



Health Research
Authority

Data governance

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**AI and machine learning in clinical imaging
research, 6 November 2018**

What does the HRA do?

- We protect and promote the interests of patients and the public in health and social care research
- We make sure research is ethically reviewed and approved
- We facilitate and make it easier to do research
- Our research ethics committees protect the rights, safety, dignity and wellbeing of research participants
- Our Confidentiality Advisory Group advises on the use of patient data without consent

Criteria for CAG support

- Is there a practical alternative?
- Can consent be obtained?
- Can anonymised data be provided?
- Are there appropriate standards of data protection, security and governance in place?
- Would the public interest outweigh the breach?
- Have patient groups been consulted the about acceptability of the data use?

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Public involvement is central



Standard 1: INCLUSIVE OPPORTUNITIES

We offer public involvement opportunities that are accessible and that reach people and groups according to research needs.

Standard 2: WORKING TOGETHER

We work together in a way that values all contributions, and that builds and sustains mutually respectful and productive relationships.

Standard 3: SUPPORT & LEARNING

We offer and promote support and learning that builds confidence and skills for public involvement in research.

Standard 4: COMMUNICATIONS

We use plain language for timely, two way and targeted communications, as part of involvement plans and activities.

Standard 5: IMPACT

To drive improvement, we capture and share the difference that public involvement makes to research.

Standard 6: GOVERNANCE

We involve the public in our governance and leadership so that our decisions promote and protect the public interest.

It doesn't have to be difficult

Home > Planning and improving research > Best Practice > Best practice in public involvement >

Top tips for public involvement in your research application

Last updated on 21 Jun 2018

www.hra.nhs.uk

10 questions to ask about your public involvement

- 1. Who is involved** – who are the patients, carers, service users, or members of the public you're working with, and how many are there?
- 2. How is their experience relevant** – why is this valuable for your study?
- 3. What specifically are they doing** – at which stages of the research?
- 4. How is their involvement changing your research** – what difference does it make?
- 5. How is their involvement helping you to address the study's main ethical issues?**
- 6. How is their involvement making a difference to the research design and methods** – for example, is it shaping the research question, intervention, and/or the outcome measures?
- 7. How is their involvement making a difference to how you'll manage potential risks and burdens** – for example, is it helping to identify potential emotional or practical obstacles for participants?
- 8. How is their involvement making a difference to the recruitment process** – for example, is it helping you to decide how best to approach potential participants?
- 9. How is their involvement making a difference to the consent process** – for example, are you co-developing the participant-facing information so participants will be able to understand the study and be able to make an informed decision about whether or not to take part?
- 10. How is their involvement making a difference to how the study results will be shared** – for example, is this helping you to plan how to make the study results available in a way that will be accessible to different audiences?

What do patients think?

