

# Identifying and recruiting participants for health research:

A public dialogue for the Health Research Authority

Report

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<b>Author(s)</b>	Dr Tracey Bedford, Sophie Wilson, Oliver Ritchie
<b>Quality Assurance by</b>	Suzannah Kinsella
<b>Main point of contact</b>	Dr Tracey Bedford
<b>Telephone</b>	0207 239 7838
<b>Email</b>	Tbedford@opm.co.uk

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## OPM

252B Gray's Inn Road  
London  
WC1X 8XG

0845 055 3900  
[www.opm.co.uk](http://www.opm.co.uk)  
[info@opm.co.uk](mailto:info@opm.co.uk)



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## Executive summary

### Objectives

The Health Research Authority (HRA) in conjunction with Sciencewise<sup>1</sup> commissioned OPM Group to run a public dialogue on identifying and recruiting participants for health research.

The specific objectives of the dialogue were:

1. To inform the development of the HRA's new UK wide Policy Framework to replace the Research Governance Framework and its associated operational guidance.
2. To provide opportunities for members of the public and patients to discuss and explore their aspirations and concerns about the governance of health research in relation to recruitment, data and consent, especially:
  - a. How patient data might be used in order to invite people to join research studies and who participants think should be allowed to access patient records in order to check eligibility
  - b. Different models for approaching potential research study participants including consenting to being approached directly about research
  - c. The plan to develop simplified models of consent for simple and efficient clinical trials of already licensed drugs and other interventions in common use.

### Method

Four reconvened deliberative events took place in England and Wales in November 2014. 110 members of the public, 23 specialists, and expert patients took part in workshops held in Liverpool, Nottingham, London, and Cardiff.

The same participants attended both workshops in each location, allowing them to develop a good understanding of the relevant issues so that they could provide informed and insightful feedback. A [video](#) made at one of the reconvened workshops gives a flavour of the participant experience.

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<sup>1</sup> Sciencewise is the UK's national centre for public dialogue in policy making involving science and technology issues.

The OPM Group also created a website for the dialogue including an online forum and survey, and a Twitter presence.

## Summary of key findings

The overall key findings from the workshops were:

1. The majority of participants expect the main clinical staff that are responsible for their care to have access to their patient notes. There was less awareness that non-clinical staff (such as GP receptionists) acting in a supporting role to the clinical care team would also have access to their notes.
2. The majority of participants did not believe that research nurses currently had access to patient notes in hospitals or GP surgeries.
3. However following discussions, the majority of participants were open to the idea of research nurses having access to patient notes with the proviso that patients are informed and have they have the ability to opt-out. For research active general practices, posters in the waiting room alone were not seen as being sufficient to ensure all members of the surgery were actively informed about changes to access to patient records.
4. Whilst the majority of the participants accepted the use of consent to approach lists in principle, there were concerns about both of the models reviewed. For approaches in the waiting room, participants wanted sensitive, common sense approaches by someone identifiable as being attached to the hospital. There was a preference for this being a member of NHS staff, not a patient volunteer or a third party.
5. For approaches by post, the participants were concerned that many people would not read the leaflet or realise they had consented by default to be on the consent to approach list. A suitably long period was required to elapse (eg. 6 – 8 weeks) to allow people enough time to opt out before they could start to receive invitations to specific studies.
6. The majority of participants supported the use of simplified consent. The opt-in model raised fewer concerns about the impact on patient- GP relationships than the deemed consent model. Most participants agreed with using a simplified patient information sheet which did not repeat the information contained on drug pack inserts assuming the studies were not blinded.
7. The forthcoming Clinical Trials Regulations allow for the option of no consent in cluster designed clinical trials. Most people agreed with the use of zero consent in appropriate low risk studies with minimal intervention. However there was concern about 'scope creep'.

8. Common themes arising from the discussions included raising public awareness of the role of NHS patients in health research; ensuring patients were made aware of changes in who can access their data by more proactive methods than using posters alone; eliminating the potential for scope creep when allowing more people access to records or introducing zero consent; and ensuring personal data would not be passed on for commercial use by insurance companies.

### ***Public knowledge on health records: content and access***

- Participants widely thought personal information, medical history, test results, current conditions and treatments, and some medically relevant contextual information would be contained in a health record.
- There was strong consensus across locations that GPs and practice nurses, hospital doctors and nurses who care for you would have access to health records.
- Participants widely disagreed on whether receptionists at GP surgeries and hospital admin staff would be able to access health records in full.
- Many participants initially felt hospital doctors who do research either within your hospital or at another hospital would not have access to health records, but during discussions a number of individuals came to the conclusion that they would in fact have access.
- A very small minority of participants believed that that research nurses would be able to access health records currently.

### ***Views on extending access to research nurses***

- Most participants supported the idea of making it easier for research nurses to access data to identify patients who might be suitable and willing to take part in research trials because research based on a larger number of people was seen as a good thing.
- However, participants had a number of concerns about how this might happen in practice. These included:
  - As the number of people who have access to records increases, the risk that data will be misused increases;
  - There is a possibility of scope creep if access for researchers is increased, potentially leading to data becoming available to private companies;
  - If parts of the NHS are privatised, how will data be protected?

- Participants suggested ways of increasing the accountability of the system and introducing measures that ensure data cannot be transferred outside of the NHS.
- Some participants felt that they would prefer researchers who are funded by private pharmaceutical companies not to have increased access, but others conceded that this might not be possible.
- The type of person who would be accessing patient data was an important consideration for some participants.
  - Typically, more senior researchers and clinical professionals were preferred. This was often based on their perceived trustworthiness and professionalism.
  - Some groups felt that access should be limited to NHS staff from the same institution in order to place a limit on how widely data could be shared.
- Some participants were more comfortable with researchers accessing anonymised data

### **Views on GP practices where patients have the opportunity to take part in health research (Research Active General Practices)**

- Many participants were comfortable with the suggested proposal for research active general practices as long as all patients were informed, there was a way of opting out at any time, and data was safeguarded appropriately.
- Participants had mixed views on whether asking for consent for research nurses to have access to records should be an opt-in or opt-out system.
  - Some participants believed an opt-in system would not get sufficient take up and might take too long to gain consent.
  - Others thought an opt-in model would ensure that everyone had made an informed decision and those included would be more motivated to participate in future research.

### **Views on consent to approach lists**

Two models for consent to approach (also known as consent4consent) lists were presented.

- Participants' views on model one: approaching patients in a waiting room to opt-in to a consent to approach list, differed:



- Some participants felt this would not be acceptable as patients might feel under pressure and be in the wrong state of mind to make an informed decision.
  - Others saw the waiting room as a good opportunity to efficiently approach relevant patients and saw it as potentially a useful distraction.
  - Participants across locations highlighted the importance of approaching patients in a sensitive and considerate manner. This was regarded by many as more important than the individual approaching.
  - Groups widely agreed that those approaching should be NHS employees.
  - Many participants thought that patients should not have to share personal information in a waiting room as this would breach their confidentiality.
- Participants suggested a number of reassurances that would make them more comfortable with the traditional consent to be approached model:
  - Clarifying it is ok to talk to a patient before beginning to discuss the list.
  - Data will not be passed on.
  - More information on what sort of research they could be approached about in the future.
  - More information about how frequently you could be approached.
  - Only being approached two or three times a year regardless of how many conditions you have.
- Participants had contrasting views on model two in which patients receive a leaflet in the post asking them to opt-out within three weeks or be placed automatically on a consent to approach list.
  - Many felt this model provided more privacy than model 1, giving patients extra time to consider their decision.
  - Other participants had concerns that patients may not receive letters in the post or may not open them, preventing everyone from being informed about being placed on a list.
  - Some felt an opt-out system would increase the number of people on the list, potentially increasing the number of people taking part in health research (most prevalent in Cardiff).
  - However, other participants felt that an opt-out system could lead to large numbers of people being included on lists without their knowledge or without making an active decision to be on the list.
  - Participants again wanted to be reassured that their data would be safeguarded and not passed on to private companies.

## Views on simplified consent

Participants discussed the use of a simplified consent procedure in clinical trials of existing licensed products or commonly used treatments. At the point of diagnosis, a patient's GP tells them that a trial is taking place, and asks if they want to take part. The patient is given a simplified patient information sheet to read, and if they chose to take part, they would sign a consent form during the consultation. Because the study would not be blinded, patients would then get the full drug pack including the pack insert leaflet giving details about the treatment. Participants in the workshops were offered alternative scenarios which covered a range of information giving; one explicitly asking for the patient to opt in and the other a deemed consent model where the patient could choose to opt out.

- Almost all groups expressed in principle support for simplified consent processes in appropriate low risk trials.
- There were varying levels of concern associated with the way in which this would be implemented in practice. Some of the concerns raised included:
  - Making sure that patients were still given time and information to make a meaningful decision
  - Patients may feel increased pressure to take part in the research as it may be hard to say 'no' to your doctor face to face
  - Patients may be less likely to be switched to a different drug if they react badly to the one they are given, to avoid affecting the trial data
  - Patients might be put forward for a trial due to quota or financial pressures when they should be getting a slightly different treatment.
- Many participants supported the opt in model of simplified consent where patients are asked to explicitly sign their consent to take part in a trial.
- There was greater disagreement around an opt-out model where patients would be told that a trial is taking place and they would be involved unless they asked to opt-out.
  - Some participants saw advantages to this model for example it would take less time away from a GP appointment, while others thought that it would change the balance of the patient-doctor relationship.

## Views on zero consent

Under the forthcoming EU clinical trials regulations, it will be possible to not seek consent in some cluster design trials where taking consent might not be feasible. In the workshops, participants were asked to discuss the possibility of zero consent trials where patients are automatically involved in an experimental intervention, without their consent being sought beforehand. For example, one scenario was based on a randomised controlled trial of two or more types of memory foam mattresses in hospitals in order to prevent pressure sores.

- Most participants agreed that a zero consent approach to recruitment would be acceptable in some very low risk situations with minimal intervention such as the mattress example used in the presentation.
- However opinions were divided about which other situations would also be appropriate.
  - Most participants thought that so long as studies were equally low risk, then they would be just as acceptable
  - Some participants felt that treatments that are invasive i.e. enter the body in some way (including catheters and any medication) were too invasive to be appropriate for zero consent.
  - Some others emphasised the importance of allowing patients to make their own decisions where possible.
- One concern that was raised around zero consent was about the possibility for 'scope creep' and that very clear guidelines would need to be put in place.
- Some participants on reflection, went back to the earlier scenario comparing existing licensed treatments and concluded that if there was genuine uncertainty then it might be acceptable to not seek consent in these more interventional scenarios.

# Introduction

## Background and Objectives

This public dialogue was commissioned by the Health Research Authority (HRA) in conjunction with Sciencewise.<sup>2</sup> The objective of the dialogue was to engage the public in order to inform the HRA in developing its future policy framework and guidance. The findings will inform the HRA as it becomes a non-departmental public body and develops a new UK wide policy framework to replace the existing Research Governance Framework and associated operational guidance in 2015 for research ethics committees and health researchers.

Dialogue differs from social research by engaging with participants in a more active process. Instead of simply being asked for their views, members of the public can have conversations directly with the professionals and specialists responsible for creating or implementing guidance for health research. Since the dialogue is about complex technical issues, the process allows time for participants to be provided with extensive information to inform deliberation, and for them to ask questions of specialists. Rather than answering a series of questions, as happens with social research, dialogue is more about understanding how the public frames debates and thresholds of acceptability for new processes.

The specific objectives of the dialogue identified by the HRA are:

1. To inform the development of the HRA's new UK wide policy to replace the existing Research Governance Framework and its associated operational guidance
2. To provide opportunities for members of the public and patients to discuss and explore their aspirations and concerns about the governance of health research in relation to recruitment, data and consent, especially:
  - a. How patient data might be used for research including perceived benefits and risks and who participants think should be allowed to access patient records for research
  - b. Different models for approaching potential research study participants including consenting to being approached directly about research

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<sup>2</sup> Sciencewise is a BIS funded programme to improve Government policy making involving science and technology by increasing the effectiveness with which public dialogue is used. They provide co-funding and specialist advice to help Government Departments and Agencies develop and commission public dialogue. [www.sciencewise-erc.org.uk](http://www.sciencewise-erc.org.uk)

- c. The plan to develop simplified models of consent for simple and efficient clinical trials of already licensed drugs and other interventions in common use.

The Office for Public Management Group (OPM Group) designed and delivered four reconvened public workshops in England and Wales throughout November 2014. The events followed a deliberative process design. This form of engagement was chosen because it allowed the public to learn about current and potential research recruitment processes and actively informed and engaged participants in discussion and debate and provided the chance to ask questions and discuss with specialists in the room. The OPM Group also developed a website and Twitter presence for the dialogue. The full methodology and objectives for this public dialogue are discussed in the following chapter.

## Policy context



*“To make the UK a great place to do research, where more money invested in research goes into carrying out relevant, good quality research.”* AMBITION OF THE HRA

The [NHS constitution](#) outlines the right of all patients to be informed about research studies they are eligible to take part in. However healthcare professionals may not always know about relevant research opportunities or the associated inclusion and exclusion criteria, or may be too busy to discuss research with patients.

As the HRA becomes a non-departmental public body, there is an opportunity to review the principles underlying health research in the UK including the methods for identifying and recruiting participants for health research. This comes at a time of changes to the EU Clinical Trials Regulation allowing for greater proportionality to distinguish between high-risk and low-risk research. This

context provides the potential to make changes that could make it easier for patients to learn about relevant health research and increase the number of participants involved in health research.

The HRA wished to explore who the public think should have access to their data in order to tell them that they might be eligible to take part in a study, different models of consent to approach and simplified consent processes in trials of existing licensed products. These issues have been considered by the public throughout this dialogue and their views are outlined in the chapters below.

### Current Research Governance Framework for Health and Social Care

## Explaining the Issues

### Clinical trials

Clinical trials are used to test the efficacy and safety of treatments. This is to make sure that healthcare can continue to improve over time, by giving doctors and other healthcare professionals more information about which treatments are best for which patients.

Clinical trials are used to test new or existing medicines. They can also be used to test whether giving a treatment in a different way will make it more effective or reduce any side effects. As well as testing drugs, they can be used to test medical devices, surgical techniques, diagnostic tests and new ways to help people change their behaviour.

New drugs go through a number of stages of testing before they are allowed to be used in the general public. In early stages (sometimes called Phase 1), experimental treatments are given to healthy volunteers to find out if they are safe to use in humans and what the main effects of the drug are. In later stages (stages 2, 3 and 4 trials), drugs that have already been shown to be safe in humans are tested in patients to find out how effective they are at treating disease. This public dialogue is about the later stages of research; phases 2 to 4.

### Getting Involved in Research

This public dialogue exercise covered the identification and recruitment of patients into health research. In particular, it focused on three key areas:

- Who can look at patient records to tell them that they might be eligible to take part in a study
- Different models of consent to be approached about possible research studies
- The use of a simplified consent process in large pragmatic trials of existing licensed products.

### Patient Identification and Consent

As outlined in the NHS Constitution, the NHS has a duty to inform patients if they are eligible to take part in a health research study.

Clinical trials often have lengthy inclusion and exclusion criteria that are used to see if a person can take part in a study. This means that patient notes (medical records) have

to be screened to identify suitable candidates. The suitable candidates are then contacted to see if they would like to take part in the clinical trial.

Traditionally, potential study participants are **identified** and **approached** by a member of their clinical care team. Once identified, the potential participant can then be sent an invitation letter on headed paper, signed by the member of the clinical team, possibly the GP or a hospital doctor if they have one. This system means patients may not always be made aware of relevant clinical trials because their clinical team is unaware of the trial or is too busy to identify and inform a potential candidate.

**Clinical Care Team:** the team responsible for your care. This could be your GP, a practice nurse or a hospital doctor or other health care professional who provides you with care.

Once a patient expresses interest in discussing a particular health research study, they will be asked to give their informed consent to taking part. Participants of health research studies can withdraw their consent and opt out of a study at any time.

## 1. Access to patient records

Patient records include those held by a GP, and also hospital records. Most records will use numeric codes to describe what conditions the patient is suffering from and what treatments they have received. However, medical records may also include some text including possibly sensitive notes.

Who has access to patient records for research purposes is covered by both the Data Protection Act and the 'common law'. A large part of the common law is based on public expectation. At the moment the searching of patient records for potential research subjects to invite them to take part in a clinical trial, can be done legally by fulfilling any of the following criteria:<sup>3</sup>

1. The search is conducted by a health or social care professional who has a 'legitimate relationship' with the patient, such as the clinician providing care or supporting administrative worker.
2. The search is conducted by a researcher who is also part of the clinical care team.
3. The system allows for electronic searches which can enable searches of patient records to be carried out whilst still maintaining the privacy for the patient.

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<sup>3</sup> The Information Governance Review (2013) P. 68  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/192572/2900774\\_InfoGov\\_ernance\\_accv2.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGov_ernance_accv2.pdf)

4. The clinical care team gains the explicit consent of every patient with a record in the group being assessed in advance of someone outside of the care team searching the notes.

In practice, many researchers will ask a member of the clinical care team to look through their patients' medical records to see if any are eligible to take part in a clinical trial and make the first approach to the patient

There was no proposal to allow pharmaceutical companies or insurance companies access to identifiable patient data. This dialogue was interested in asking the public about their concerns and feelings around whether an NHS based research nurse or doctor who is not part of the clinical care team could access medical records. These people would still be bound by professional codes of confidentiality, which would lead to sanctions if they did not keep patients' data confidential. If the public are comfortable with other healthcare professionals like research nurses having access to health records, this could potentially lead to a change in the guidance.

## 2. Approaching Patients

One way of increasing the opportunity for patients to be involved in health research is what is sometimes called 'consent to be approached', also known as 'consent4consent'. This is where individuals are asked in advance if they would be happy to put their contact details on a register so that they could be approached if a health research study came up which they would be eligible to take part in. These lists mean that if researchers decide that someone might be eligible for a study, the organisation is able to approach the person directly, rather than having to make this approach through the patient's doctor. These registers or lists are normally run by NHS organisations but occasionally they are set up and run by medical charities to support particular diseases.

Agreeing to be on one of these lists does not mean that a person automatically consents to take part in research; it simply means that they are happy to be approached in order to be asked in the first instance. If they are interested in taking part in the study, they would still have the freedom to decide whether to participate, once the study has been explained to them. They would be given written information about the research study (this is known as the **Patient Information Sheet**) and they would be asked to give informed consent to taking part in the study. As part of this process patients would then sign a consent form.

The advantage of setting up these registers of potential participants is that it makes it easier for researchers to access data about a patient to see if they are eligible to take part. A researcher would then be able to approach the patient directly or via the NHS organisation, rather than via a member of their clinical care team. The researchers will usually be staff members at the NHS organisation that is caring for the patient.



There are different ways in which people can be added to the list; for example:

- Patients could be approached by their own doctor or another member of their care team and asked if they are willing to put their name on a register
- Patients might be approached randomly in a hospital setting such as patient waiting room and asked whether they would be willing to put their name on a register.
- An NHS organisation or a medical charity might choose to write to patients based on the services they have received so far and ask if they might be willing to provide their details for such a register.
- Some disease specific lists are web based, and patients go online to sign up. These may be organised by the NHS or a medical charity which undertakes research.

The aim of these lists is to make it easier for medical researchers to identify patients to take part in clinical trials. Researchers always need ethical approval before they invite any potential research participants to join a study, regardless of whether they use a register.

### 3. Simplified consent in simple pragmatic trials in primary care

In medicine we overwhelmingly use treatments that are safe and effective, including different drugs and other kinds of intervention like surgery or physiotherapy. We are able to build up the evidence for whether a new treatment is safe and effective by taking them through a series of clinical trials. However we do not always have the evidence we need for existing treatments which are regarded as part of 'standard care'. Healthcare professionals often do not know which out of a number of commonly used treatments is the most effective or the most cost effective. In order to find this out, researchers need to undertake large clinical trials comparing one treatment directly with another to gather evidence comparing the effectiveness of established treatments. This is important because the NHS could save money if they knew which treatments worked the best.

For some conditions a number of different treatments seem to help and improve patient outcomes. For example, there are five types of statin available in the UK, used to help bring down cholesterol levels in the blood. We know that these statins are safe and effective but we do not know how well they compare with each other since they have not been compared head to head in large scale clinical trials with long term outcomes.

