reflected in the NHS Constitution, related government policy and the Francis Report⁶.

B.4 The Department of Health has also made involving patients and the public an important part of its strategies for health and social care research since it set up the NHS Research and Development Programme in 1992.

B.5 More recently, the National Institute for Health Research's vision for public involvement in research has been expressed by Professor Dame Sally Davies, Chief Medical Officer and Chief Scientist for the Department of Health as follows:

"...public involvement in research should be the rule not the exception. It is fundamental to ensure high quality research that brings real benefits for patients, the public and the NHS."⁷

⁶ Health and Social Care Act 2001, the NHS Constitution for England and National Health Service Act 2006, including Real Involvement – Working with People to Improve Health Services October 2008 (Guidance for NHS organisations on section 242(1B) of the NHS Act 2006, the duty to involve and good involvement practice), The Francis Report - Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, February 2013.

⁷ Staley K. (2009) Exploring Impact: Public involvement in NHS, public health and social care research. INVOLVE, Eastleigh.

Appendix C: What are our principles and standards for public involvement?

C1 We will adopt key principles for the involvement of patients and the public in our work that we have identified from a range of organisations that fund and manage health research and that fit with our organisational values.

These include:

- Being clear about what we mean by public involvement
- Openness and honesty about why we are involving people, how much involvement is possible and the influence that it will have
- Transparency and openness about the way we will involve people
- Providing support for people to be involved including information, training, expenses and funding
- Involving a diverse range of individuals and groups
- Reviewing the effectiveness of the way we involve people and the difference it makes to us, our work and the people whom we involve
- Embracing and building on the unexpected consequences of public involvement such as sensitive or difficult issues that people may raise from their lived experience
- Sharing examples of effective public involvement and good practice

C2 When we involve patients and the public in our work we will ensure there is:

- Support for public involvement at senior management level linked to our strategy and objectives
- Adequate resourcing to ensure we can support those we involve to contribute fully
- Defined roles, responsibilities and objectives for those who we involve to ensure they know what is expected of them
- Good partnership working that leads to co-production, which means those we involve contribute as equals with our staff to the work they are doing
- Effective evaluation of our involvement and the difference it makes, sharing the lessons learnt
- Feedback to the people we engage with and involve in our work. This will include the extent to which we have been able to use their input, following a “you said, we did” approach. Where it has not been possible to use their input in full we will explain the reasons for that

C3 We will use a range of methods of involvement appropriate to the individual tasks and contributions we seek. This is because involvement cannot be effective through a “one size fits all” approach. Each and every time we want to involve patients and the public we will consider:

- Whether involving patients and the public will make a difference to the task or area of work and add value?
- If so then whether there are clear tasks or roles patients and the public can fulfil and how?
- Whether those we involve will have the necessary skills for the roles or tasks or could acquire them quickly?

C4 Further, we will seek to be creative in the ways we involve the public in keeping with our values, principles and standards for involvement. We will also seek input from patients and the public on the way that they would like to be involved.

C5 We believe that effective public involvement:

- happens early and continues throughout a process;
- is inclusive;
- is informed;
- is fit for purpose;
- is transparent;
- is influential, it makes a difference;
- is two-way and includes feedback and continuous improvement
- is proportionate to the issue.

C6 Our approach to involvement is consistent with our values as an organisation that has:

- **Inspiring leadership:** Delivering the best possible service for patients and the public, through effective leadership, teamwork, creativity and flexibility, and by working with our partners to make the UK a global leader for health research
- **Integrity:** Being credible and fair, and delivering consistently to the highest quality

And is:

- **Trusted:** Inspiring respect through dedication, engagement, delivering on our commitments, continually striving for excellence and adhering to high ethical standards
- **Transparent:** Communicating effectively, both listening and being open about all aspects of our work
- **Collaborative:** Finding new ways to support innovation through collaboration, forward thinking and inspiring new ideas
- **Empowering:** Being supportive and respectful in all our working relationships – both internal and external – whilst encouraging independent decision-making