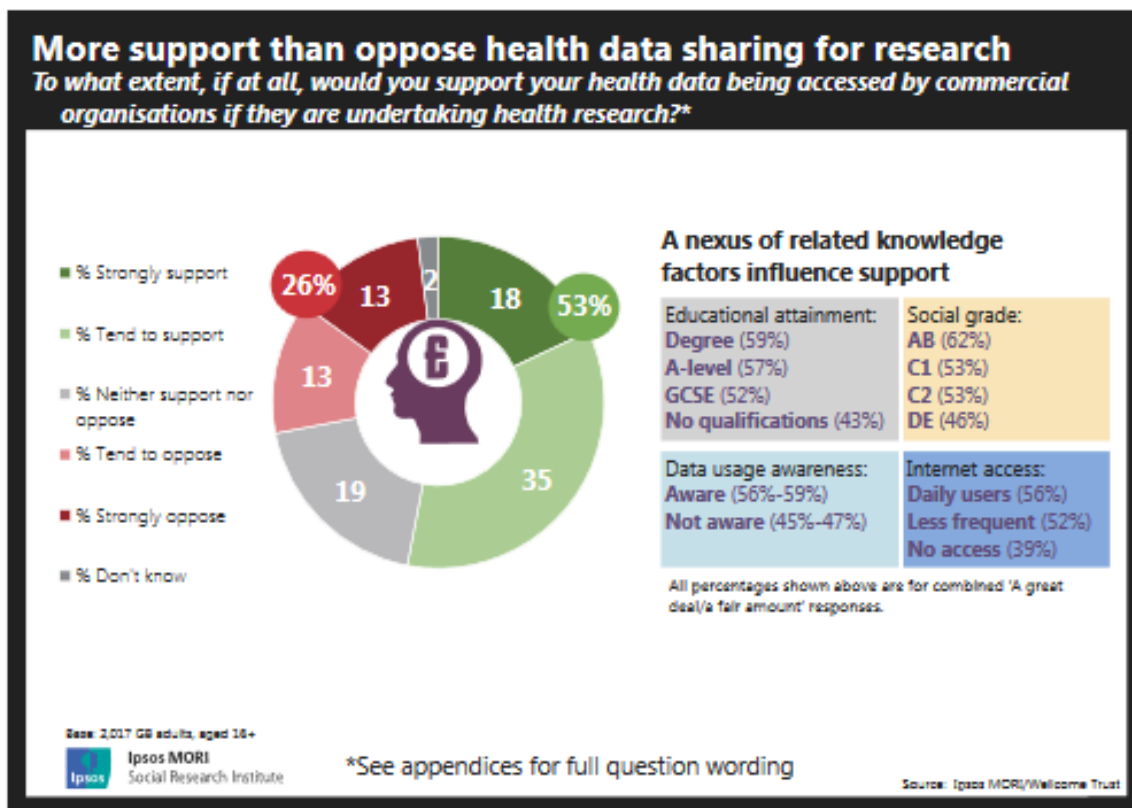
- The **NHS is highly trusted** compared to others
- Support is informed by **who** has access to patient data
- Most people support sharing patient data for individual care and most support sharing for research **where there is public benefit**
- Support exists even though there are concerns
- Using real examples, being transparent and encouraging genuine dialogue are ways in which organisations can increase their trustworthiness

Trust

Which, if any, of the following would you trust with data about you? (Please select all that apply)	Total	18-24	25-34	35-44	45-54	55+
Base: All GB adults online	2023	233	296	355	359	780
Central government	37%	35%	40%	38%	33%	38%
Local government	41%	43%	44%	39%	38%	41%
NHS & healthcare providers	64%	67%	61%	64%	59%	65%
Offline retailers	10%	22%	15%	10%	8%	6%
Online retailers	22%	36%	26%	26%	17%	16%
Banks and credit card companies	57%	60%	57%	57%	52%	57%
Medical research charities	24%	39%	26%	20%	21%	21%
Marketing & advertising companies	2%	4%	3%	2%	1%	1%
Insurance Companies	32%	30%	32%	30%	33%	33%
Social media organisations	10%	25%	17%	12%	5%	5%
Universities	25%	63%	37%	28%	19%	11%
Family and friends	57%	65%	55%	56%	52%	58%
None of these	13%	6%	11%	10%	17%	15%
Don't know	7%	7%	9%	9%	6%	6%

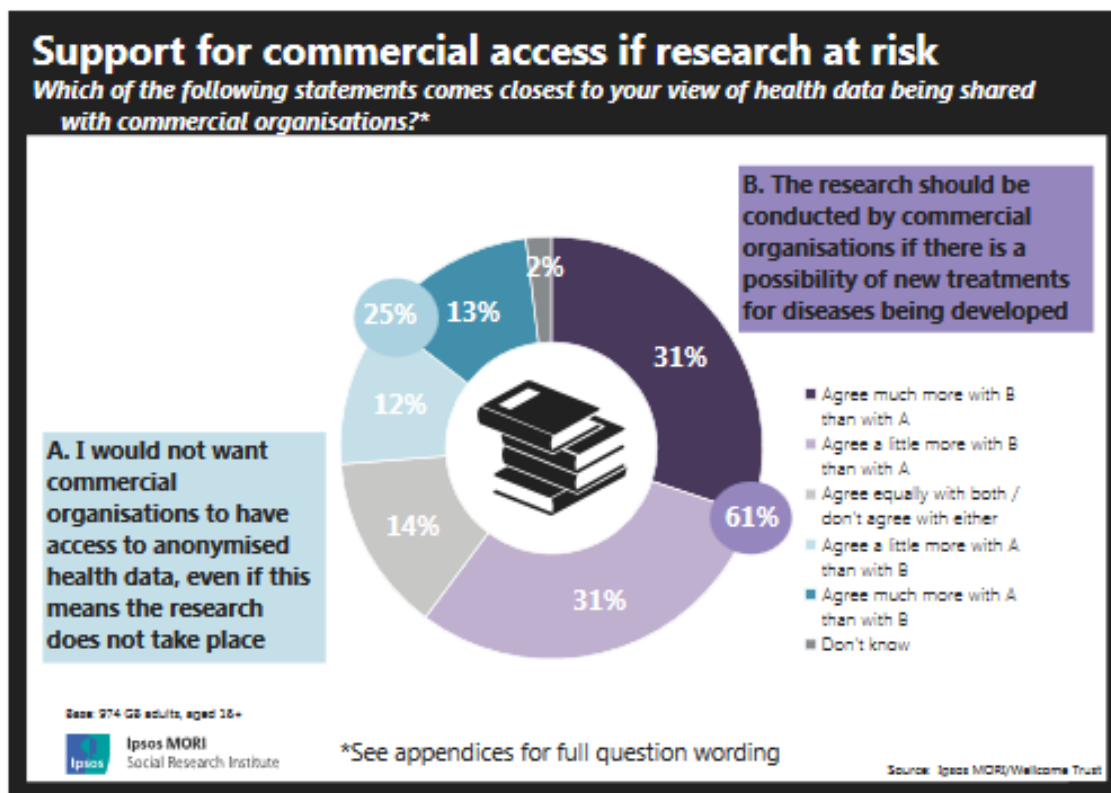
‘Attitudes towards sharing data’ Open Data Institute/ YouGov, 2018