Recruiting for large scale clinical trials can be very time consuming and costly as doctors have to make sure they have gained **informed consent** from a potential

participant. This can take doctors 20 minutes to talk through the trial, and participants will be asked to read long information sheets (sometimes up to 9 pages long). Normally patients will be asked to take the information home, discuss it with their family and/or friends, and come back and see the doctor before signing a consent form.

Informed consent is an important process and those taking part in research need to have an understanding of the potential benefits and risks involved. Most clinical trials involve new medicines or treatments which only small numbers people have been exposed to and so may expose the patient to a level of unknown risk. However the sort of studies discussed here involve only commonly used and already licensed medicines. The treatments are deemed to be safe and the side effects of these treatments are usually well known. A lengthy patient information sheet and complex consent process can put some people off taking part in a trial and also deter doctors from asking patients if they would like to take part.

Given the low risk nature of the types of clinical trials proposed here, it may be possible to simplify both the process and the amount of information given to the patient in consultation with the doctor. Instead, a simplified consent process could be used in **simple and efficient trials** involving minimal or no risk. These would be trials where the treatment a patient receives is equivalent to the treatment they would receive if they were not taking part, that is, standard care. The patient would not have to do anything differently, although in some cases they may be asked to have more regular check-ups with their doctor.

In such studies the main outcome would usually be routinely recorded information which could be extracted from the patient record electronically. The specific treatment a patient receives would be randomly allocated to them, although it would always be something commonly used within the NHS and would not normally include a placebo arm unless doing nothing is an option under standard care. It should be noted that such studies would not be blinded, that is all participants would know which arm of the study they were in and what treatment they would be taking. Because participants would receive real prescriptions rather than blinded medication prepared especially for a trial, they would be able to access the pack insert included with the treatment which gives a detailed description of known side effects, interactions and instructions on how the drug should be used.

The simplified consent procedure should still provide the necessary information for potential research participants to consider taking part in a trial and they can opt-out at any stage. However, the information sheet would be shortened compared with a typical information sheet. Some types of information might be removed from the sheet (an example information sheet is included in the materials annex). For example, the side effects from medications would not be included on the information sheet because they will already be in the pack insert which comes with the medication. This level of reduced information is possible because simplified consent will never be used for novel experimental treatments. Rather it is proposed that it would only be used to compare the outcomes between two or more safe treatments that are already being used in

everyday healthcare in the UK. Participants in the workshops were asked to identify which elements of the patient information sheet needed to be retained and which elements could be left out.

It is hoped the shorter consultation would increase the opportunity for people to take part in clinical trials, increasing our understanding of what works in medicine, and providing the evidence to improve our healthcare in the future.

New EU Clinical Trials Regulations are due to come into force at the end of 2016/ early 2017. Once in force, the Clinical Trials Regulation will allow informed consent to be obtained by '**simplified means**' in a very specific type of research known as a '**randomised cluster trial**'.

**Randomised cluster trials** are a type of research design that randomises the drugs or treatments being investigated to different groups or clusters of individuals (such as households, primary care practices, hospital wards, classrooms, neighbourhoods or communities), rather than individuals.

Under this Regulation researchers will be able to obtain informed consent by "**simplified means**", without the traditional face-to-face discussion, provided that the following conditions are met:

- Trial is conducted in one member state
- No contradiction with national law
- Low intervention trial using licensed drugs
- Trial methodology requires groups of subjects (e.g. randomisation by GP practice or hospital) to be allocated to treatment rather than individuals
- No interventions other than standard treatment
- Protocol includes justification for gaining "informed consent by simplified means".

Under this Regulation informed consent may be "deemed" to have been obtained if the potential subject, after being informed, does not object to participating in the clinical trial. This means that a patient could be included in the research unless they explicitly opt-out of taking part.

This represents a significant departure from the current UK Clinical trials Regulations/EU Clinical Trials Directive, which require the potential subject to have been duly informed of the nature, significance, implications and risks of the trial in a prior interview with the investigator or a member of the investigating team. Participants in the workshops were asked to consider the acceptability of a '**no consent**' scenario.

## How to read this report

This report provides a full overview of the dialogue process. In Chapter 2, we outline the methodology of the dialogue process including detailed information about the design and delivery of the project. In Chapter 3, we discuss the findings from the workshops, describing the views of members of the public towards the dialogue topics. All stimulus materials and presentations from both workshops are available in Annex 2.

A note on language: at the workshops discussions and in stimulus material, we used the term medical records interchangeably with patient records for the sake of simplicity. When discussing specific locations, we distinguished this further by using the terms hospital records and GP records. In this report we use the term health records to describe patients' records in general, as well as hospital and GP records to describe specific records.

# Methods

## Summary

A series of reconvened workshops was held with 110 members of the public, a range of specialists (N=23) and expert patients. OPM Group undertook a rapid evidence review, and interviewed a number of stakeholders in order to inform the design of the dialogue, for example by explaining relevant issues from their professional perspective and providing balance. HRA provided the in depth content for the workshops.

Public workshops were held in four locations: Liverpool, Nottingham, London and Cardiff. In each location there was one evening workshop, followed by a reconvened evening workshop two weeks later. The same participants attended both workshops in each location, allowing them to develop a good understanding of the relevant issues so that they could provide informed and insightful feedback. A range of specialists were also present at the workshops, in order to discuss topics in more detail and answer any questions from participants.

**Figure 1: Participants in Nottingham**



## Oversight group

The HRA established an oversight group (OG) to oversee the dialogue process and ensure it provided a balance of perspectives to the public. Members of the group had the opportunity to provide expertise and share their experience of the issues being covered prior to the dialogue and through advising on the materials between meetings. The main Oversight Group meeting to discuss the proposed methodology of the dialogue was held on 7<sup>th</sup> October 2014. OG members also proof-read the dialogue materials and website text outside meetings, making sure materials were fair, accessible and covered a collection of different views.

The group was made up of a range of experts with different areas of knowledge and experience. It was chaired by Simon Denegri from INVOLVE. The following people sat on the OG:

- Angela McCullagh, Patient Expert
- Shelley Mason, Patient Expert
- Mark Taylor, Confidential Advisory Group
- Rachel Quinn, Academy of Medical Sciences
- Prof Roger Jones, Royal College of General Practitioners
- Adrienne Clarke, GlaxoSmithKline
- Ben Goldacre, member of the research community
- Alex Newberry, National Institute for Health and Social Care Research, Wales
- Sam Smith, medConfidential
- Suzannah Lansdell, Sciencewise
- Amanda Hunn, HRA
- Clive Collett, HRA

## Rapid review and dialogue questions

The dialogue process began with a rapid review of key documents relating to health research and recruitment. These documents were identified by HRA with the purpose of ensuring the OPM Group facilitators could derive a working knowledge of the topics under examination. Examples of the documents include previous HRA dialogue reports and draft guidance documents. Additionally, four stakeholders from the Oversight Group (OG) were interviewed to gain insight into the issues from a range of perspectives and to ascertain a sense of what a balanced dialogue would cover.

At the same time, OPM Group worked closely with the HRA, Sciencewise and the OG and to finalise the questions to be answered by the dialogue participants. Since the dialogue aimed to cover a range of topics within the reconvened groups, this element of the process ensured the questions being asked were those where participants could influence the formation of guidance, and analysed the information needs of participants to create informed discussions.

## Recruitment

The **public** recruitment was undertaken by OPM's partner recruitment company in line with a strict quota. The quota was developed and agreed with input from the Oversight Group, based on recruiting 28 participants per location to ensure at least 25

participants attended each workshop. Primarily, the quota was purposive and aimed to hear as many different voices as possible within the sample. In particular, the OG was keen to ensure the sample included participants over the age of 75. We aimed to ensure the views of those groups known to hold the greatest concerns about health research were heard, namely people from lower socio-economic groups and ethnic minorities. The only quota which was representative rather than purposive was for ethnic minorities, where we matched the quota for ethnicity to the census data for the locations of the workshops to ensure the mix in the room felt right for the area.

The public participants were recruited on street from a mixture of locations, including outside supermarkets, shopping centres and stations, at a variety of times. People involved in health services, pharmaceutical companies or health research related areas or who had taken part in a similar process within the last year were exempted from the sample.

Age group	No.	Ethnicity	No.	SEG	No.	Gender	No.
18-24	18	Asian	15	AB	31	Female	58
25-34	19	Black	17	C1	26	Male	52
35-44	16	Mixed Race	4	C2	26		
45-54	17	White	71	DE	27		
55-64	15	Other	3				
65-74	19						
75+	6						
TOTAL	110						

**Figure 2: The demographics of the participants who attended the workshops in the four locations**

The public participants were provided with incentives for attending the workshops at the end of each workshop (£40 for the first workshop and £60 for the second), which encouraged a very high turnout rate, with at least 26 public participants attending every workshop.

The recruitment of **specialists** and **expert patients** was undertaken by HRA for the three workshops in England and the National Institute of Health and Social Care Research for Wales. The specialists included researchers, research nurses, patients and others working on simplified consent, consent to approach models and information governance issues. Around six specialists and expert patients attended each

workshop, joining the discussion tables to answer questions and join the conversations. When possible, specialists were briefed in advance to encourage them to participate in discussions without arguing for a particular perspective.

## Workshop 1 and 2

**The objectives for workshop 1** were as follows:

1. Explain the purpose of the dialogue and how participants' input will be used.
2. Benchmark the current level of understanding about health records and who can access them.
3. Provide the participants with expert input and materials to allow them to have working knowledge of the clinical research process, access to health records and forms of consent.
4. Have discussions about the potential changes to who can access records to identify patients for research.
5. Understand the general balance of opinion, what informs it and how it differs depending on severity of health problems.

**The objectives for workshop 2** were:

1. Bring together public, patients and stakeholders/specialists to discuss their views on the implications and acceptability of any potential changes to the recruitment, data and consent aspects of health research.
2. Understand the general balance of opinion, what informs it and if it differs depending on health problems for:
  - Different models of approaching patients in order to be able to inform them in the future that they might be eligible to take part in a study, including consent to approach lists
  - The concept of simplified consent for trials of commonly used treatments across a range of scenarios
  - what the minimum information requirement is for a patient information sheet accompanying a simplified consent process for a clinical trial of already licensed products

## Process design and materials development

The facilitation team held a brainstorming meeting to design the workshop process. Having previously proposed using the first workshop as an information-giving session and the second as the detailed discussions, the team decided this would require too much information to be given to participants in one sitting. Therefore the process was revised to break the topics into clear, manageable sessions. The first workshop aimed to baseline the level of knowledge of the participants and provide background



information about health research processes, particularly clinical trials. Following this, participants discussed potential changes as to who could access patient notes to identify candidates for research trials.



Access to medical records stimulus video

Materials were designed to maximise learning without participants feeling they were in a classroom. Hence, mixed methods were employed, including the use of presentations, question and answer sessions, stimulus cards, a [stimulus video](#) and a play.

The materials were agreed with the HRA and Sciencewise, and signed off by the OG.

The second workshop centred around two separate discussion topics: consent to approach models and simplified consent. Again presentations, stimulus cards and a second [stimulus video](#) were utilised.

Facilitators were provided with an in depth briefing prior to each round of workshops, to understand and refine the detailed process plans (see Appendix A). The briefing was presented several days in advance of the first workshop so facilitators had time to familiarise themselves with the materials. A second briefing was held for the location-specific facilitation teams on each day of the workshops.

## Workshop 1 outline

Participants were invited to arrive at 5.30pm for a 6pm start. This allowed enough time to sign everyone in and enjoy some food from a buffet provided to ensure participants were not hungry during the evening (6-9pm) and could remain focused on the workshop content. Approximately seven or eight participants were sitting at four separate tables, along with specialists including expert patients with each table based discussion led by a facilitator.

After a welcome to the event, the lead facilitator explained the objectives for the day and answered any questions from participants. A representative from the HRA also introduced the broad purpose of the public dialogue through a short presentation.

Participants were then asked '**what** is in a health record' at their tables. They worked individually noting down their initial reaction to the question on post-its as a naïve baseline exercise. The table then discussed their thoughts as a group. After the HRA gave a presentation outlining what is in a health record, a spontaneous and prompted discussion followed about **who** has access to health records. Again this was designed to illustrate participants existing knowledge as a naïve baseline exercise.



**Figure 3: Facilitators performing a play on recruiting for clinical trials**

A presentation and short play introduced participants to different types of data, health research and clinical trials. An additional presentation from the HRA followed, with a [stimulus video](#) introducing the discussion topic on access to patient records. Throughout these information giving sessions, participants had the opportunity to ask any questions about what they had heard so far, drawing upon the expertise in the room.

The table discussion on access to patient records in a hospital setting was designed to understand participants' opinions towards the topic and what was deemed as acceptable. This was followed by a second discussion topic on access to patient records in a general practice setting, introduced by the HRA through a presentation.

At the end of the first workshop participants were given a homework exercise to take away with them. They were asked to read an example of a long patient information sheet in preparation for some of the topics covered in workshop 2. This gave participants the opportunity to fully engage in the information sheet, something that would have been difficult within a workshop setting due to the length of the document.

Evaluation forms were handed out for participants to complete at tables while table facilitators stepped outside.



Figure 4: Top line agenda of workshop 1 including key questions

A full process plan for the first workshop can be found in Appendix A.

## Workshop 2 outline

As in workshop 1, participants arrived at 5.30pm for a 6pm start and were provided with a buffet. The session ended at 9pm. Participants were sitting at four separate tables, with each discussion led by a facilitator.

After welcoming participants back, tables discussed whether they had talked about the first workshop with family and/or friends and if they had visited the website or read the homework exercise. This was designed as a warm-up session, allowing participants to re-engage with the issues discussed at the first workshop held two weeks beforehand.

A presentation introduced participants to consent to approach principles followed by an explanation of a first model where patients are approached in a hospital waiting room.

A table discussion followed, asking how acceptable participants found the first model and whether they had any concerns. Next a second model of consent to approach was explained to participants in which patients are sent a leaflet in the post, and participants subsequently discussed this at tables.

After the break, a [stimulus video](#) and presentation given by the HRA introduced simplified consent and participants had the opportunity to ask questions. This was followed by a discussion of participants' views on the acceptability of the proposals and what reassurances they might need. At tables, having been provided with examples of



Still from the simplified consent video

simplified information sheets and pack leaflets, participants were taken through a checklist covering what may and may not be included on the proposed simplified patient information sheet. This was designed to provide an understanding of participants' opinions on what needs to be included on a simplified information sheet. A final table discussion looked at zero consent option following on from a brief presentation introducing the proposal.

As in the first workshop, participants were again provided with an evaluation form and asked to fill this out at tables while facilitators left the room. To finish, the HRA explained what would happen next and thanked participants for their insights and time.



Figure 5: top line agenda of workshop 2 including key questions

A full process plan for the second workshop can be found in Appendix A.

## Facilitation

Each location had a facilitation team comprised of a lead facilitator and three support facilitators, working with four tables of participants overall. The teams stayed the same for each of the reconvened workshops, although the participants were randomly assigned to different tables for the second workshop.

The lead facilitator, along with the HRA representative, took responsibility for introducing the process, topics and information. Table facilitators were responsible for facilitating and recording the discussions in line with the detailed process plan, encouraging all participants to join in the dialogue. Discussions were digitally recorded, with facilitators capturing notes on a pro forma. These notes were written up following the workshop, with verbatim quotes taken from the digital recordings.

## Analysis and reporting

The workshops were analysed thematically by location, with four location reports of key findings being created. These key findings identified common themes, key differences and necessary reassurances raised by the participants in relation to each of the three topic areas covered: access to health records, consent to approach lists and simplified consent. In early December the HRA, Sciencewise and the OPM project team had an analysis session, working through the findings from the four locations to identify overall findings and main messages.

A second wave of analysis returned to the detailed notes to identify additional issues before the development of this final report. The report was commented on by HRA, Sciencewise and the Oversight Group prior to final drafting.

Additionally, participants at the London workshop were interviewed and filmed by Elliot Manches, Close-up Research, for a documentary video.

## Evaluation

The dialogue was independently evaluated by 3KQ. The findings of the independent evaluation will be made available in a separate report at a later date.

# Findings

## Access to Patient Records

### Introduction

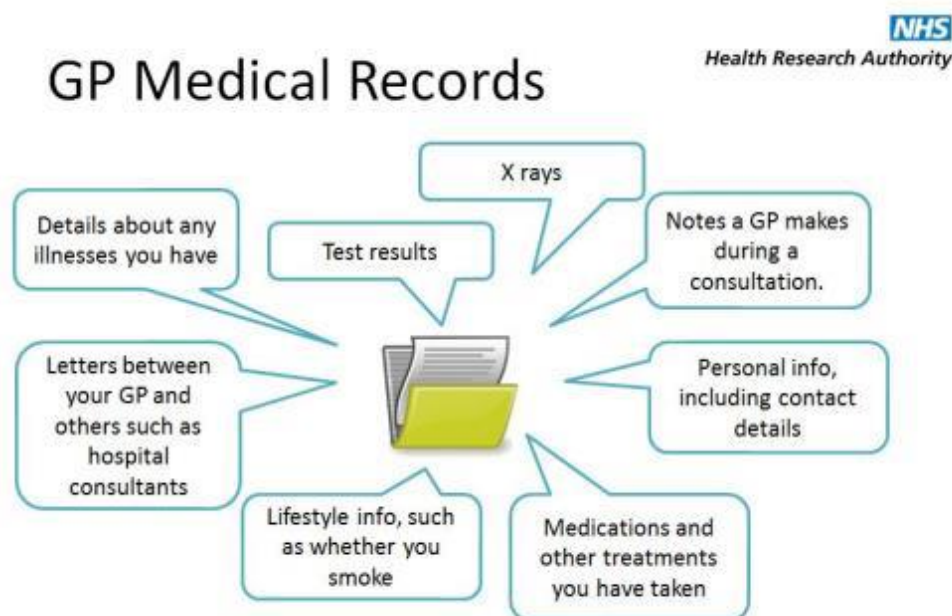
Participants began by discussing their baseline knowledge of what information is collected in GP health records, noting down any ideas on post-it notes. They were then asked whether they felt this would be the same for health records kept by a hospital. Next, the groups discussed who would have access to GP and hospital health records, with table facilitators noting down the groups' spontaneous thoughts. Participants were shown a set of stimulus cards each with a different practitioner role, first from general practice, followed by roles from a hospital setting. These included:

- GP
- A practice nurse who works with your GP
- The receptionist at your GP surgery
- The hospital doctor who is responsible for your care
- A hospital nurse who cares for you
- Allied health professionals who are involved in delivering your care
- Hospital admin staff
- A research nurse based in your hospital, but who does not care for you
- A hospital doctor who works and does research in the hospital that you attend, but who does not deliver your care and has never met you
- A hospital doctor based at another hospital who conducts research across many NHS sites and does not deliver your care and has never met you

As each card was shown, tables discussed whether they believed the practitioner would have access to health records. Participants were subsequently presented with information on these issues, and asked to reflect on what they had seen.

Participants were also introduced to the possibility of research nurses having access to patient records, in order to help them identify patients to take part in studies.

Figure 6: Stimulus material showing types of information held on a medical record



## What data is on your patient record? Who has access to your patient record?

<p><b>Questions Asked:</b></p> <ul style="list-style-type: none"> <li>What data is on your patient record?</li> <li>Who has access to your GP and hospital medical records?</li> </ul>	<p><b>Materials Provided:</b></p> <ul style="list-style-type: none"> <li>None initially (naïve responses sought)</li> <li>Flashcards with different types of professionals who may have access</li> </ul>
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Participants were asked to discuss what data exists in their records, and who has access to this data. These discussions took place before participants were provided with any information on these matters, in order to develop an understanding of baseline knowledge and assumptions that participants held.

The types of information that participants thought would be on their records were relatively consistent across different groups. Many of the items corresponded to information that exists on GP records, including personal information (date of birth, gender, address etc.), medical history, test results, current conditions and treatments, and some medically relevant contextual information such as whether they are a smoker.





Other suggestions that were less commonly raised included ethnicity, profession and blood type. Some participants disagreed over whether they thought some of these would be on your health record or not.

There was less strong consensus on how records held by their GP might differ from those held in a hospital setting. Many participants thought that the record in a hospital setting was likely to be less detailed than the record held by their GP, although there was some disagreement about exactly what the differences might be. In contrast, a minority of participants thought that the record at a hospital would be the same as the record available to your GP.

### Who has access to this data?

Participants were asked whether they thought the following people would have access to their records:

<b>GP</b>	There was a strong consensus among all groups that GPs would have access to your patient record.
<b>A practice nurse who works with your GP</b>	Most groups thought that a practice nurse would have access. However, there was disagreement in three of the 16 groups. Some participants in these groups thought that access would be limited to certain kinds of information only.
<b>The receptionist at your GP surgery</b>	There was disagreement in most groups about this, with some thinking that they do, and others that they do not have access. A number of participants thought that they have access to limited



	parts of the record, for example, some thought receptionists would only have the information needed to help book appointments. Some participants who thought that receptionists do have access expressed that they did not want them to.
<b>The hospital doctor who is responsible for your care</b>	There was a strong consensus among all groups that these doctors would have access to your patient record. Participants in one group thought that access might be more limited than a GP's access.
<b>A hospital nurse who cares for you</b>	Most groups thought that a nurse who cares for you would have similar access to hospital doctor. However there was some disagreement in a few groups, largely around whether they would have full access, or only access to relevant parts of the record.
<b>Allied health professionals who are involved in delivering your care</b>	A few groups thought that they would have access, but most thought that they would have access only on a need to know basis, i.e. they would only be allowed to access information relevant to the work that they were doing.
<b>Hospital admin staff</b>	There was a good deal of disagreement on this issue, with most groups failing to come to a clear conclusion. Many participants thought that they would not have access, however others argued that they might need access to some information for pragmatic purposes. Few participants thought that they would have full access to notes.
<b>A research nurse based in your hospital, but who does not care for you</b>	There was an almost unanimous response that they would not be allowed access. Some groups thought that they would have access, <i>'but only with consent'</i> .
<b>A hospital doctor who works and does research in the hospital that you attend, but who does not deliver your care and has never met you</b>	Most initially thought that they would not have access, however during discussions a few groups and individuals came to the conclusion that they would have access. Some groups discussed that the notes were probably available to them if they wanted to look, but thought that they would only be supposed to look if they had a reason to do so, e.g. they had to provide you with some care.
<b>A hospital doctor</b>	The response to this question was similar to the previous one.

**based at another hospital who conducts research across many NHS sites and does not deliver your care and has never met you**

While some participants thought that they would not have access, others thought that from a pragmatic point of view they would have access, and they would be allowed to look in situations where they needed access to help you.

Additionally, some groups discussed anonymous data, and thought that these doctors would have access to your data in a non-identifiable format.

During the above discussions, a common theme that participants discussed was whether particular types of professional needed access to the data to provide good

care. There seemed to be an underlying assumption in many discussions that the people who have access to patient records are those that need access in order to help patients. While this is similar to the idea that a clinical care team has access, an important difference is that many participants thought that some professionals would only have access to those parts of a patient record that were relevant to their job. Some participants recognised that this might be impractical to enforce, but still thought that some professionals were not *allowed* to look at certain parts of a record, even if there are no physical barriers to stop them from doing so.



**Presentation slide on your clinical care team**

A minority of participants thought that records were much less accessible than described above. For example, one participant thought that only a patient's GP has access to the records.

Some individuals thought that additional people might have access to records in certain circumstances. While these suggestions varied widely between groups, indicative examples include: the police, members of the legal profession, your next of kin and your employer. Many of these suggestions were highly context dependent, for example, the police might have access only if this is to help with a specific criminal investigation, or an employer might be able to request limited information to discover if an employee is being truthful about employment related medical circumstances.

Importantly, despite suggestions that a range of other professionals may have access to patient records, most participants believed a research nurse would not have access.

*"I'd say no - I don't see why she would need to. If I go in a hospital I want to see a doctor. If the doctor needs access to my records to help me that's fine, but I don't see why the [research] nurse, cleaner and decorator really need access to my medical records."* LIVERPOOL WORKSHOP PARTICIPANT

## Who should be allowed access to your patient record?

<p><b>Questions Asked:</b></p> <ul style="list-style-type: none"> <li>• How do participants feel about research nurses accessing their records to identify participants?</li> <li>• How do participants feel about non-clinical care team doctors accessing their records? Does it matter where they are based if they still part of the NHS e.g. a different hospital?</li> <li>• What type of data should they be able to access?</li> <li>• Does this change depending on type and seriousness of illness (bring in expert patients to provide their experience)</li> <li>• Who can access records to find results?</li> <li>• Who should never have access to their patient notes? For research?</li> <li>• If research nurses or other doctors are to have access, what reassurances need to be in place to make them feel safe?</li> </ul>	<p><b>Materials Provided:</b></p> <ul style="list-style-type: none"> <li>• Post it notes for initial responses</li> <li>• Video link in main presentation</li> <li>• PowerPoint slides –(main presentation)</li> <li>• Data-type information cards</li> </ul>
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This session took place following a presentation about who currently has access to a health record. In the presentation, the possibility of research nurses having greater access to records was raised. It was explained that this was to make it easier to identify patients who might be suitable for clinical trials.

Broadly speaking, there was in-principle support among participants to find ways to make it easier to access data to identify patients who might be willing to take part in research and clinical trials in particular. However, participants had a number of concerns about how this might happen in practice. Discussions around these concerns took up much of this session. There was a small difference between the areas, with Nottingham generally revealing a lower level of concern about data sharing than the participants in some of the London and Liverpool groups.

Different participants and tables differed in their level of concern around these issues. Some were much more cautious, proposing tight restrictions, and raising wide ranging concerns. Others had few, if any, concerns about increasing access to patient data, only commenting that it should be encouraged so long as it is done for the sake of the greater good.

*“You’ve got to ask the question if it’s going to be good for the patients, and if the answer is yes then it must be a good thing.”* LIVERPOOL WORKSHOP PARTICIPANT

*“I don’t think there’s any harm in research nurses accessing your data, it can only lead to helping other people.”* CARDIFF WORKSHOP PARTICIPANT

*“I think if it would improve my chances of getting better and getting a cure, I would be all for it.”* NOTTINGHAM WORKSHOP PARTICIPANT

### **Benefits of increased access to patient notes in hospitals**

Many groups saw increasing access to research as a valuable aim, and commented that it would be good to get more people involved in studies.

*“As long as it improves health outcomes it is a good thing”* CARDIFF WORKSHOP PARTICIPANT

There were some discussions, often initiated by a patient expert or table specialist, about how it would be advantageous to get a more representative sample of patients involved in research. Several groups highlighted this would give a better set of statistics and range of statistics, for example any ethnic variations.

Benefitting ‘the common good’, and leading to general improvements to healthcare were also commonly suggested themes.

*“Medicines and treatments are flying along at leaps and bounds but with these changes things could move faster, there could be lots of positive off shoots and knock on benefits if they do more research.”* CARDIFF WORKSHOP PARTICIPANT

There was an acknowledgement from a few participants that this might make new and innovative treatments available to more patients, which would be especially beneficial for those with more serious conditions. This type of comment was most commonly made in relation to increasing access to innovative cancer treatments. One very positive group in Nottingham concluded that a research nurse accessing records would:

*Be very acceptable;*

*Provide a lot of information;*

*Be a brilliant improvement.*

### **Raising public awareness of health research**

This is a theme we heard throughout the discussions. There was a sense that people do not currently know and understand the role of research in health. Participants in one group in London believed that wider knowledge and sharing of details of the recruitment process would help research recruitment. They felt general information campaigns targeted at the public might encourage involvement in clinical trials. This was partly raised because there was a sense that the more participants learnt about

research, the more positive they became about it. However, they also recognised they would not have felt as strongly before the hours of explanation and discussion.

### ***Concerns around allowing many more staff in hospitals greater access to patient records***

Participants' concerns related to a number of underlying issues and themes. Some of these were about minimising the possibility that data could be used in a malicious manner by rogue individuals, however the majority related to possible legitimate uses of data that patients considered unacceptable.

#### **Risks from increased volume of access**

One concern that was raised on a number of tables was that participants were not worried about research nurses having access per se, but they were worried about any large increase in the *volume* of people with access to records.

*"The more people have access to your information, the more chance of that falling into the wrong hands by whatever means." NOTTINGHAM WORKSHOP PARTICIPANT*

They felt this because of a perception that many of the possible issues around confidential data such as information being abused, lost or leaked become more likely when more people have access. Participants in London discussed the increased risk of leaked data more than the other workshop areas. One table suggested they needed more, qualified information about the level of risk before they could make an informed decision.

*"Are you able to identify how much enhanced risk there is? How often does people's data get into the wrong hands in hospitals? From this can you not work out the increased risk if more people have access to records? What we don't understand is the extent of the real risk. Are we ten times more likely to have our dirty washing on the front of the Sun?" LONDON WORKSHOP PARTICIPANT*

A few participants suggested ways to increase the accountability of the system, in order to minimise the possibility of foul play, and to reassure patients. One possible reassurance was that a record should be kept of every time a researcher has accessed notes, even for paper records. Another was that patients should have access to information about when and why their records have been viewed.

A minority of participants questioned the salience of concerns around malicious data use. It was not evident to them why anybody would want to access a patient's records, and what harm they could do if they did. A corollary to this was that a couple of groups suggested it was the records of famous people and politicians that needed protection, rather than their records. However, the reassurance of a confidentiality clause was essential to the acceptance of whichever professional accessed patient notes.

*"I really don't care who has access to my notes. If someone wants to opt-out let them tick a box somewhere to say so. Surely researchers have better things to do than discussing individual peoples' notes."* LIVERPOOL WORKSHOP PARTICIPANT

*"I think any health professional is regulated enough, so I have no concerns"* LONDON WORKSHOP PARTICIPANT

*"You are bound by confidentiality. It depends on your decency, not your training or seniority."* SPECIALIST NOTTINGHAM

Participants discussed whether there are particular situations or illnesses in which it would be less appropriate for patients' notes to be accessed. Participants in a number of groups mentioned sexual health issues as being particularly sensitive. However, an specialist in Nottingham explained that this already happened for sensitive conditions, for example sexually transmitted diseases. He highlighted the problems this can cause, such as optical experts and researchers not being able to identify people with syphilis who might also have related eye problems.

### **Scope Creep**

Scope creep was a common theme throughout the discussions. Specifically during this discussion, some participants were worried about the possibility of who else might eventually gain access to patient records if access for researchers was increased. A key concern was that data might become available to private companies that are funding research, and that this commercially sensitive information could be used in ways that are not in the patient's interest. An example mentioned in several of the group discussion was a concern that data might be sold to an insurance company, who could increase insurance premiums for certain individuals as a result.

*"As soon as you open Pandora's box and you allow people to have access to records, what is to stop someone selling these records to insurance companies and deciding what would be a premium for the life insurance because they found out they had depression or whatever"* LIVERPOOL WORKSHOP PARTICIPANT

An important caveat was that if data is shared with research nurses, there should be measures in place to ensure that the data can go no further.

### **The relationship between the NHS and privately funded research**

One expert patient in Nottingham highlighted that they would feel differently about research access to hospital records if it was for the commercial advantage of the pharmaceutical company rather than the NHS. They suggested it was likely that research nurses, on short term contracts, would be likely to move between the NHS and commercial research companies which could have negative impacts on the level of data security.

*"Providing it's still the NHS it shouldn't be an issue."* CARDIFF WORKSHOP PARTICIPANT

The way that data is stored was also an important issue for participants. One concern in particular was that if parts of the NHS are privatised, the bodies managing patient



databases might become private organisations. Participants wanted there to be robust safeguards to ensure that data would be protected in this situation.

In the context of the above concern, some groups, predominantly in Liverpool, said that they would prefer researchers who are funded by private pharmaceutical companies not to have increased access. These views could have been influenced by a vocal expert patient who made his worries about pharmaceutical company involvement known to the participants as a whole. A few people conceded that this might not be avoidable, but sought assurances that data would only be available to the NHS researchers, and not to the company. This concession was suggested following input from table specialists, who explained that it is inevitable that private companies would be involved in research, because of the way that major trials are funded.

*“If you cut down on pharmaceutical companies’ involvement you are dramatically cutting down on the number of studies that can take place.”* SPECIALIST EXPERT  
NOTTINGHAM

A separate concern was whether an increase in income from private companies might undermine the trust relationship between patients and doctors. Although only a very few participants raised this issue, it was a repeated theme throughout the discussions.

*“Do some GPs have a vested interest in research because they are offered payment by pharmaceutical companies?”* LONDON WORKSHOP PARTICIPANT

The underlying fear about the payment of doctors was that it meant the patient's best interests were no longer the only issue for medical staff. Indeed, several participants wanted to emphasise that even if more trials were made available to patients, they should not be put under pressure to participate if they did not want to.

### ***What types of person should be allowed access to your patient record?***

Typically, more senior researchers and clinical professionals were preferred. This was often because of their perceived trustworthiness and professionalism. Participants in one group believed that clinical staff take an oath of confidentiality, which they found reassuring. A few participants were particularly concerned about administrative staff including receptionists or medical students having access, due to their perceived propensity for gossip.

*“Think it is good to have research nurses because you need someone with time, confidentiality and expertise in the research area to identify potential participants.”*  
LIVERPOOL WORKSHOP PARTICIPANT

Some groups were worried that improving access for research nurses might prove the ‘thin end of the wedge’ and this would allow other professionals to also have increased access. One group wanted to make it clear that while they agreed with the need to increase access to research in this manner, this did not include students’ research projects. Interestingly, even in those groups where the majority had been opposed to research nurses having access to their records, most members of the group eventually

agreed that research nurses should have access to records. The change in opinion was brought about by discussion with the table specialist, who explained the purpose and benefits of allowing a research nurse to have access.

Another important consideration regarding the type of person accessing data was that some groups felt that access should be limited to NHS staff from the same institution, to place a limit on how widely data could be shared. A few members of one group held the opposite view, arguing that people from further away are less likely to know the patient, so their personal information will mean nothing to them.

### ***In what format should your patient record be accessed?***

A number of participants discussed what type of data researchers would be looking at. Some drew a distinction between whether researchers should be allowed access to identifying information, or whether they would only have access to data in which key identifiers had been hidden (pseudonymised data). Participants were typically much more comfortable about researchers accessing data which hides personally identifying information such as name and address. Whilst the presentations explained that many hospital records were hand written, those discussing the format thought if computer systems allowed anonymised searching of records this would be better.

*“Could technology help with this? The condition information could be looked at by researchers and the rest looked at by a computer programme.”* LONDON WORKSHOP PARTICIPANT

Participants at one table said that they did not mind researchers having access to information, so long as that information is ‘totally anonymous’. When interrogated about what ‘totally anonymous’ meant to them in this context, participants said that they were content to have a code being included in the data to link back to an individual, so long as the key to that code was held securely (pseudonymised data). This observation highlights that throughout these discussions, participant’s usage of terminology may differ slightly from the technical definitions of those terms.

### ***How should patients be involved in increased access to their records?***

It is interesting to note that although the idea had not yet been presented to participants, a number of groups suggested that some sort of opt-in or opt-out list be developed to show which patients are willing to have their records looked at by researchers. Some groups raised this suggestion because they were uncomfortable about their records being accessed, and they thought that it should be an opt-in only process to protect confidentiality. Other groups who were more broadly in favour of researchers having access suggested that it would be good to have the option to opt-out for individuals who do not want their records to be accessed.

*“I would never say no – but I’d want be asked first. If I knew it was for treatment or diseases I would give my consent, but I want to it to be done with my say so. People*



*should not be passing on my records without me knowing.”* NOTTINGHAM WORKSHOP PARTICIPANT

## Reassurances

Whilst the participants were generally in favour of research nurses and doctors being allowed access to medical records to recruit research participants, several reassurances were suggested.

1. Patients who did not want to have their records accessed should be provided with the opportunity to opt out.
3. Information should never be released for commercial purposes such as marketing or insurance.

*“I can’t see a problem in accessing records if it’s for research, just not if it was used for marketing”* LONDON WORKSHOP PARTICIPANT

4. If a patient is identified as being a potential research recruit, they should not be put under any pressure to join the trial.
5. All data must be held securely. Where possible data should be accessed in anonymous or pseudonymous format.
6. All researchers accessing the data should have signed a data protection agreement or a professional duty of confidentiality.

Another suggestion, but less frequently mentioned was:

If patients had some sensitive conditions or background details they should have the option to have these stored in a non-accessible format.

*“An off the record option, where you ask your doctor to record the information in a different place.”* LONDON WORKSHOP PARTICIPANT

## Access to patient records in General Practices to recruit for research

<b>Questions Asked:</b> <ul style="list-style-type: none"><li>• Are the planned communications enough?</li><li>• Should existing patients be informed?</li><li>• Who should inform patients and how?</li><li>• What other reassurances might patients need?</li></ul>	<b>Materials Provided:</b> <ul style="list-style-type: none"><li>• Presentation delivered by HRA</li><li>• Table handouts of the slides</li></ul>
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### The Scenario

Participants were given a presentation outlining another example of research nurses accessing health records within a GP surgery in order to identify relevant patients for research. In the hypothetical example, staff from a Research Network team, including research nurses could access identifiable GP health records in order to identify potential research participants. This could be a way of reducing the burden on GPs to find suitable patients as a research nurse would be able to complete the search process instead. Research nurses would be NHS employees with an honorary contract with a GP practice; they would not be directly employed by the GP practice itself. They would be subject to guidelines including a confidentiality clause in their contract. All new patients would be informed about who might look at their notes and would be asked to sign up to this. Posters and leaflets would be placed in waiting rooms to inform patients. Practices would operate an opt-out process for existing patients. This proposed method could lead to an increase in the number of patients able to participate in clinical trials, as more may be identified by research nurses where doctors may currently be too busy to carry out a detailed search.

Participants were asked to discuss their perceived benefits and risks of research nurses having access to patient records within a GP surgery. They were also asked whether the proposed communications of posters and leaflets would be enough to inform patients.

**Figure 8: Presentation slide outlining the positives and associated concerns of increasing access to patient records to research nurses.**



### ***Who should be actively informed?***

Participants were given an example of a General Practice informing new patients that if they joined the surgery, their notes may be accessed by an NHS research nurse to identify potential research participants. Those who were already patients at the surgery would only be informed through posters in the surgery.

Participants across all groups were happy with the communication for new patients but felt that the proposed communications with existing patients were insufficient. There was concern that existing patients may not see posters in a GP surgery if they attend infrequently, or because there are already lots of posters on display.

*"If you haven't been to the GP, how would you know?" LONDON WORKSHOP PARTICIPANT*

Across locations there was consensus that existing patients should be informed that research nurses would be accessing patient notes in order to be able to identify eligible research participants, in contrast to the proposal that only new patients would be informed.

Most participants felt everyone needed to be aware of the change so they could be actively offered a choice and could make their own decision whether to participate or not.

*“Proactive notification is needed; you have a right to know.” LONDON WORKSHOP PARTICIPANT*

*“What if you had a miscarriage 5 years ago, but had not visited your GP since – you probably don’t want other people knowing this.” LIVERPOOL WORKSHOP PARTICIPANT*

One of the specialists in Nottingham probed why some participants at the table had a problem with research nurses accessing their GP records without being informed when in earlier conversations they had been very positive about opening up their records to research. The group responded that this was a question of principle. Whilst they would be happy for a research nurse to access their records, some people might not be happy, in which case they should be offered the opportunity to opt-out.

Several public participants raised concerns about whether most people would understand what the changes meant, given their own lack of awareness of research and patient notes at the beginning of the workshop.

*“I think people should be kept informed that your notes might be looked at now in one of these surgeries. Although on the other hand, many of us didn’t know who had access to them in the first place, so you would have to explain what the change actually was.” CARDIFF WORKSHOP PARTICIPANT*

*“I think it shows that we have had three hours of quite intense discussion about it and there is still some lack of clarity and understanding, so how are we going to get the wider population to understand? And with the newspapers scaremongering.” LONDON WORKSHOP PARTICIPANT*

### ***How they should be informed***

Participants in nearly all groups agreed that posters were an insufficient form of communication. They acknowledged people tended to browse posters whilst in the waiting room, however there was a common belief the volume of posters on surgery walls meant not everyone would notice this particular poster. Moreover, older people and those who did not have English as their first language might find it difficult to read a poster.