Sharing for research



‘One-way mirror’
Wellcome Trust, 2015

Sharing with companies



‘One-way mirror’
 Wellcome Trust, 2015

Use of technologies in care

The public wants:

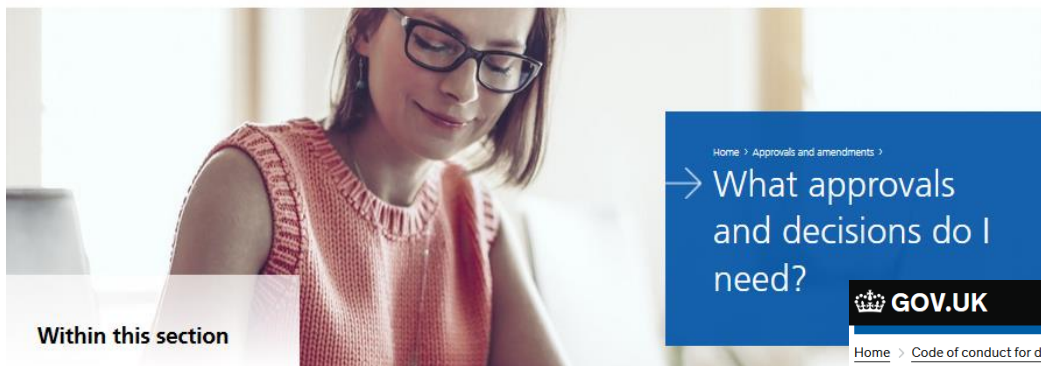
- equitable access to, and distribution of, the benefits of new technologies
- to preserve the clinician-patient relationship and face-to-face interactions at the point of care

Research by the Academy of Medical Sciences (unpublished)

Summary

- Patients don't need to be an obstacle: they support research and are open to public/private collaborations
- But trust is contingent on the nature of public benefit, who data is shared with
- Involving the public and patients is key to maintaining trust and confidence in the appropriate use of data
- Involving the public and patients is also key to gaining support for use of data without consent via HRA/CAG

Where to go for advice



Home > Approvals and amendments >

→ What approvals and decisions do I need?

Within this section

HRA Approval →

Research Ethics Committee review →

Confidentiality Advisory Group →

To understand what approvals and decisions you need from the HRA, firstly <

Is my project research?

One of the first steps in deciding which approvals you need for your project

Department of Health & Social Care | MHRA | NHS Health Research Authority | NHS Digital

Clinical Safety Guidance

Governance and regulatory requirements for decision supporting and making software in the NHS and Adult Social Care

Published January 2018

GOV.UK

Home > Code of conduct for data-driven health and care technology

Department of Health & Social Care

Guidance

Initial code of conduct for data-driven health and care technology

Published 5 September 2018

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- Overview

Introduction

Today we have some truly remarkable data-driven innovations, apps, clinical decision

Thank you
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