*“If you put a poster up, most people won’t notice.” CARDIFF WORKSHOP PARTICIPANT*

*“They are not sufficient, leaflets must be sent to everybody.” LIVERPOOL WORKSHOP PARTICIPANT*

Some participants felt it was essential to provide a verbal explanation of the changes from someone at the surgery to complement any written explanation for those who needed it. Some participants felt it would be inappropriate for a researcher or research nurse to inform patients and this might make some people angry. Others felt a doctor or practice nurse should explain the changes in person.

Several participants stressed the need to use a variety of different types of communication. Again, this was a common theme throughout the discussions.

*“It’s about how the information is conveyed, how well it’s explained, how thoroughly it’s explained. It all depends on the individual it is explained to.” NOTTINGHAM WORKSHOP PARTICIPANT*

Common suggestions for alternative communications included sending letters, emails or text messages to all patients. A national advertising campaign explaining to the country as a whole the possible changes to who can access patient notes in GP surgeries was raised by several groups. The specialists tended to be supportive of introducing changes in cost effective ways, which excluded a mailshot or advertising campaign, especially since not all surgeries would be making changes at the same time. However, groups in Nottingham and Cardiff still felt there needed to be a large advertising campaign even after it was explained to them that this would be costly and inappropriate as not all GPs surgeries would be becoming research active.

*“You imagine the surgeries will get money for this, so they should be writing everyone a letter.” LONDON WORKSHOP PARTICIPANT*

Some participants raised concerns about letters, emails and text messages not reaching patients, while others recognised that widespread communications may be expensive. Nevertheless, most participants thought that it was important to make the effort to inform all patients of the changes.

*“Advertise locally on billboards? Or put lorries on the street with signs on?” CARDIFF WORKSHOP PARTICIPANT*

Many participants felt that a GP surgery should inform patients about the changes either with communications coming from the practice or from a doctor at the surgery.

*“I think if the communications went through my GP, I’d be happy with that.” LIVERPOOL WORKSHOP PARTICIPANT*

### ***Should patients be able to opt-in or opt-out of this process?***

The participants were not asked to debate whether they would prefer to opt-in rather than opt-out of having their notes accessed by researchers. However, this was a theme which came up in many discussions and was discussed in every location. Several times the topic was introduced by the expert patients at the table, who felt it altered the social contract with patients.

*“Why is it opt-out rather than opt-in?” EXPERT PATIENT LIVERPOOL*

*“It’s only ok for a researcher or research nurse to go through your records once you’ve opted in.” LIVERPOOL WORKSHOP PARTICIPANT*

By contrast, the specialists tended to support the opt-out process, explaining to participants that it was expensive and inefficient to try to extend research recruitment through an opt-in process.

*“What happens if people don’t get the letter, or a lot of people just don’t respond? That could lead to not enough people with certain types of conditions or characteristics coming forward.”* SPECIALIST LIVERPOOL

*“There is a cost associated with informing them and a low response rate with opt-in.”*  
SPECIALIST LONDON

One expert patient in Nottingham continued to feel that having an opt-out system changed the relationship between patients and the NHS without informing the patient, as up to this point everything within the NHS has been based on an opt-in system.

*“I do think the NHS has saddled itself with a bit of a problem because it has always been opt-in not opt-out. So whilst I totally agree with you, opting in will give less people and be less satisfactory, I just can’t see a way round it. It is just not acceptable to change the terms of the reference for people that are used to the system without telling people first. Research active practices will have to write to all their patients I would have thought.”* EXPERT PATIENT NOTTINGHAM

Throughout the discussions public participants had mixed views on whether asking for patient consent for research nurses to have access to records within a research active practice should be an opt-in or opt-out system.

Some participants recognised an opt-in system would not get sufficient take up and might take too long to gain consent, which would have a negative impact on the number of people recruited for health research. Others thought an opt-in model would ensure that everyone had made an informed decision and those included would be more motivated to participate in future research. For example, one group in London strongly felt that opting in provided an ‘active yes’.

There was some discussion as to whether, even with adequate communications the opt-in scheme really provided consent. A group in Cardiff observed that whilst people may not particularly agree with a scheme, they did not tend to put in the effort required to opt-out. Talking about when the opt-out system of organ donation was introduced into Wales, a participant said:

*“You saw adverts, but I don’t know of anyone who did anything as a result of it.”*  
CARDIFF WORKSHOP PARTICIPANT

At the conclusion of the discussions with the specialists, the majority of the public participants accepted that opt-out was the most suitable option if a General Practice wanted to use a research nurse to access patient records.

*“Opt-out makes sense once you understand the pitfalls of opting in.”* LONDON  
WORKSHOP PARTICIPANT

### ***The importance of being able to opt-out***

Most participants were comfortable with the suggestion that research nurses might have access to patient records in research active practices. However, as well as having

been adequately informed that this was taking place, a theme that came out from discussion was how essential it was to be able to opt-out.

*“An opt-out clause is important.” CARDIFF WORKSHOP PARTICIPANT*

*“Being able to opt-out is key.” LIVERPOOL WORKSHOP PARTICIPANT*

*“My opinion is that there should be a good attempt to communicate with people and then an opt-out.” LONDON WORKSHOP PARTICIPANT*

This ability to opt-out was sometimes raised as the means of preserving patient autonomy and keeping the doctor-patient relationship in balance. Several groups highlighted the need to ensure the ability to opt-out it was made easy. For example, the research active practice should provide a phone number which was not the surgery receptionist's line, so opting out would not interrupt the work of the surgery or stop patients from getting through to make appointments.

### ***What reassurances would be needed?***

1. Everyone should be actively informed. Posters in general practice waiting rooms would not be sufficient as those who do not access the surgery regularly would be unaware of the changes.
2. For those with comprehension or reading difficulties, there should be an option to talk someone in person about the implications.
3. Everyone should be able to opt out.
4. A key reassurance needed by participants concerned the safeguarding of data. It was seen as important that data is kept safe, especially if it is being held as part of a larger database rather than locally.

### ***Summary of discussions about access to hospital and GP records***

Participants discussed who should be allowed access to health records in order to identify patients who might be suitable to take part in clinical trials. There was widespread in principle support for research nurses and non-clinical care team NHS doctors accessing patient records in hospitals to identify patients for research.

The main caveats suggest this would be acceptable under the following conditions:

1. High levels of data security must be maintained. This is especially true if data is not held on the hospital site.
2. Where possible data should be accessed anonymously or pseudonymously, utilising computer systems and key word searches.
3. Where possible more senior staff should access the information. If a research nurse or doctor is involved, research participation identification and findings searches should not be passed on to people at an administrative level.



4. Data should never be made accessible to commercial third parties, such as advertisers, market researchers or insurance companies.
5. This method should not be utilised to identify participants for students' projects.

In general, participants felt research nurses should be allowed access to patient notes in GP surgeries to identify potential health research participants. However, the caveats raised suggest this would only be acceptable under the following conditions:

6. Everyone at the surgery is actively informed about the change. It is not sufficient to simply inform new joiners since this is an opt-out model.
7. Posters and leaflets in waiting rooms are not sufficient methods of informing members of the practice of the change.
8. A campaign of letter writing, email or text messages would be necessary to ensure patients are fully informed of the changes and to reassure patients that their data will remain secure. Someone should be available to talk to if a member of the surgery would like further information.
9. It is essential that members of the surgery can opt out of the scheme easily. For example, it is not sufficient to have to ring the receptionist's line to opt out, as this would interfere with the working of the practice.



# Consent to Approach Lists

## Introduction

Given the difficulties that researchers face in identifying people who might be eligible to take part in individual research studies, a number of organisations have started to move proactively to setting up registers of people who have agreed that they are willing to be approached in the future about relevant clinical trials or other studies. Through these registers or lists, patients can register their interest in being approached by researchers at a later date with a view to being invited to take part in a research study. This is often known as the 'consent for consent' or 'consent4consent' approach.

Participants were presented with two different examples of consent to approach lists.

## Consent to approach lists

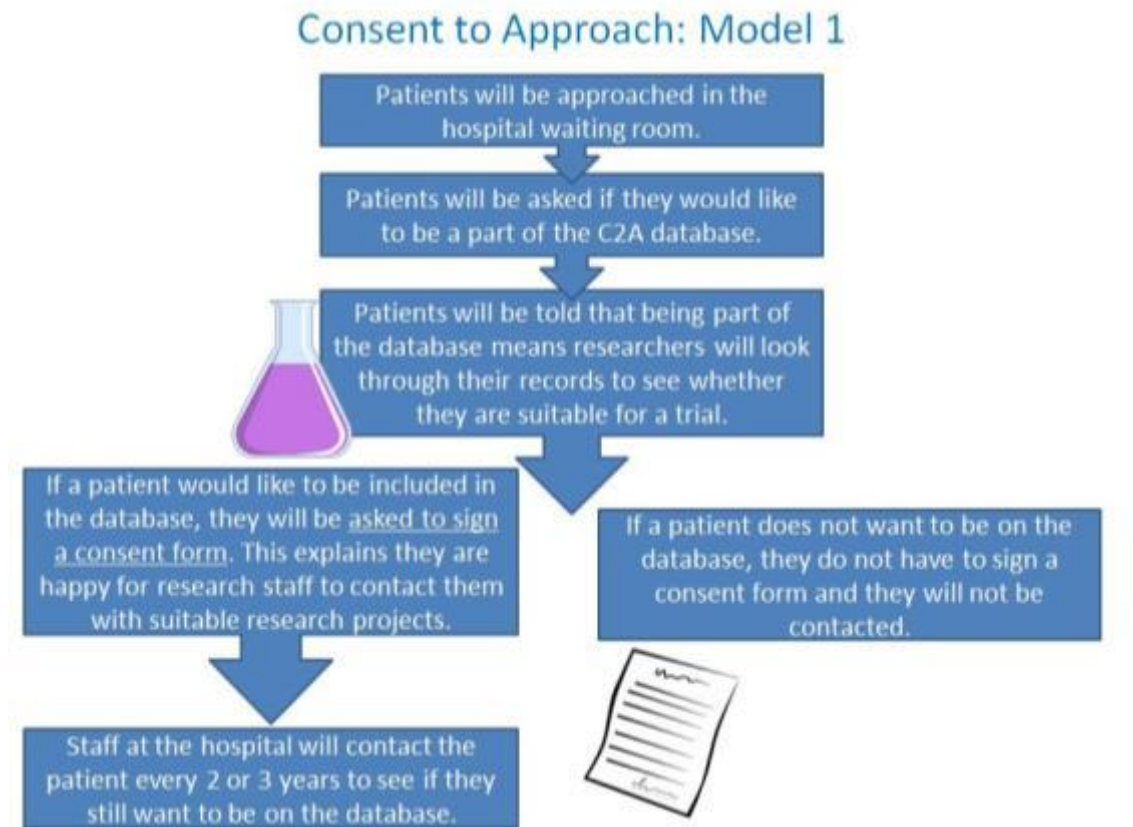


## Model 1: Approaching a patient in a hospital waiting room

<b>Materials provided:</b> <ul style="list-style-type: none"><li>• Presentation delivered by OPM</li><li>• Table handouts of the slide explaining the model</li><li>• Example consent to be approached information sheet</li></ul>	<b>Questions asked:</b> <ul style="list-style-type: none"><li>• How acceptable do people find the model?</li><li>• What concerns do people have?</li><li>• How do you feel about different people approaching patients for consent to approach lists in the waiting room?</li><li>• Is it acceptable for the person approaching you in a waiting room to have seen some details about you/your condition in advance?</li><li>• What changes or reassurances might people need to allay concerns?</li><li>• Would willingness to join a list differ by severity of illness?</li></ul>
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First, model 1 was explained through a presentation given by the HRA, following which tables discussed how they felt about the proposal, and whether they had any concerns or sought any reassurances. Participants were also asked whether their willingness to join a list would differ by the severity of their illness.

In Model 1, patients are approached by a member of the hospital staff in a hospital setting, probably in a waiting room, and asked if they would like to be included in a consent to approach list. If a patient would like to be involved, they can opt-in by signing a consent form. Staff at the hospital will contact the patient every 2 to 3 years to confirm if they still wish their contact details to remain on the list. Patients can opt-out of the database at any time and if they were approached to take part in a specific study they would be asked for their consent to participate.

**Figure 9: A slide explaining model 1: approaching patients in a hospital waiting room**

### ***Approaching patients in a hospital waiting room (Model 1)***

Participants' views on the acceptability of approaching patients in a hospital waiting room differed, both amongst public participants and expert patients. The main issue discussed in different ways across the workshops was around the trade-off between the efficiency of approaching people when they are waiting versus the sensitivity of the approach, especially if it is not a doctor or nurse from the clinical care team who approaches the patient.

Some participants felt it would not be acceptable to approach people in a waiting room as patients might feel under pressure and be in the wrong state of mind to make an informed decision as they are focused on their health and their upcoming appointment. Indeed, one Nottingham patient expert questioned, "is it ethically correct that they can just approach you in a waiting room?" Another expert patient felt that an individual may feel nervous and less rational than normal the closer they get to finding out about a condition and this could them more likely to say no.

*"The closer you get to finding out about your condition, the more stressed you get. You may be a bit worked up as a patient."* EXPERT PATIENT

However, other participants saw the waiting room as an opportunity to efficiently approach relevant patients and as potentially a useful distraction and good use of time. This was certainly the view of several of the specialists present. One participant

suggested that because patients are in a waiting room to be treated, their health is at the forefront of their mind therefore it is *“good to get their consent then and there.”*

Another ethical issue discussed in a few of the groups was whether an in-person approach, when a patient was feeling vulnerable, could put undue pressure on them.

*“It might be hard to say no in a waiting room environment.” LIVERPOOL WORKSHOP PARTICIPANT*

One Cardiff patient expert on the table explained his experience of being approached to take part in research: he was a renal patient and was approached by a nurse to be asked to take part. He said he felt comfortable with the process because he felt like no one was forcing him and that they were very calm in the way they approached him.

### **Sensitivity of the approach**

Participants across locations highlighted the importance of the way a patient is approached. This should be in a sensitive, calm and caring manner, and take account of the individual patient.

*“You might not be in the right frame of mind, you’re worried, you’re concerned, you haven’t got your definite results back. But then on the other hand you could be there first to try this treatment. I think it is purely up to the individual.” NOTTINGHAM WORKSHOP PARTICIPANT*

A few groups discussed whether or not a patient should never be approached on their first appointment, believing they would be at their most vulnerable and worried at this point. Others felt that this model should not be used in certain locations. For example, several participants argued that it should not be used in an Accident & Emergency Department as patients may be vulnerable and in pain. Several participants felt that it was acceptable to approach a patient in a waiting room for a specific condition, like a renal clinic, but not in a general waiting room where the lack of a condition specific clinic could result in them having to discuss a condition openly in a public space.

Many participants thought that patients should not have to share personal information in a waiting room as this would breach their confidentiality. One specialist in London suggested taking patients to a small room where they could discuss the list in more depth, something participants at the table supported.

*“If they approach you, and you say you’re happy to do it, they should take you out of there.” LIVERPOOL WORKSHOP PARTICIPANT*

### **Type and severity of condition**

Some participants’ views differed on the acceptability of the model for different conditions. In London, one group was divided on whether it would be a welcome distraction for patients with more severe conditions or if this would make someone

more anxious and feel under increased pressure. Other participants felt patients with serious conditions may be more receptive to taking part as they may be aware of the potential benefits of research.

In Liverpool, an expert patient added that it would be inappropriate to approach the older people in the clinic as they *‘might find it harder to discuss what’s going on because it’s traumatic for them’*.

An expert patient in one group explained that she had a severe illness and would welcome being approached in a waiting room. However, a number of participants believed this model is not suitable for sensitive conditions such as sexually transmitted diseases, or for anyone in pain or trauma.

*“If I am not in pain, it wouldn’t bother me. But if I was in pain or suffering, I’d want to tell them to bugger off”* NOTTINGHAM WORKSHOP PARTICIPANT

*“Common sense needs to prevail”* was the perspective of a Cardiff expert patient. He believed that there would be patients in certain waiting rooms who are likely to have certain conditions that should not be approached. This should be obvious from the waiting room.

### Sample bias

A key concern arising from a few of the discussions is that the Model 1 consent to approach list could exclude eligible people simply because they did not happen to be at the hospital when the list was being compiled. A Cardiff specialist confirmed this was a potential downside. He pointed out that results based on approaching people in clinics tend to miss the less severe people and so skew the results. Thus, when using consent to approach models like this one, there is a risk the robustness of the research results could suffer. However for some long term conditions all patients are expected to attend for routine appointments at hospital and so the risk of bias would be lower.

### Who should approach?

Participants widely agreed that NHS employees should approach patients, and they should be identifiable by a uniform or badge. Some participants favoured doctors while others felt research nurses would be acceptable as they would be able to talk knowledgeably about the research process.

*“I wouldn’t mind so long as they have an NHS name badge.”* NOTTINGHAM WORKSHOP PARTICIPANT

*“You need to know who they are and what they are doing.”* LIVERPOOL WORKSHOP PARTICIPANT

*“You need to trust the person approaching you is part of the NHS if they are taking your details.”* LIVERPOOL WORKSHOP PARTICIPANT

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*"I don't mind who approaches me, but it would have to be someone from the NHS if I was to say yes."* CARDIFF WORKSHOP PARTICIPANT

However, specialists in Liverpool questioned whether this was an appropriate use of time for staff and might be better conducted by volunteers.

*"Do we have enough staff to do this?"* LIVERPOOL SPECIALIST

Many participants believed they would feel uncomfortable being approached by someone they did not know. It was important that the person approaching a patient was someone they could trust either because of their manner, the training they had received, their knowledge of the trial or their role within the hospital.

A number of participants across locations suggested alternative ways of informing patients about the consent to approach lists before sitting down in a waiting room. Some participants suggested sending information to patients in advance for example with their appointment letter, for example, one expert patient felt she would not feel comfortable unless she had seen the paperwork beforehand.

*"I think if everybody got sent a letter and you could then either opt-in or opt-out, personal choice. So then you are not under pressure from appointments and such."* NOTTINGHAM WORKSHOP PARTICIPANT

Others thought patients could be informed by a receptionist when registering, or could be told during a consultation. Several participants felt it would be helpful to be able to take information away with them to think about the decision, while others wanted the opportunity to talk about the proposed consent to approach list with someone in person. For example, one participant suggested being approached by a patient already involved in the list. This would provide an opportunity to ask practical questions about both the list and clinical trials.

### ***Knowing details in advance***

The participants were asked to debate whether they thought the person approaching them should have some details about them and their condition so that the approaches could be targeted and informed. Discussions suggested a tension between reducing the number of approaches that might be made to people with multiple conditions or who had frequent appointments and maintaining patient confidentiality if the person approaching was not part of the clinical care team.

Participants had differing views about being approached by someone who had seen details in advance. Some felt it was important for those approaching to have some details about the person so they did not approach the wrong people.

*"I think they would need to know it really before they approach you."* NOTTINGHAM WORKSHOP PARTICIPANT



However, many participants thought it was essential that this was a non-targeted approach. A number of participants thought that a researcher accessing information before approaching someone would be a breach of trust.

A small minority of participants across locations had fewer concerns about patient records being searched by individuals outside of a clinical care team or patients being approached for trials. For example in Cardiff two participants felt it would be fine for researchers to approach individuals about relevant clinical trials directly rather than getting consent for approach first.

Once again the issue of public awareness of clinical research was raised in a few of the discussions. One expert patient suggested that there needs to be more advertising of the role of research within hospitals so that patients are prepared and expect requests. Whilst people were aware that some hospitals were research hospitals, it did not mean people knew what this meant for patients. Educating the public about the role of research was seen as a necessary change in culture by another expert patient.

### *Clarity of information*

A number of groups discussed the need for people approached in the waiting room to receive details about how their information would be used and who had access. One of the London specialists explained to a group that because it was paper based hospital records, that might mean signing up to have their full record accessed by a range of people. This led to general group concern that vulnerable patients would need to have this made clear to them at the point of approach in the waiting room. However in practice, access to the registers is normally limited to a small group of R&D staff who can conduct an initial sift of suitable patients from the register in order to generate an anonymised extract of patient data which can then be given to the researcher to refine further. Once the researcher has identified suitable patients, the extract is then handed back to the R&D office who can then make an approach to the patient about an individual study on behalf of the researcher.

Several participants wanted reassurance that data from lists would not be used for any other purpose and that contact details would not be passed on.

*'Researchers do research into lots of different things, and lots of people call themselves researchers. There's a risk of information getting into the wrong hands.'*

*LIVERPOOL WORKSHOP PARTICIPANT*

Others wanted more information about what sort of research they could be approached about in the future, how frequently they would be approached, and what would happen to their information next.

How this information was presented was once again raised as an important theme. Many participants felt this sort of information should be discussed with the patient by the person signing them up. There were concerns that the example leaflet given

to the participants was not engaging enough. It should be user friendly, with pictures, clear information and obvious contact details.

### **Reassurances**

In addition to being approached by an NHS employee, participants suggested a number of reassurances that would make them more comfortable with the proposed consent to approach model.

1. The number of times a patient is approached to be placed on the list should be limited. Preferable, they should only ever be asked to take part once regardless of how many appointments or conditions they have.

*“We shouldn’t get to a situation where people not interested get continually approached when they are at the hospital”. CARDIFF WORKSHOP PARTICIPANT*

2. If placed on the consent to approach list patients should not be bombarded with approaches; an acceptable limit would involve individuals being contacted a maximum of two or three times a year. The level of commitment should be made clear to the patient at the point of being recruited to be on the list.
3. A number of participants emphasised the importance of clarifying with the patient that it is reasonable to talk to them in the waiting room and not approaching someone who is with their family or friends. If the approach reveals or requires any personal information, there was widespread agreement that patients would have to be taken to a separate room to provide details.
4. How personal data will be held and used should be clarified at the point of being signed up to the consent to approach list. This data cannot be used for any other purpose.
5. Some people suggested having a clearly listed phone number or website where patients who had been approached could access more information. Additionally, it was essential to have a clear method to easily opt out of the list at any time.

*“If you thought about it more, you should be able to opt out of the list.” CARDIFF WORKSHOP PARTICIPANT*

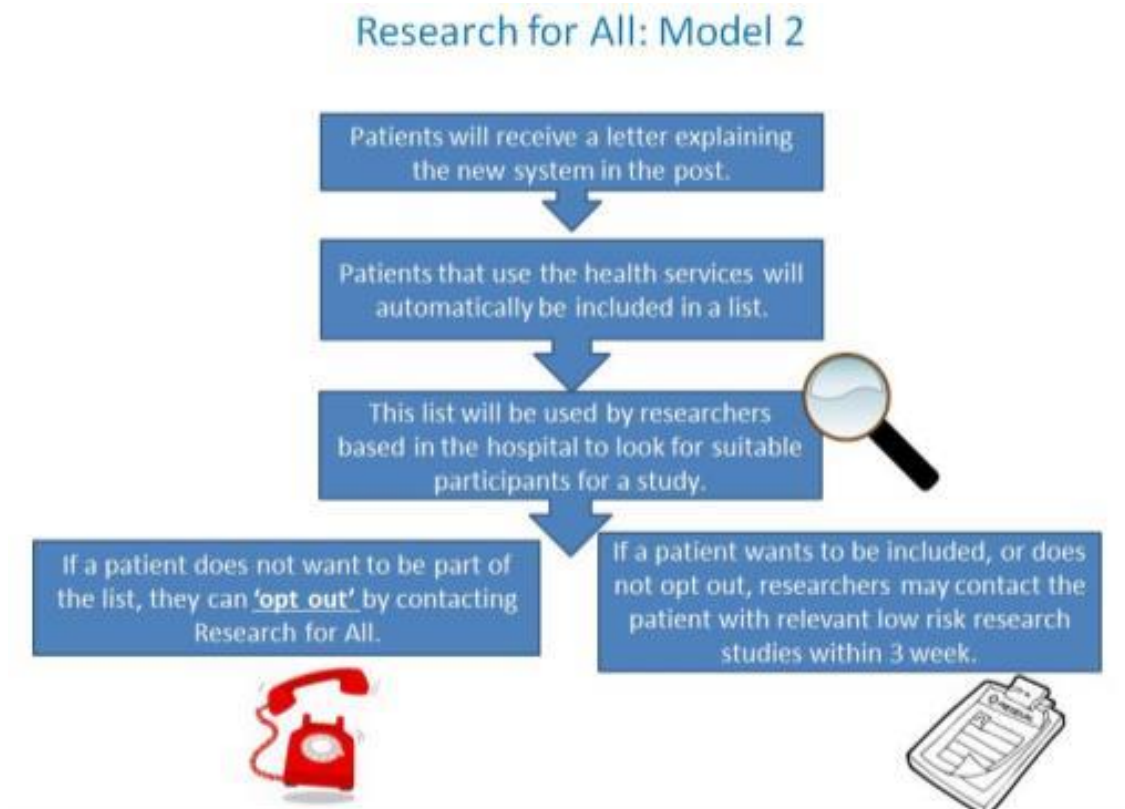


## Model 2: Receiving a letter in the post

<b>Materials provided:</b> <ul style="list-style-type: none"><li>• Presentation delivered by OPM</li><li>• Table handouts of the slide explaining the model</li><li>• Example Research for All leaflet</li><li>• Example leaflet labelled with a mental health trust</li></ul>	<b>Questions asked:</b> <ul style="list-style-type: none"><li>• How acceptable do people find the model?</li><li>• Would willingness to join a list differ by severity of illness?</li><li>• What are your views on the time limit imposed on opting out?</li><li>• Do views on the acceptability of opting out change when they know the model is about mental health?</li><li>• What concerns do people have?</li><li>• What changes or reassurances might people need?</li></ul>
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In Model 2, patients in receipt of a particular service were sent a leaflet explaining the new system in the post. In the outlined scenario patients were automatically included in the list but could opt-out by contacting the organisation. The list would be used by researchers based in the hospital to look for suitable participants for research studies. If patients do not opt-out or want to be included on the list, they may be contacted with relevant research studies after three weeks. Patients would always be asked for consent again before they are included in a study, after the specific research study has been explained fully.

Participants were introduced to this model through a presentation delivered by HRA, which was further explained and discussed at tables with an example leaflet. Half way through the discussion, table facilitators introduced a second leaflet with the identity of the research organisation revealed as a mental health NHS trust. Participants were asked whether the acceptability of the model changes when they know it is about mental health.

**Figure 10: A slide from the presentation explaining model 2: receiving a letter in the post**

### ***Receiving a leaflet in the post (model 2)***

Once again, participants had contrasting views on model 2 in which patients receive a leaflet in the post asking them to opt-out within three weeks or be placed on a 'consent to approach' list. The discussions at the different tables in locations often covered different concerns and came to contrasting conclusions. Because of this it is difficult to conclude what the overall level of consensus is for model 2.

Many participants felt this model provided more privacy than model 1, giving patients extra time to consider their decision and talk about it with family and friends rather than feeling under pressure to make a decision on the spot.

*"With the letter you have more time to think about it"* LONDON WORKSHOP PARTICIPANT

*"It's a bit more discrete isn't it? I like that it is more private; you are not in public when you are being approached and it seems more confidential."* LONDON WORKSHOP PARTICIPANT

Some participants also argued that model 2 is more cost effective and would reach a greater number of people when compared with model 1 where patients are approached in a waiting room.

*"It's important to me that the NHS does things in a more efficient cost effective way".* CARDIFF WORKSHOP PARTICIPANT

One group felt this removed the selection bias of only including patients who attend a hospital or GP surgery, which they had identified in the previous model.

*“This is good because it would have less selection bias than model 1 – it’s not just people who have been to the hospital recently” LIVERPOOL WORKSHOP PARTICIPANT*

However, other participants had concerns that patients may not receive letters in the post or may not open them, preventing everyone from being informed about being placed on a list. A number of participants felt the model could impact busy people and those who have trouble reading, placing them on a ‘consent to approach’ list without fully informing individuals of the change.

A specialist in Cardiff raised the idea that quite a few people might never read the leaflet or realise they were being put on a list, and that this might be an issue. However, the public participants at her table did not see a problem with individuals not reading the leaflet as long as they have the option to opt-out when finding out about the list, for example when approached to take part in a trial.

*“Whether in the past people were not reading the information, it might still have been to their benefit that they were approached. I don’t see that it would be to anyone’s detriment, even if they haven’t read it.” CARDIFF WORKSHOP PARTICIPANT*

*“You can’t spoon feed people can you? You can give them as much info as possible to make an informed decision, but you can’t force people to do something- it will be the same whatever you do whether it is opt-in or opt-out, people will be going either side. If it is opt-out you end up forgetting some people who probably would have opted out if they had read it, if you do the opt-in you will get lots of people who would have done it if they had got the information – it’s just how info gets out. So long as you give enough info to make an informed decision you have done as much as you can.” CARDIFF WORKSHOP PARTICIPANT*

Much of the difference in attitudes towards this opt-out model was dependent on whether participants thought the efficiency of signing people up by this method outweighed the ethics of uninformed consent. For example, two groups in Nottingham discussed how this model would increase the numbers of people on the consent to approach list. A participant in the first group responded sarcastically:

*“It would mean they got a lot more people on their list, so it would be successful even if no-one read it” NOTTINGHAM WORKSHOP PARTICIPANT*

The group went on to agree that the cons of this model outweighed the pros. However, the other table felt there was no problem as people could opt-out later and decline to participate in the studies.

### **Personalisation of the leaflets**

One of the key themes that arose in the discussions was how personalised the leaflets ought to be. The model proposes a personalised envelope with a patient’s name and address, containing a leaflet without any identifiable markers. The leaflet had been designed this way to avoid a breach of confidentiality. This was not accepted as the best approach by many of the participants. Some participants believed that patients



**Example research for all leaflet given to workshop participants**

would be more likely to read a leaflet if it contained information such as your name or the clinic responsible for sending the letter on the leaflet or letter inside the envelope. Others thought this level of information might draw attention to a condition that someone might want to keep private. In particular, some participants highlighted this could be an issue in shared houses where residents may not know about a patient's health condition.

A number of participants liked the look and feel of the leaflet, commenting that it contains all the information you need, and is 'more user friendly' than the leaflet from Model 1. However, others believed the general style of the leaflet made it unappealing.

*"No-one would read it if it looked like that" NOTTINGHAM WORKSHOP PARTICIPANT*

One key concern raised by a couple of groups was that if the leaflet was not engaging there should be an explanation of how to opt-out of the consent to approach list on the first page. In this way people who were not interested did not have to search for the way to opt-out.

Most participants felt it was important to have the NHS logo on the leaflet making it look more official.,

### **Opt-out system**

Participants had contrasting views towards the opt-out system used in the model where patients would be included on a 'consent to be approached' list unless they said otherwise. Many participants felt an opt-out system would increase the number of people on the list, potentially increasing the number of people taking part in health research.

*"I like it – I think it reaches more people and I think it's good that only the people who feel strongly against it would opt-out." LIVERPOOL WORKSHOP PARTICIPANT*

In Cardiff, participants largely agreed that an opt-out system would be beneficial, comparing it to the opt-out organ donation system used in Wales that was seen to be working well. However, some participants at remaining locations felt that an opt-out system could lead to large numbers of people being included on lists without their knowledge or without making an active decision to be on the list.

*"It is obtaining consent by stealth. That's not okay" NOTTINGHAM WORKSHOP PARTICIPANT*

*"I'm not happy with this – I would want to be in control of my data and with opt-out I'm not." NOTTINGHAM WORKSHOP PARTICIPANT*

Many participants suggested it was important that patients could opt-out of the list at any time, and that this needs to be made very clear. Participants also felt it was important that opting out was made as easy as possible, with a free phone number open beyond 9am-5pm or freepost envelopes.

*“The main crux of it is that you’d want the chance to opt-out. It’s common courtesy, you’d want to be asked.” LIVERPOOL WORKSHOP PARTICIPANT*

### **Time limit of three weeks**

Many, probably a majority, of participants felt the three week time limit to opt-out was too short. Participants emphasised that patients could be on holiday for longer than three weeks or not get around to dealing with the letter within this time.

*“What if there were problems with the post, or people throw it away as junk mail, or vulnerable people might not have the means to respond, this means people might never know.” NOTTINGHAM WORKSHOP PARTICIPANT*

*“I might forget to reply within the timeframe.” LIVERPOOL SPECIALIST*

A more appropriate timeframe suggested by participants was six to eight weeks. A few participants thought three weeks was acceptable. Those who supported the three week time limit emphasised that you can always opt-out at a later date, for example when contacted about a relevant research trial.

### **Severity and type of conditions**

Some participants felt the model may not be appropriate for all conditions, highlighting that some, like sexual health, are more sensitive than others, meaning patients may wish to keep information confidential and may react differently to a letter. A group in Nottingham, which contained several people who had health problems, spontaneously discussed this model being inappropriate for people with mental health conditions or under stress, yet being a more appropriate way than model 1 to approach patients with a traumatic or terminal condition. Others argued that patients already receive post about their condition from the NHS so these leaflets would be no different from other communications.

*“It could be a concern if you have an illness that you don’t want people to know about - might be hard to hide from people” CARDIFF WORKSHOP PARTICIPANT*

*“You know they would be bound by rules, so not a problem.” CARDIFF WORKSHOP PARTICIPANT*

Table facilitators introduced a second leaflet labelled with a mental health trust logo. Participants were asked whether their views changed when they found out that the model could be used for mental health patients. A number of groups highlighted that the term ‘mental health conditions’ encompasses a wide range of conditions and individuals.

*“There are so many different degrees of mental health anyway, anxiety, depression to paranoid schizophrenia, so it depends on the condition” LONDON WORKSHOP PARTICIPANT*

Some participants believed this did make a difference, with one group in London who had been very supportive of getting more people into research tempering their enthusiasm for the model. They emphasised an existing stigma around mental health conditions that may make the information more sensitive, or that individuals with mental health conditions may find the letter more worrying or not be in a good position to respond.

*“They could be able to give consent one week and not able to the next week.”* CARDIFF WORKSHOP PARTICIPANT

There was no consensus among the expert patients. However, one of the strongest voices against this being used as an approach to mental health research recruitment was an expert patient in Nottingham. She stated she was shocked to see this being sent to people with mental health conditions because they could not always look after themselves, may not answer their post for months, and in very rare cases could be vulnerable, for example seeing it as a message from God.

Other participants saw no difference between mental health and generic conditions, especially if the mental health conditions were mild or the patient was stable. Some participants who identified themselves as having mental health issues said they did not feel any less able to respond to a letter as a result of their condition.

Several participants suggested that you may be more concerned about someone a patient had not told seeing the leaflet if it had a mental health logo on it, while others felt this may make an individual more likely to read the letter.

*“Having the logo of the NHS trust makes me feel keener. If I have a stake in the disease I would be more keen to do research especially if I recognised the local group.”* EXPERT PATIENT NOTTINGHAM

Many participants felt the time limit should be extended beyond three weeks if it is being sent to individuals with mental health problems. One participant felt this was particularly the case if an individual has a support worker who only comes once a month.

## **Reassurances**

1. As well as extending the timescales to respond to six to eight weeks, participants again wanted to be reassured that their data would be safeguarded and not passed on to private companies.

*“You need some kind of guarantee, what happens if misuse of data happens?”* LONDON WORKSHOP PARTICIPANT

2. Several felt that the credentials of the research organisation should be explained clearly on the letter, or that there should be a link to a website to verify the authenticity of the research. The NHS logo should be used to provide legitimacy, although it did not need to be the specific logo of the clinic.



3. If this approach was to be used, then some groups suggested it is vital to make the method of opting out very accessible and free. There should be a unique number on the letter/leaflet which meant they could state the number on the phone or website without having to give their personal details. How to opt out should be the first thing on the leaflet.

4. Other participants sought further information about the kind of research patients could be approached about, what it would involve, what information will be used for.

*"You should be told how often you will be contacted. Will it be every six weeks?"*

LONDON EXPERT PATIENT

*"What commitment am I making?"* LONDON WORKSHOP PARTICIPANT

5. Some participants emphasised the importance of making the leaflet easy to read and eye catching. It should be in accessible, plain English.

*"It needs to grab my attention, or it'd just get recycled and not read."* NOTTINGHAM

WORKSHOP PARTICIPANT

6. Additional reassurances discussed include having the leaflet available in multiple languages and containing Patient Advice and Liaison Service (PALs) information in case you want to complain.

### **Summary of both models**

There was less clarity about the acceptability of the two 'consent to approach' models than with the other topics discussed in the workshops. Participants had mixed views on approaching a patient in a hospital waiting room in order to discuss a consent to approach list or sending a leaflet through the post. To some extent this reflected the fact that people had personal preferences, which is likely to be the same for patients. For example, it was impossible to reconcile the views of those who felt patients may be in the wrong state of mind, feel under pressure, or not feel comfortable discussing sensitive information in a public space with the views of others who felt approaching someone in a waiting room could act as a good distraction and efficient use of time while a patient waits for their consultation. Participants also disagreed as to whether this changed with a severe condition, with some seeing no difference while others felt this could increase the anxiety and pressure experienced by a patient.

Therefore, we are more tentative with our summary of when and how the two models of consent to approach should be applied.

For **Model 1**, approaching in the waiting room, there were two key issues which need to be taken into consideration:

1. The way a patient is approached was regarded as key across locations, with participants emphasising the need for sensitivity and understanding.



Patients should be asked if they are happy to talk further. Any confidential information should be collected in a private space.

2. Patients should be approached by an NHS employee, and they should be identifiable as being attached to the hospital by a uniform or badge.

Other recommendations were as follows:

- Anyone who is in pain, looks severely anxious or is in A&E should not be approached.
- Approaches should not be made to people accompanied by friends and family.
- The person who is approaching should not have seen patient details in advance. However, participants suggested people should not be approached multiple times, which would be difficult to ensure if approaches are random and inclusive of everyone in the waiting room.

For **Model 2** based on a leaflet sent through the post, there were concerns raised about whether it was acceptable to include patients on a list potentially without their knowledge or consent. However, participants in Wales were more supportive of the opt-out approach, comparing it to their system for organ donation. However those who supported this approach, liked it because it gave patients time to think about things and discuss them with others.

If this approach is to be used, it is necessary to ensure the leaflet is eye catching and personalised enough to be read by recipients.

The three week time period for opting out was not viewed as being sufficient. This should be extended to six to eight weeks. The methods for opting out should be multiple, simple and clearly listed on the leaflet.

Whilst there was disagreement about this approach to recruiting for mental health consent to approach lists, a sensible middle ground might be to ensure those with severe mental health problems are not recruited by this method.

For **both consent to approach models**, participants wanted reassurance that data from lists would not be used for any other purpose and would be safeguarded. The patient must be provided with information about the list, what kinds of research they could be approached about and how their information will be used.

# Simplified Consent

## Introduction

<p><b>Questions asked:</b></p> <ul style="list-style-type: none"> <li>• How do people feel about simplified consent?</li> <li>• How do you feel about the confirmation approach (case study 1)?</li> <li>• How do you feel about the opt-out approach (case study 2)?</li> <li>• What should and should not be included on the information sheet for simplified consent?</li> <li>• Working through the matrix, how important is each element seen as being and why?</li> </ul>	<p><b>Materials provided:</b></p> <ul style="list-style-type: none"> <li>• Presentation delivered by HRA</li> <li>• Simplified consent video</li> <li>• Table handout explaining case study 1</li> <li>• Table handout explaining case study 2</li> <li>• Simplified consent: what might change handout</li> <li>• Example short patient information sheet</li> <li>• 2 example package leaflets</li> <li>• Matrix</li> </ul>
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Participants saw a presentation by the HRA on the need for pragmatic trials of existing licensed drugs in primary care and were given an example of a simplified consent study involving statins (a range of drugs used to lower cholesterol.) Workshop participants were also shown a video presented by [Ben Goldacre](#).

Pragmatic trials are required because lack of evidence about comparative effectiveness of existing treatments; doctors and health care practitioners do not always know which available drug or treatment is the most effective for their patients. This is because pharmaceutical companies conduct trials on the efficacy of their drug or treatment but do not look at how it compares with other drugs or treatments on the market using long term outcomes

Pragmatic trials are described as such because they would be used for drugs or treatments that have been through all of the necessary trials and are already in use by the NHS for the condition the patient is seeking treatment for. The patient would be fully informed of what drug or treatment is being prescribed so there would be no need for comparison with a placebo unless no treatment is one of the standard options, for example, as in 'watchful waiting'.

Pragmatic trials in primary care may focus on long term outcomes. For example, rather than measuring the level of cholesterol in the blood, a pragmatic trial of statins would focus on the number of heart attacks, stroke and mortality.

Finally pragmatic trials may be unblinded if they do not involve a placebo arm since participants are unlikely to have preference for a particular treatment within a class of treatments, in which case the participant may receive an actual prescription with all the

information that comes within the pack insert rather than a specially packaged blinded treatment.

Currently, clinical trials of already licensed drugs follow all the same procedures as clinical trials of unproven treatments with a higher risk. Trials of existing licensed products may be expected to use the same length patient information sheets when recruiting participants as trials of unlicensed treatments. In order to follow long term outcomes, pragmatic trials need to be very large and recruitment to these trials can be difficult as GPs find the process time consuming and burdensome. Pragmatic trials could be more cost effective if they could take a simpler approach to recruiting participants using a simpler patient information sheet which could be viewed in addition to the pack insert. Long term data could be gathered through general practice electronic health record systems and so could be easily anonymised.

In a standard clinical trial, potential participants are given a day or more to go away and think about whether they want to take part. In a pragmatic trial the patients are being told they need to take a particular treatment for their condition anyway and in this scenario, it is proposed that potential participants would be asked to consent in the consultation after a simple explanation of the research study.

In this discussion, two forms of simplified consent were explored. They are described in more detail later in this section.

Figure 11: A presentation slide explaining the background to simplified consent



**Background**

NHS  
Health Research Authority

- Doctors and health care professionals do not always know which commonly **available** drug or treatment is the most effective for their patients
- Failure to address these uncertainties may result in harm to patients and wasted resources in the NHS
- We need to know which medicines work best to inform evidence-based prescribing

## Overall reactions to simplified consent

Almost all groups expressed in principle support for simplified consent processes in appropriate low risk trials:

*"It's the obvious option, they should use the data available to them – why not use it?"*

LONDON WORKSHOP PARTICIPANT

*"I like the idea of using the NHS as a machine to suck information and lower the cost and make it simpler that way. That's a good thing. You need checks and balances, but if it's for our health and our children's health it's a good thing."*

LONDON WORKSHOP PARTICIPANT

*"If it is all going to help, why do I need to be told about it?"*

CARDIFF WORKSHOP PARTICIPANT

One table in London suggested this type of approach was acceptable, because rather than being a clinical trial with some form of intervention, the studies criteria for simplified consent meant it was closer to observation than research.

There were varying levels of concern associated with the way in which this would be implemented in practice. Many participants had few worries, while others raised specific issues that they wanted to see addressed.

## Time and information pressures



Still from the simplified consent stimulus video

One theme of concern related to making sure that patients were still given sufficient time and information to make a meaningful decision about whether to take part. A particular concern was that patients might not be able to read and think about a patient information sheet in the time available in a GP appointment.

*"I can't concentrate here and read it."*

LONDON WORKSHOP PARTICIPANT

NOTTINGHAM

*"I can't see you reading this in a consultation."*

A few suggestions were made about ways to give patients a little more time. For example, one participant suggested that patients could make the decision shortly after their appointment, and inform the GP receptionist. Others suggested a 'cooling off period' where patients are allowed to change their mind after an initial decision, possibly after going home and talking to their family or friends.

A related concern, discussed by groups in both Cardiff and Nottingham, was that GP appointments are already very tight on time. Participants were worried that additional simplified consent procedures would take up valuable time in the appointment. To counteract this, some participants suggested that GPs should make appointments longer if they know they are likely to be recruiting someone to a study. In particular,

pregnant women were identified by a few participants as a specific group who could need more time to ask questions and be reassured about the implications for their unborn child.

Some participants were concerned that simplifying processes in this way might make patients feel pressured to take part. One reason for this is that doctors are seen as authority figures, and it might be hard to say no to them face to face, especially if you don't have time to think about the decision, and may have just been diagnosed with a serious illness.

Participants also sought reassurance that this would not feel like a one-off decision. It should be made clear how patients can change their mind later, if you no longer want to be involved. A few participants also thought that being able to opt-in later, after initially saying no would also be important. One reason given for this is that it would reduce the pressure on the patient to agree immediately, if they knew that this was not their only chance to get involved. Another reason is that they may decline to be involved initially, but then regret their decision on further reflection.

*"The biggest point is that it is clear they can opt-out and they don't have to take part."*  
CARDIFF WORKSHOP PARTICIPANT

The suggestion of having posters or leaflets available in waiting rooms was seen by some as a way to help patients to start to think about whether they might want to take part before the appointment, so that it does not come as so much of a surprise. Others questioned whether these would actually be read.

*"Leaflets don't make a difference. I only skim read them, I want the chance to talk it through."* LIVERPOOL WORKSHOP PARTICIPANT

It was suggested that while most patients would be happy with a simplified process, it was inevitable that some people would want more information. Many participants thought that provision should be made for such people, for example by having more detailed information sheets on hand or by making staff available for longer discussions about the research. There were differences in opinion about whether these discussions should take place with the GP or by having a research nurse available if needed.

### ***Impacts on patient care***

Many participants sought reassurance that patient care would not be negatively affected in any way. One of the most commonly raised concerns was that if a patient does not react well to the drug that they are given, they might be less likely to be switched to try a different one to avoid affecting the trial data. Another concern was that patients might be put forward for the trials to meet sign up quotas or to get funding, when in other circumstances they might have received slightly different treatment for their condition.

Another concern was about whether the nature of the patient-GP relationship would be changed by them being paid to be involved in these trials. One group in Nottingham discussed how if a GP had any incentive to sign people up to a trial using simplified consent they might not present the information to patients in a balanced way. These concerns about the role of payment for recruiting participants into research echoed across the workshops, underlining how some people are wary of the profit motive in medicine.

*"I would want to know if the GP was getting paid to put me in the trial." Cardiff*  
WORKSHOP PARTICIPANT

## Scenario 1- Opt-in model

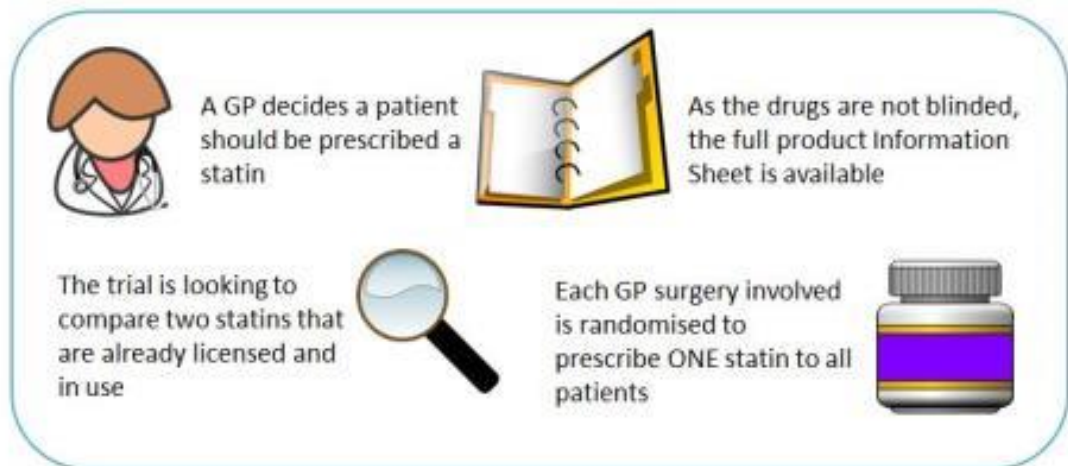
The first model that participants discussed was one in which patients have to opt-in to be involved in the trial. At the point of diagnosis, a patient's GP would tell them that a trial is taking place, and ask whether they want to take part. The patient would be given a simplified patient information sheet to read, and if they chose to take part, they would sign a consent form during the consultation.

Participants learnt that this model differs from current consent arrangements in a number of ways. Firstly the patient information sheet used would be much shorter, containing only key information about the research element because this was not a blinded trial, so they could have access to all the information about the medication through the pack insert, for example, potential side effects are listed in the pack insert. Patients would also be able to go away and look at additional information, for example, through a website or talk to someone at a central point by phone. Secondly participants would usually decide whether to take part there and then, rather than having the requirement to go away and think about the decision before signing the form.

The scenario described a trial comparing two statins that are already licenced, regarded as standard treatment and in use. The study would use a cluster design which means that rather than randomising individual patients to different treatments, each general practice would be randomised to a particular statin.

Tables worked through the scenario discussing how they felt about the approach.

## Case study 1 – Clinical Trial of Statins in General Practice



**Figure 12:** Slide from the presentation given to participants explaining the first simplified consent model.

Many participants reacted favourably to the opt-in model. One reason that some participants gave in support of this model is that they felt that giving patients an open choice reduced the issues of them feeling pressured to take part. Other participants thought that the act of choosing to take part might make you feel more actively involved in the trial, meaning that you can feel good about supporting research.

Another argument in favour of this approach is that it ensures that a discussion takes place between you and your GP, meaning that you will be able to ask any questions



that you may have. Since participants realised that they would be getting the same treatment that they would have received anyway, this approach was largely viewed as acceptable.

A minority of participants thought that this model would involve unnecessary paperwork. Indeed, in London some groups pre-empted the discussions about zero consent. Their view was that research should be taking place in situations like this across the NHS, and that it was therefore unnecessary to seek consent in every case.

## Scenario 2 – Deemed consent (Opt-out) model

Participants also discussed a model of simplified consent in which patients would be told by their GP that a trial is taking place, and that unless they asked to opt-out, they would automatically be included in the study. The practicalities of this model are similar to the one above, however there is a change of emphasis in that the patient has to actively engage in order not to take part (e.g. request not to be part of the study), rather than engaging in order to take part. A patient would not need to sign a consent form to take part in the trial. Like the first example, patients would be able to go away and find out more information perhaps through a website or a telephone number.

Tables again worked through the scenario discussing how they felt about the approach.

### Case study 2 – Clinical Trials of statins

  
Health Research Authority

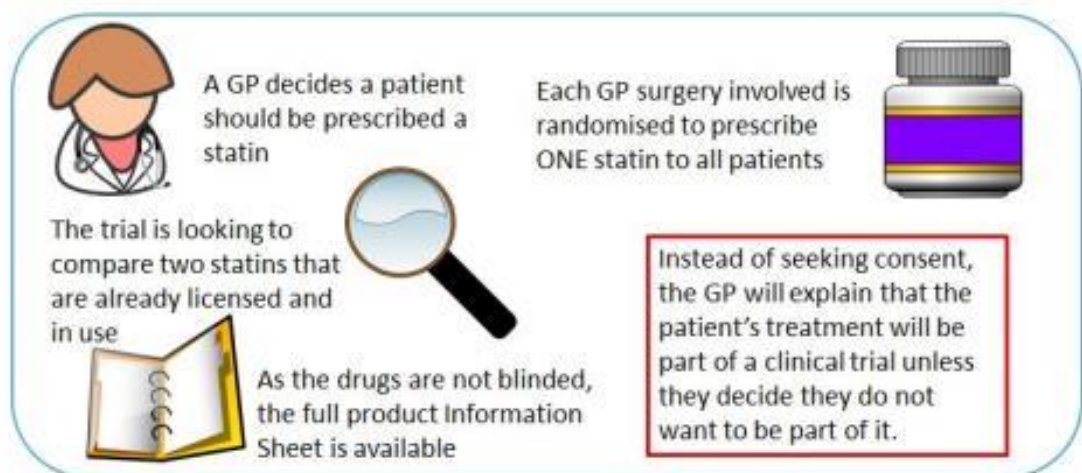


Figure 13: Slide from the presentation given to participants explaining the second simplified consent model.

Views on the deemed consent (opt-out) model were more divided. Some participants saw advantages to it, while others thought that it would exacerbate the general concerns that they had around simplified consent.

One advantage identified was that this model would minimise the additional time taken out of a GP appointment. A few participants did not think that the types of trials proposed for use with simplified consent were something that people should be concerned about. They therefore argued that the less time is wasted on bureaucracy, the better.

Another advantage was that it reduces the number of decisions that a patient needs to make. Some participants thought that it would be less stressful for participants to be told what to do, than to be worried unnecessarily by relatively inconsequential decisions.

This deemed consent approach registered more concerns with the participants than the opt-in model. One issue raised was that it might make people feel coerced or pressured into taking part, without really understanding what it is that they are agreeing to. On a related note, some participants thought that this approach could harm the trust relationship between patients and GPs, because they might feel that the GP is not acting in their interests, but in the interests of research. Moreover, it changed the nature of the GP-patient relationship to remove the autonomy of the patient. In that way, the deemed consent model was viewed as a more substantial and less desirable change than the opt-in model.

## Reassurances:

Regardless of which model was being discussed, a number of reassurances were suggested by participants to ensure simplified consent was implemented in an acceptable format.

1. The key reassurance sought by participants was that the treatment prescribed would continue to be for the good of the patient not research.
2. It was recognised that GPs would not have time to talk through the issues in depth. However, participants felt a patient should be able to talk to someone further if they wanted to know more about the research or their part in it.
3. Appointments should not be disrupted because of the time pressures attached to the use of simplified consent.
4. Outcome data should always be anonymised.
5. The data should never be released to insurance companies.
6. Simplified consent should not be used for conditions where the GP has to make a subjective opinion about the outcomes for the patient, e.g. depression.

7. Additionally, most participants felt simplified consent should be an opt-in/sign to consent process.

## What should be included in the information sheet?

Participants were asked what information should be included in the simplified patient information sheet. They were provided with information about what is currently in a patient information sheet, and a proposal of what might be on a simplified version, to provide a starting point for discussions. A conventional patient information sheet for a blinded trial would contain information about the different drugs that you might receive as part of that trial. It was explained to participants that in the case of simplified consent, patients would know what drug they were receiving, and would receive the same pack insert with that drug that patients would receive as part of normal treatment. The pack insert normally covers the following information:

- The drug name
- What medical conditions is the drug used for
- Information necessary before taking the medicine
- Dosage to be taken and how to take it
- Possible side effects
- Interactions with other medication, food and drink
- Contra-indications - that conditions where the drug should not be taken, for example, pregnancy.

Participants were asked to comment on whether it would be acceptable to omit these details from the patient information sheet describing the research, given that they were going to receive some of them anyway as a pack insert with the drug.

A matrix was given to each participant to select which details should be included in the simplified information sheet and tables collectively discussed their thoughts going through the matrix together.

There was widespread agreement with the use of the proposed simplified information sheet.

*“As someone who has signed these forms, it is intimidating. I think the simplified forms proposed would be less intimidating. I think I would have preferred to have them.”*

EXPERT PATIENT LIVERPOOL

It should be noted that often groups' opinions of what should be included were influenced by decisions that they had made as a group. For example, a number of groups thought that a simplified patient information sheet should be backed up with more detailed information, either online or available on request as a hard copy. Some of these groups argued for a much leaner simplified patient information sheet, on the

grounds that patients would be able to look up more detailed information if they wanted it.

*"It would be a good back up to have all the information available, but it doesn't have to all be on the sheet."* CARDIFF WORKSHOP PARTICIPANT

Some individuals and groups argued that the suggested simplified patient information sheet is still too complicated. They proposed that the sheet be much more simplified with only absolutely essential information on it.

*"It's not a big deal so why make a fuss out of it."* LONDON WORKSHOP PARTICIPANT

One group felt it was essential for the patient information sheet to make a distinction between what was information about the trial and what was about the medication.

The following tables provide a more detailed breakdown of participants' views on what the simplified patient information sheet should, and should not contain:

Information that participants typically felt should be <b>included</b> in a simplified information sheet	
Information	Comments
Invitation and brief summary	There was widespread agreement that this should be included.
Purpose of and background to the research	There was widespread agreement that this should be included, however a few participants suggested this could be given verbally by the GP to save space on the sheet.
Why am I being asked to take part in this research?	There was widespread agreement that this should be included. As above, a few participants suggested that this could be covered orally. On one table, the specialist argued that it would be good to have it written down just in case the GP forgets. Many group members were convinced by this argument.
What would taking part involve including name of drugs to be taken and for what conditions	There was widespread agreement that this should be included. A few participants suggested this could be given verbally by the GP to save space on the sheet.
What are the possible disadvantages and risks of taking part?	There was widespread agreement that this should be included. A few participants suggested this could be given verbally by the GP to save space on the sheet.
Do I have to take part? Can I withdraw?	There was widespread agreement that this should be included.
What if new information is found that might affect whether I would want to continue in the trial?	There was widespread agreement that this should be included. Participants at one table thought that this point duplicates circumstances in which a participant might be withdrawn from the trial. Participants at another table thought that this could just be raised with the patient at the stage that any new information is found.

What will happen if I don't want to carry on with the study?	There was widespread agreement that this should be included. Participants at one table thought that this is the same as being able to withdraw at any time, so it is not necessary to have both.
How will my information be kept confidential?	There was widespread agreement that this should be included.
What will happen to the results of this study?	There was widespread agreement that this should be included.
Who is organising and funding this study?	There was widespread agreement that this should be included. A few participants thought that this would not be of interest to most patients, and so it would be sufficient to have this information available elsewhere for those who are interested.
Contact details/website for further information	There was widespread agreement that this should be included.
What are the alternatives?	There was a good deal of agreement that this should be included, but not all tables agreed.
What happens when the research study stops?	There was widespread agreement that this should be included.

Information that participants typically felt could be **omitted** from the simplified information sheet

Information	Comments
Probability that you would receive either drug (e.g. 50 % chance of receiving either drug etc.)	While most participants thought that this would be unnecessary, a notable minority thought that it should be included, so that the patient has a good understanding of what they might be prescribed. One group said that this information would be important if individual level randomisation is being used, but they had fewer concerns about it being used for cluster randomised trials.
Insurance arrangements	<p>Most participants thought that this would not need to be included, so long as you were getting safe standard treatment, however a minority had strong opinions to the contrary. Some of these wanted to know what would happen if their condition deteriorates on the treatment. One group was told by a specialist that there would be no insurance arrangements in simplified consent, however a couple of group members still thought that this should be made clear.</p> <p>A specific issue that was raised at one table was whether being on a simplified consent trial might affect patients own insurance arrangements, e.g. their travel insurance. They sought reassurance on this point.</p>
Who has reviewed this study? (e.g. a research ethics committee)	Most participants were happy for this not to be included. Some thought that it would be important to reassure people that it had been reviewed, but that it was not important to go into detail about this process or who had reviewed it. One expert patient thought this was necessary to include.
How have patients and the public been involved in this study? (e.g. in its design, not just by taking part)	There was widespread agreement that this can be omitted, with only a couple of individual expert patient dissenters.

Comments on whether information which will be included in a pack insert with the treatment that participants receive should also be included in the simplified information sheet

Information	Comments
Name of the drug	Participants typically felt that this should be included
What medical conditions is the drug used for?	Participants typically felt that this should be included
Information necessary before taking the medicine	Participants typically felt that this could be left out to avoid duplication. However, some argued that because people rarely read the pack information, the key points should be confirmed

	either orally or on the PIS.
Dosage to be taken and how to take it	Participants typically felt that this could be left out to avoid duplication
Possible side effects	Participants typically felt that this could be left out to avoid duplication

Most participants agreed with the suggestion that the name of the drug and the conditions it is being used for should be included, but the remaining information would not need duplicating. However, a minority of participants argued that people rarely read the information that is provided with a new treatment. Participants in one group therefore argued that the doctor should provide at least a verbal explanation of the key points. A few participants thought that it might be helpful to have this verbal summary written down as well.

Information about which there was <b>a good deal of disagreement</b> as to whether it should be included in the simplified information sheet	
Information	Comments
How many participants will be involved in the study?	There were mixed opinions on this point. A number of participants thought that this information would not be of interest. Some thought it would be of interest, but that it was not really essential to include it. Some thought that it would be good to include, because participants would be reassured by seeing that large numbers of other patients will be taking part.
How long will it take?	There were mixed opinions on this point. Some participants thought that it was absolutely essential to know how long your data will be used for, while others saw it as unnecessary information that could easily be made available elsewhere e.g. online.  Those arguing that this should be included sometimes referred to the possibility of taking additional tests as a result of the trial, and wanting to know how long these might continue. Another argument was that it would not take up much space to include, and could be helpful for some people. There appeared to be some confusion among a few participants about whether at the end of the trial your treatment might be changed. Participants thinking it might be changed were particularly vocal this information on the length of the trial should be included.
Circumstances in which the participant would be withdrawn from the trial	There were mixed views on this point.  Some thought that this was unnecessary if you already know that you can opt-out, and you are receiving 'normal treatment' with safe drugs.  Others thought that it would be important to briefly reassure people that they would be withdrawn if their health is being impacted.



### ***Summary of what should be included on the simplified information sheet***

The following table summarises what should and should not be included in the patient information sheet. Three areas revealed a lot of debate about whether or not they should be included on the simplified information sheet. Of these three areas, we would tentatively suggest that an indication of how long the trial is likely to last and the circumstances under which a patient would be withdrawn from the trial should be included on the PIS. However, the number of people taking part in the study is less important to be included, due to fewer participants mentioning it and the strength of their concerns.

<b>Information</b>	<b>Should be included</b>	<b>Should not be included</b>	<b>No clear consensus</b>
Invitation and brief summary	✓		
Purpose of and background to the research	✓		
Why am I being asked to take part in this research?	✓		
What would taking part involve including name of drugs to be taken and for what conditions	✓		
What are the possible disadvantages and risks of taking part?	✓		
Do I have to take part? Can I withdraw?	✓		
What if new information is found that might affect whether I would want to continue in the trial?	✓		
What will happen if I don't want to carry on with the study?	✓		
How will my information be kept confidential?	✓		
What will happen to the results of this study?	✓		
Who is organising and funding this study?	✓		
Contact details/website for further information	✓		
What are the alternatives?	✓		
What happens when the research study stops?	✓		

Information	Should be included	Should not be included	No clear consensus
How many participants will be involved in the study?			✓
Probability that you would receive either drug (e.g. 50 % chance of receiving either drug etc.)		✓	
How long will it take?			✓
Insurance arrangements		✓	
Circumstances in which the participant would be withdrawn from the trial			✓
Who has reviewed this study? (e.g. a research ethics committee)		✓	
How have patients and the public been involved in this study? (e.g. in its design, not just by taking part)		✓	
<b>Details of the drug(s) to be used in the research:</b>			
Name of the drug	✓		
What medical conditions is the drug used for?	✓		
Information necessary before taking the medicine (including precautions, warnings, interactions with other medicines or foods, information for special groups of patients (pregnant or nursing mothers), and any effects the medicine may have on the patient's ability to drive)		✓	
Dosage to be taken and how to take it		✓	
Possible side effects		✓	

## Zero Consent

New EU Clinical Trials Regulations are due to come into force at the end of 2016/ early 2017. Once in force, the Clinical Trials Regulation will allow informed consent to be

obtained by **‘simplified means’** in a very specific type of research known as a **‘randomised cluster trial’**.

**Randomised cluster trials** are a type of research design that randomises the drugs or treatments being investigated to different groups or clusters of individuals (such as households, primary care practices, hospital wards, classrooms, neighbourhoods or communities), rather than individuals.

Under this Regulation researchers will be able to obtain informed consent by **“simplified means”**, without the traditional face-to-face discussion, provided that the following conditions are met:

- Trial is conducted in one member state
- No contradiction with national law
- Low intervention trial using licensed drugs
- Trial methodology requires groups of subjects (e.g. randomisation by GP practice or hospital) to be allocated to treatment rather than individuals
- No interventions other than standard treatment
- Protocol includes justification for gaining “informed consent by simplified means”.

**Under this Regulation informed consent may be “deemed” to have been obtained if the potential subject, after being informed, does not object to participating in the clinical trial. This means that a patient could be included in the research unless they explicitly opt-out of taking part.**

This represents a significant departure from the current UK Clinical trials Regulations/EU Clinical Trials Directive, which require the potential subject to have been **duly informed of the nature, significance, implications and risks** of the trial in a **prior interview with the investigator** or a member of the investigating team. Participants in the workshops were asked to consider the acceptability of a ‘no consent’ scenario.

<p><b>Questions asked:</b></p> <ul style="list-style-type: none"> <li>• How do people feel about no consent at all in very low risk studies?</li> <li>• Where should zero consent be applied/limited?</li> <li>• What reassurances would you need?</li> </ul>	<p><b>Materials provided:</b></p> <ul style="list-style-type: none"> <li>• Presentation delivered by HRA</li> <li>• Table handout explaining zero consent (case study 3)</li> </ul>
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Participants were presented with a scenario where patients would not be asked to consent to taking part in a clinical trial, instead being automatically being involved. As with simplified consent, this would only happen in pragmatic trials where commonly used standard treatments are being compared to find out which works best and could only take place in a cluster designed trial.

In a cluster trial, patients are not assigned to groups on a patient by patient basis, but in larger groups. These groups will typically be all the patients at one GP practice, or all the patients at one hospital or hospital ward. One reason to group patients like this is that it reduces the amount of administration and doctors' time involved in conducting a trial, as you do not have to randomly assign every new patient to a treatment.

The scenario presented to participants in the workshops was based on a study looking at pressure relieving foam mattresses. It was explained that different foam mattresses are already in routine use, however there is insufficient evidence regarding which works best and they can be expensive. To find out whether one mattress has better results than another, routine clinical data on the number of pressure sores experienced by patients would be collected from the hospitals involved and patients would not be subjected to any greater risk than standard care or any additional interventions.

In this hypothetical example no consent would be sought from patients as the mattresses involved are already used in standard care and patients have to sleep on a mattress; there is not normally a conversation or a choice for patients about what type of bed they would like to sleep on. Posters would be displayed in waiting areas and on wards to inform patients that a trial is taking place and it would be possible to inform the hospital if a patient did want their data to be used. Data would be collected in line with standard procedures and would be anonymised.

Additional examples of zero consent were brought into discussions by table facilitators for example the use of different types of catheters. Clinicians can use different sorts of catheters: some impregnated with antibiotics, some lined with silver to deter bacteria and others have no coating, all are commonly used. Some researchers would like to be able to test these in a trial without consent. Different hospitals could be randomly allocated to test different catheters and all the patients getting a catheter fitted at one hospital would all get the same sort of catheter.


Participants were asked how they felt about no consent at all in very low risk studies and whether it was ever considered to be acceptable together with any reassurances they would need. Groups also discussed where simplified and zero consent models should be applied or limited.

Figure 14: A presentation slide describing the mattress example of zero consent


**NHS**  
Health Research Authority

## Case study 3 – Clinical Trial of pressure relieving mattresses in hospital


The trial mattress is already in routine use



There is insufficient evidence regarding which works best and they are very expensive



Only routine clinical data will be used in the trial and patients will not be subjected to any greater risk than in standard care



There will be no additional interventions other than standard care

Most participants agreed that a zero consent approach to recruitment would be acceptable in some situations, including the mattress example used in the presentation.

*“If it won’t change my treatment I don’t mind.”* CARDIFF WORKSHOP PARTICIPANT

Many participants commented that using a zero consent trial to test different mattresses seemed like a sensible approach. Indeed, several participants actively endorsed testing more equipment with zero consent trials, in order to advance research. A few people felt that with studies like this, it is better not to ask for consent as the consent process would provide unnecessary paperwork for patients, and may concern them unduly.

One group in Nottingham raised a different set of concerns about zero consent. Because patients were not made aware that a clinical trial was underway, they had no opportunity to feedback information which could be salient to understanding the best equipment. For example, a mattress might reduce pressure sores, but it could also increase backache.

### ***Use of personal data***

Some members of the public were initially sceptical about how much information would be needed in the mattresses case, arguing that data could just be collected about the number of pressure sores without needing to know anything about the patients. The table specialist explained that they would need to include some personal data, such as

age, sex, condition and perhaps weight. The group was mostly accepting of this level of data use so long as the data was sent anonymously.

*"I doubt that would be your full medical history though - I would be fine with that."*

NOTTINGHAM WORKSHOP PARTICIPANT

*"I don't see a difference between a doctor seeing my medical records and a researcher seeing them."* CARDIFF WORKSHOP PARTICIPANT

In one group in Liverpool, the expert patient suggested that the use of patient data might be a more important consideration than the use of an intervention.

One expert patient in Nottingham highlighted her concern about the need for personal data to be linked by someone if it was to be used. She suggested that it was an oversimplification to say that the data would be collected anonymously. She argued that there needed to be more awareness of how data would be used within zero consent.

A few participants did have concerns about the use of personal data in relation to the mattress example. While they were not generally worried about being involved in the experimental intervention without consent, there was concern that personal data should not be used without the patient's knowledge. It was felt that just displaying a poster would be insufficient to inform people, and that greater efforts should be taken to find out whether it is ok to use somebody's personal information.

*"It would be better to have a chat and the information there to read; a poster is not enough."* LIVERPOOL WORKSHOP PARTICIPANT

*"It takes dignity and respect away from how you treat patients."* LIVERPOOL WORKSHOP PARTICIPANT

In contrast, a couple of groups discussed the possibility that displaying posters could worry people unnecessarily, and make people concerned that there may be problems with their mattresses.

*"I don't think you should tell people because you would not want to know that you might get bed sores. And people will start to complain more about their mattresses and imagine things."* LIVERPOOL WORKSHOP PARTICIPANT

### **Zero consent in other situations**

Opinions were divided regarding the use of zero consent in other situations. Some participants thought that so long as studies were equally low risk, then they would be just as acceptable as the mattress example.

For a large number of participants, however, there were salient differences between the mattress example and other examples presented to them, including the example of testing different catheters, and testing different recovery positions after a stroke. Many participants felt that in one or both of these examples, a zero consent approach would

be inappropriate. Some felt that these are much more serious than a mattress example, with greater potential for harm if anything goes wrong. Others contrasted their essentially clinical nature with the more everyday nature of a mattress, and felt that this was why they required more rigorous consent.

Participants discussed what features of a study might make it appropriate or inappropriate for zero consent. Where these were discussed, participants typically agreed that the guidelines presented to them were essential (low risk, lack of evidence that one treatment is better, it is not practical to gather consent, non-invasive). Many groups proposed additional criteria to supplement these. For example, it was felt on a number of tables that treatments that enter the body in some way (including catheters and any medication) were too invasive to be appropriate for zero consent.

*“For anything where you are not being put on medication, then I am not worried. I know there might be some data privacy concerns, but it would be really hard to do, and I don’t know why someone would want to track you down.”* CARDIFF WORKSHOP PARTICIPANT

*“It depends whether it is going in your body or not”.* LIVERPOOL WORKSHOP PARTICIPANT

Finally, some groups emphasised the importance of allowing patients to make their own decisions where possible: zero consent should only be used in situations where it is genuinely impractical to seek consent. Common criteria suggested were:

- Anonymised information
- Low-risk areas
- Non-intrusive
- Genuine lack of knowledge about best treatment
- The patient is unlikely to be aware that there is a different option to the equipment

### **Scope creep**

One concern that was commonly raised around zero consent was about the possibility for scope creep.

*“It’s the thin end of the wedge.”* NOTTINGHAM WORKSHOP PARTICIPANT

*“It could open the floodgates to other processes not requiring consent.”* NOTTINGHAM WORKSHOP PARTICIPANT

One expert patient in Liverpool (a different person to the patient raising concerns about data collection above) felt the mattress example was a one off, which had clear and simple outcomes, with data which could be collected anonymously. He suggested it was unlikely there would be many other examples which were this straightforward. The group at his table agreed the catheter example given was a ‘step change’ away from



the mattress scenario, which validated their concerns about mission creep if zero consent was agreed as a concept.

Many participants felt that very clear guidelines would need to be put in place to ensure that zero consent did not start to become used for inappropriate studies, or more types of study than initially intended. Some groups were concerned that the 'grey areas' between acceptable and unacceptable treatments would be almost impossible to define, making it difficult to effectively regulate.

### ***Reflections on the possibility of a broader scope for zero consent***

It is interesting to note that the discussions of zero consent led some participants to reflect further on the previous discussion around simplified consent. On a few occasions, during discussions about the possible scope of what could be included in zero consent, some participants argued that previously discussed examples might be appropriate for a zero consent approach. For example, participants in more than one group said that they would be comfortable with the idea that a statins trial be conducted on a zero consent basis, so long as all the possible treatments that they might get were already considered to be medically appropriate. Some groups in London and Wales were very supportive of the zero consent approach and its potential for improving NHS outcomes.

*"As long as the GP can withdraw if they want to, then I'd be happy for zero consent for statins too."* LONDON WORKSHOP PARTICIPANT

### ***Summary***

Overall, participants expressed a good deal of support for simplified consent processes. The opt-in model was generally favoured over the deemed consent model because it preserved the integrity of the doctor-patient relationship, leaving autonomy with the patient. Principles for the use of simplified consent included:

- Patient care should not be compromised for the sake of research, this includes not hurrying the discussion about the condition to capture consent within the appointment time.
- Patients should be given the option to discuss whether they wish to take part in more detail if they wish.
- The treatment prescribed would continue to be for the good of the patient not research.
- Patients should be told they are allowed to opt-out if they change their mind following the appointment.
- Data should be anonymised.

The use of a simplified information sheet in simplified consent was generally viewed as being acceptable. However, there were practical concerns raised about whether a patient would have time to read and understand the sheet during an appointment.

Participants broadly supported HRA's suggestions of what should and should not be on a simplified information sheet, with information provided on pack inserts not being viewed as essential to repeat.

There was a good deal of support for the use of zero consent in some situations, although the extent of this support varied between participants. Whilst a few participants thought that so long as risks were low, the zero consent model could be used widely, more people thought the circumstances in which it should be used must be limited. As well as having a genuine, practical reason for not asking for consent, those circumstances were identified as:

- Using anonymised information
- Low-risk areas and should not apply to drugs
- Non-intrusive equipment use
- Genuine lack of knowledge about best treatment
- The patient is unlikely to be aware that there is a different option to the equipment

There were concerns expressed around the potential for scope creep if zero consent was implemented. Therefore, there should be reassurances that zero consent will only be used when absolutely necessary.

## Conclusions and recommendations

The dialogue revealed there is strong support for health research as a key part of ensuring there are continuous health improvements. Increasing access to health research participants was supported as a common good.

The NHS is trusted to maintain patient confidentiality. However, there was a lot of concern voiced across the dialogue about too much or third party access to patient records undermining this trust in patient confidentiality.

### **Access to patient records by research nurses**

At the very start of the dialogue, participants did not expect research nurses to have access to patient records. However from what we heard in the dialogue widespread support emerged for research nurses and doctors being able to access patient records to identify participants for health research in hospitals providing certain conditions are met

Where GP practices are research active and have a research nurse accessing patients' notes, the participants felt that all practice patients, whether new or existing, needed to be fully informed about who will be accessing records.

Moreover, from the discussions it is clear that most participants believed that having the ability to opt-out of research nurses accessing their records was essential to maintain trust in GPs and patient privacy.

### **Consent to approach lists**

There were mixed views on the use of consent to be approached lists.

Model 1. There were mixed views about whether it would be appropriate to approach someone in the waiting room. Workshop participants were broadly supportive of approaches being made to patients in NHS waiting rooms to ask if they might be willing to join a register so they could be approached about health research studies in the future, provided that:

- All approaches are made by NHS employees appropriately badged and identifiable as such
- Approaches are not made in waiting rooms where people are likely to be in acute pain or where the patients are likely to have a sensitive condition, for example, sexual health clinics.
- No undue pressure is placed on an individual
- No confidential information is sought in a public place
- It is made clear that data will not be provided to a third party

- The person making the random approaches is not party to confidential personal information about the individual prior to the approach being made.

Model 2. Again there were mixed views about an opt out approach by letter. On the positive side, it was seen as more private and less pressured. However, the main concern raised was that it was likely some people would not realise they were on a list. The opt-out model was viewed as more acceptable in Wales because of their organ donor scheme which also works on a opt out basis.

The three week time period for opting out used in the scenario was felt to be too short, and could catch people on holiday. 6-8 weeks was viewed as being more acceptable.

There were differences in opinion about whether this would be an appropriate model for recruiting people with mental health problems. In general, it was concluded that the type and severity of the illness was a more important consideration than mental health issues per se.

Reassurances included:

- Eye catching letter or leaflet to ensure it was read
- The covering letter or leaflet demonstrated authenticity and trust without revealing the patient condition
- Easy to opt-out at any time
- Data use was explained and safeguarded.

### **Simplified consent in large pragmatic trials in primary care**

The dialogue revealed good support for the process of simplified consent where the research process did not have an impact on the type or quality of the care provided.

There were some concerns about whether patients might feel pressurised into taking part, with suggestions about how more thinking time could be built-in. Moreover, participants remained unsure as to whether the simplified patient information sheet could be read and understood within the space of the appointment. An ability to opt out later was raised as a key reassurance.

The opt-in model was preferred to the deemed consent model, since this kept the patient-doctor relationship intact with patients maintaining agency.

Participants generally supported the HRA proposals for what should be included and excluded on a patient information sheet. Areas where there was no clear agreement among participants were:

- How many participants will be involved in the study?
- How long will it take?

- Circumstances in which the participant would be withdrawn from the trial.

Zero consent in cluster trials was supported by the majority of the participants in the case of the mattress scenario. There were differences of opinion about using zero consent in other cases, with a few participants believing it could be used more often if there was no difference between treatments whilst others were concerned about the need to ensure there was no scope creep.

Reassurances around using zero consent included:

- Using anonymised outcome data
- Low-risk areas
- Non-intrusive or non-invasive
- Genuine lack of knowledge about best treatment (genuine equipoise)
- The patient is unlikely to be aware that there is a different option to the equipment

### **Common themes**

A few common themes were heard across the workshops, which could indicate a broader set of principles around the identifying and recruiting participants for health research.

The first was about ensuring patients are fully aware of changes made for recruiting to health research, particularly in how their data is accessed and used. This was based on a principle of preserving the integrity and trust around the doctor-patient relationship as well as concerns about misuse of their data. Posters alone in general practice were not viewed as sufficient methods of informing people about changes, since not everyone is likely to see or read the poster.

Related to this was a sense that, prior to attending the workshops, participants felt they did not know enough about the use of patients in research to make informed choices without easily accessible and comprehensive information. Thus the theme of raising public awareness of health research arose across the discussions. This was viewed as being a step change in the way the NHS works with its patients.

The theme of 'scope creep' was mentioned frequently. Participants regularly mentioned how these small changes might prove to be the thin end of the wedge or the opening of Pandora's box. There was concern that patient data will be accessed by ever more people.

Added to this, the relationship between the NHS and private companies was frequently raised by participants. The data being discussed was seen as being of value to a range of third parties who could utilise it for a profit motive which was not in the patients' interests. Insurance companies were specifically mentioned in this context, with participants keen to ensure this sort of data would not be released by researchers.

Additionally, there was a lot of discussion about the privatisation of the NHS and whether allowing further access to records would mean private sectors ended up with access to data by default. Participants were very clear that they trusted the NHS with their data and to be interested in improving health outcomes overall. This trust did not necessarily extend into privately run parts of the NHS.

# Digital Engagement

## Introduction

The overall purpose of the Health Research Authority/Sciencewise engagement was to:

“inform the HRA’s future policy framework, by exploring issues raised in recruiting suitable participants for health research, including the use of patient data to identify participants and the concept of simplified consent in order to inform the HRA’s new research policy framework and operational guidance for health research.” HRA Invitation to Tender (ITT).

Within that, purpose of the digital activity was “to open up the dialogue by providing a separate digital engagement.” HRA ITT

The strands of the digital engagement and their purpose were:

Website	Social Media: Twitter	Digital Listening
<ul style="list-style-type: none"> <li>• Providing background to the issue</li> <li>• Uploading reports and stimulus materials throughout the process to provide confidence in the openness of the dialogue</li> <li>• Having a twitter feed linked to the most appropriate hashtag</li> <li>• Hosting live Q&amp;A sessions (not delivered)</li> <li>• Providing discussion boards</li> <li>• Extending access to the public dialogue through survey of key questions asked in the workshops.</li> </ul>	<ul style="list-style-type: none"> <li>• To reach out to interested individuals and organisations to retweet our tweets and help drive traffic to the website survey and discussion boards. e.g. OG members such as Ben Goldacre with 370K followers</li> </ul>	<ul style="list-style-type: none"> <li>• Listening to the public online, including listening to relevant pressure groups and the use of social media to listen to existing discussion of relevant topics.</li> </ul>

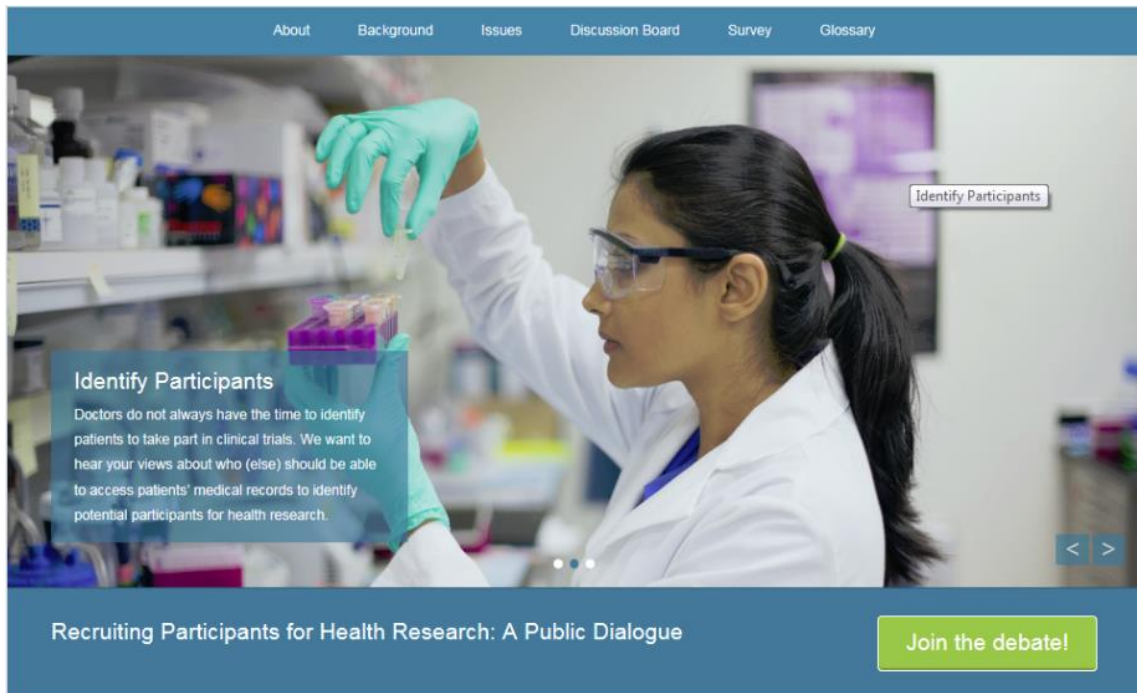
For each strand we look at the activity undertaken and the response from the public and organisations. Additionally for the website we use Google Analytics to explore web usage.

## Analysis of Website usage

This section provides an overview of the ways in which the ‘recruiting participants for health research dialogue’ website ([www.rphr.org.uk](http://www.rphr.org.uk)) was used by the public. The analysis covers the period from 3rd November 2014 when the website had its first



views, to 7<sup>th</sup> January 2015 when the survey was closed and the discussion board ceased to be actively monitored. The analysis was conducted using Google Analytics.



Detail from the website

## Overview of usage

Between 3<sup>rd</sup> November 2014 and 7<sup>th</sup> January 2015, the website was viewed 1,073 times. Of these views, 258 came from within OPM due to members of staff within the organisation working on, and checking the website, leaving a total of **805 external views**. This figure can be contrasted with the observation that there were **579 unique users**, showing that while most users visited the site only once, a notable proportion of views were from returning users.

The **average number of pages viewed per visit was four**. This provides some corroboration for the survey data, in which the most common response to a question about how much of the website had been read was "I read parts of it". This suggests that many users did spend some time looking through the website, which indicates that a good deal of information may have been disseminated.

Of the total views, **141 were on mobile devices**. This confirms that our work ensuring that the site was mobile compatible was a useful exercise, and should be repeated for future websites.

## Where users came from

**The largest body of users (628) went directly to the site**, suggesting that they were informed about it before going online. A number of users from the online survey said that they had found the website via a recommendation from a friend or colleague, which provides one possible explanation of why this figure is quite high. Another possibility is that participants from the public workshops visited the site, as they were all provided with the web address following the first of their two workshops. Finally, it is likely that a high proportion of the 258 views from OPM came by this method. This leaves at least 370 external hits that went directly to the site.

**257 users arrived at the site by referral from another site.** Of these, the largest proportion (97) were directed from [www.hra.nhs.uk](http://www.hra.nhs.uk), suggesting that cross linking between the sites was a valuable exercise. It also indicates that many of the individuals accessing [www.rphr.org.uk](http://www.rphr.org.uk) already had some interest in relevant topics, as indicated by their prior interest in the HRA website. It is notable that 15 users were referred via a link on a forum<sup>4</sup> on [www.pifonline.org.uk](http://www.pifonline.org.uk), an organisation we had contacted as part of our Twitter strategy.

**145 users arrived at the site via links from social media**, of which 142 came by Twitter, and three came via Google+. Along with the observation above about pifonline, this indicates that our promotion of the website via Twitter had some success, and should be built on as an effective strategy in future. Finally, **43 users found the site via a web search.**

## Analysis of social media activity: Twitter

In this first section we look at the Twitter activity that took place and the impact it had on the dialogue website from our dedicated twitter feed @rphrdialogue. We tweeted and re-tweeted 68 times between October and January 2015. The tweet topics fell into these categories:

- Directing traffic to the [rphr.org.uk](http://rphr.org.uk) website
- Calls for participants to the research
- Publicising of individual workshops
- Requests to different organisations to retweet about the dialogue and the different workshops
- 17 tweets or retweets contained images or videos

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<sup>4</sup> <http://www.pifonline.org.uk/involving-patients-in-health-research-have-your-say/>

During the course of the dialogue, @rphrdialogue attracted **52 followers**, 42 excluding HRA and OPM group (35 individuals and 17 organisations) and **followed 28** individuals and organisations. Our web usage analytics showed that Twitter was a relatively significant driver of traffic generating 142 of the 579 (24%) unique visitors to [www.rphr.org.uk](http://www.rphr.org.uk).

## The online survey

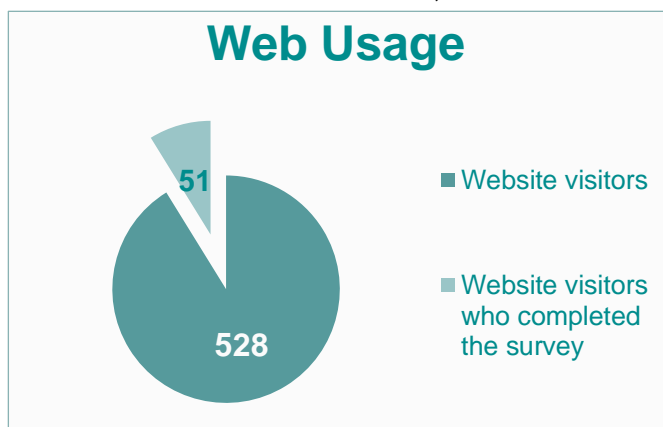
### Context

To supplement the face to face reconvened deliberative events, an online survey was conducted. This allowed people to participate who wished to share their views, but who had not been invited to one of the events. The survey was available on the website [www.rphr.org.uk](http://www.rphr.org.uk) for approximately two months: 5<sup>th</sup> November 2014 to 7<sup>th</sup> January 2015.

To ensure that the survey was fairly quick (less than 10 mins) to complete, it focused on two issues:

- Access to Patient Data
- Developing lists of people who are willing to be approached about potential studies

Of the total of 579 website visitors, 51 answered the survey.



Because this was a self-selecting sample, it is not possible to assume that their views are fully representative of the population as a whole. More detailed demographic information is provided towards the end of this document. The key findings of this are that respondents typically engaged

with the website before answering the survey, and also that a high proportion of respondents are from a professional background associated with health services.

Respondents were not forced to answer all questions on the survey. For this reason the number of respondents answering each question varies to some extent. This variation is indicated in the analysis below. The full questionnaire and results are in appendix C and D respectively.

The key finding from the survey was that, when considering who should have access to patient records to identify trial participants, confidentiality clauses for the researcher

and the ability of the patient to opt-out were of high importance to most survey respondents.

## Digital Listening

In this section we look at the extent of online discussions relevant to the topic of recruiting people to health research.

### The Online Discussion Board

An online discussion board was created on the [www.rphr.org.uk](http://www.rphr.org.uk) website to allow members of the general public to share their views and discuss the issues found on the website. This was designed to supplement the face-to-face research activities, providing the opportunity for participation more widely.

Three discussion topics were posted by OPM staff: 'Join the debate'; Simplified Consent and 'Consent to Approach' lists. The discussion board only drew in two responses. One response focused on making clinical trials accessible for patients, suggesting a centralised list where patients could sign up to give their consent to be approached about opportunities. The respondent gave two examples of interesting models for recruitment: Susan Love's Army of Women <http://www.armyofwomen.org/> , aimed at breast cancer research, and <https://www.joinementiainresearch.nihr.ac.uk/>

*"There needs to be somewhere central – it could be the UK clinical trials gateway – well advertised and marketed (not just online) where people could register their general interest in participating in research, but also (crucially) specify their condition or conditions of interest at the time of registration – whether they have the condition, or have had the condition in the past, or have a loved one with a condition. And they don't have to worry about checking to see whether there's anything suitable for them to join – the opportunities can then be directed to them when they come up."* DISCUSSION BOARD RESPONDENT

Another suggested that consent could be given by text message, when responding to a topic on simplified consent.

### Wider Online Discussions

The OPM Group conducted a digital listening exercise to investigate whether discussions about the issues covered in the dialogue were taking place online besides the [www.rphr.org.uk](http://www.rphr.org.uk) website. This was limited to discussions that had taken place within the last year (January 2014 – January 2015) on UK based websites, or with participants responding from the UK. Searches were carried out on Google.co.uk, popular social media sites such as Twitter and Reddit UK, and forums including

Mumsnet and patient.co.uk. Online news sites were also searched for relevant content and comments.

As all comments reviewed during the digital listening process have been made by a self-selecting sample of individuals, findings cannot necessarily be seen as representative of the general population but should instead be interpreted as providing insight into what is being discussed by an online community.

Although a number of websites contained information or press releases about the identifying and recruiting participants for health research dialogue itself, these did not contain discussions or comments, but rather pointed readers towards the [www.rphr.org.uk](http://www.rphr.org.uk) website or dialogue.<sup>5</sup>

## Access to patient records

We found very little discussion of the specific issues surrounding identifying and recruiting participants for health research. For example, Google searches of terms including 'research nurses accessing patient data', 'researchers access to medical records', and 'recruiting participants for health research', produced very few relevant results and no online discussions. Similar searches on Twitter, Reddit, and Mumsnet also gave no discussions specifically related to whether researchers or research nurses should have access to records in order to identify participants for clinical trials. This suggests the public are largely unaware of the processes related to identifying and recruiting participants for health research, and how this relates to patient records.

However, across sites there are wide ranging discussions related to access to patient records, including the use of records for research purposes. These discussions tend to be linked to media stories in the last year including those looking at care.data,<sup>6</sup> patient records being accessed by CQC inspectors,<sup>7</sup> and plans for all NHS patients to have access to their own GP records.<sup>8</sup> Participants in these discussions often had concerns

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<sup>5</sup> For example, the IDEAL Collaboration (3/12/2014) 'Recruiting participants in health research: UK HRA public dialogue' <http://www.ideal-collaboration.net/2014/12/recruiting-participants-health-research-uk-hra-public-dialogue/> and Patient Information Forum (5/12/2014) 'Involving patients in health research – have your say!' <http://www.pifonline.org.uk/involving-patients-in-health-research-have-your-say/>

<sup>6</sup> For example, Mohammad Al-Ubaydli (28/2/2014) 'Patients need to have control over their own information if care.data is to work' *The Guardian* <http://www.theguardian.com/healthcare-network/2014/feb/28/patients-need-control-information-care-data>

<sup>7</sup> For example, Sophie Borland (8/10/2014) 'How care watchdog is snooping on your 'private' medical data: After NHS approves controversial database, inspectors access patients' files without their consent.' *The Daily Mail* <http://www.dailymail.co.uk/news/article-2785722/How-care-watchdog-snooping-private-medical-data-After-NHS-approves-controversial-database-inspectors-access-patients-files-without-consent.html>

<sup>8</sup> For example, *The Telegraph* (13/11/2014) 'How do I access my medical records?' [http://www.telegraph.co.uk/health/healthnews/11226888/How-do-I-access-my-medical-records.html#disqus\\_thread](http://www.telegraph.co.uk/health/healthnews/11226888/How-do-I-access-my-medical-records.html#disqus_thread)

around the security of data and data being shared with the private sector including insurance companies. Many respondents emphasised that patient records can contain personal or sensitive information that they would not want shared, viewing patients as the owners of their individual records:

*“Do people want all and sundry to see GP records which could contain very personal information that in the past few had access to? It may make you think twice before giving information and potentially affect care. Most blood results are fine, but not everyone will want HiV results sharing (sic).”<sup>9</sup>*

*“My medical information should be mine to own and matters of sharing that information should be at my discretion.”<sup>10</sup>*

This suggests that some people could also have had concerns about researchers or research nurses accessing patient records in order to identify whether they are suitable for a relevant trial, however as discussions did not relate explicitly to this, findings can only be speculative.

Nevertheless, a few individuals did express caveated support in favour of using patient records for research purposes, emphasising the need for adequate protection of data:

*“The NHS has one of, if not the biggest unified database of patient data, if this data is properly anonymised with proper checks and safeguards in place, then opened to medical researchers it could have wonderful benefits.”<sup>11</sup>*

*“I suppose like many things, it depends how it's done. I can see the Good Intentions at the medical research end. But I can also see the potential for it to go pear-shaped and harm individuals.”<sup>12</sup>*

This could suggest that there may be some support for increasing access to patient records, for example to researchers, provided certain reassurances are made. However, again this can only be a speculative finding as discussions are not specifically related to the process of identifying and recruiting participants for health research.

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<sup>9</sup> Comment on patient.co.uk forum ‘access to records’ <http://www.patient.co.uk/forums/discuss/access-to-records-274216>

<sup>10</sup> Comment on *The Guardian*’s article ‘Controversial NHS patient data sharing pilot scheme may be delayed until 2015’ <http://www.theguardian.com/society/2014/dec/12/nhs-patient-care-data-sharing-scheme-delayed-2015-concerns>

<sup>11</sup> Comment on Reddit United Kingdom thread ‘NHS to carry on selling patient records to insurers – Study finds details of more than 50,000 people were passed to the academics working in universities without the necessary legal safeguards’ [http://www.reddit.com/r/unitedkingdom/comments/2nkiw0/nhs\\_to\\_carry\\_on\\_selling\\_patient\\_records\\_to/](http://www.reddit.com/r/unitedkingdom/comments/2nkiw0/nhs_to_carry_on_selling_patient_records_to/)

<sup>12</sup> Comment on Mumsnet thread ‘Opting out of NHS health data sale’ [http://www.mumsnet.com/Talk/in\\_the\\_news/a1830491-Opting-out-of-NHS-health-data-sale](http://www.mumsnet.com/Talk/in_the_news/a1830491-Opting-out-of-NHS-health-data-sale)



## Consent to approach lists and simplified consent

Online searches for simplified consent and consent to approach lists also produced few results. The lack of online discussion means findings for these topics are limited and suggests the general public may not be aware of the proposals. However, one thread on Mumsnet responding to a Newsnight report does discuss an example comparing the efficacy of adrenaline vs salt water during a cardiac arrest, where obtaining consent beforehand is clearly not possible.<sup>13</sup> Here participants express mixed views, with some arguing that consent is needed before patient data is used in a clinical trial: “Surely this is unethical? Surely patients have to sign up to be part of a clinical trial, it cannot be done to them in secret?”<sup>14</sup> Others emphasise the impracticality of this in an emergency situation and the need for greater evidence that has the potential to save lives: “I am all up for it. And would Def be a guinea pig if needed (sic). Not that I would be in a position to consent though. If they can find out they have been doing it wrong giving adrenaline then they may be able to save more lives.”<sup>15</sup>

Overall the lack of discussion surrounding the issues covered by the dialogue, such as research nurses accessing patient records and simplified consent processes, suggests that members of the general public are largely unaware of these topics. From listening to online discussions it could be inferred that some individuals may have concerns relating to privacy and the safeguarding of data, while others are supportive of greater sharing of data for research purposes in principle. However, as these discussions are not specifically related to the process of identifying and recruiting participants for research, it cannot necessarily be concluded that individuals would have the same perspective in relation to the dialogue questions.

## Conclusions

Different forms of digital engagement, from digital listening, twitter and website based engagement offer different ways of expanding engagement on a topic beyond the four walls of a deliberative workshop. We are still very much in the learning phase of what works, what doesn't and why. In the points below, we share our learnings from this exercise.

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<sup>13</sup> Mumsnet discussion thread 'Adrenaline or salt water. Changes to the way heart attack patients are treated.' [http://www.mumsnet.com/Talk/am\\_i\\_being\\_unreasonable/a2158528-Adrenaline-or-salt-water-Changes-to-the-way-heart-attack-patients-are-treated](http://www.mumsnet.com/Talk/am_i_being_unreasonable/a2158528-Adrenaline-or-salt-water-Changes-to-the-way-heart-attack-patients-are-treated)

<sup>14</sup> Comment on Mumsnet thread 'Adrenaline or salt water. Changes to the way heart attack patients are treated.' [http://www.mumsnet.com/Talk/am\\_i\\_being\\_unreasonable/a2158528-Adrenaline-or-salt-water-Changes-to-the-way-heart-attack-patients-are-treated](http://www.mumsnet.com/Talk/am_i_being_unreasonable/a2158528-Adrenaline-or-salt-water-Changes-to-the-way-heart-attack-patients-are-treated)

<sup>15</sup> Comment on Mumsnet thread 'Adrenaline or salt water. Changes to the way heart attack patients are treated.' [http://www.mumsnet.com/Talk/am\\_i\\_being\\_unreasonable/a2158528-Adrenaline-or-salt-water-Changes-to-the-way-heart-attack-patients-are-treated](http://www.mumsnet.com/Talk/am_i_being_unreasonable/a2158528-Adrenaline-or-salt-water-Changes-to-the-way-heart-attack-patients-are-treated)



1. The website was initially planned to be live for one month, which we extended for a further month. However, this is a short period of time to drive traffic to a dedicated new website.
2. We had hoped to drive more traffic to the website through the Oversight Group re-tweeting our tweets, particularly through those with large numbers of followers, but this did not happen as early or as frequently as we had hoped. Emphasising this role to OG members in kick off meetings and confirming their willingness to engage through Twitter and other social media will be helpful in the future.
3. We quickly learnt that we had to use the NHS hashtag in all our tweets to legitimise them.
4. Of the 579 web site visitors, 51 completed the survey. It would be useful to understand if this c10% hit rate for the survey compares with other public dialogue sites.
5. We originally anticipated that we would stimulate discussions by holding well publicised Q&As with selected professionals. We did not do this and feel unmoderated and unstimulated discussion boards do not have a good enough reach to be conducted in this sort of research where the decisions are not local and do not have a direct impact on people's lives.
6. The website does provide an element of openness around the discussion. In this way, having a dedicated website can be seen as being a useful addition to public dialogues around contentious issues. But the key factor is how people find out about it and why they might be drawn to visit it.
7. It is clear from the survey data that many of those using the site to provide input are in related professions. This underlines a central difference between the purposively recruited, face to face public dialogue events and the 'open to all with an interest' nature of online engagement.

Given that the forms of digital engagement utilised in this project do not allow for the online dialogue to be as balanced and deliberative as the face-to-face dialogue, inevitably a series of questions is raised. For example, how can the online comments from professionals be included alongside those of the general public? Are the findings from the online dialogue skewed towards those with existing knowledge and interest in the subject in a way which we would not find legitimate in the face-to-face element? Have those with no previous knowledge read enough of the website to ensure their comments are deliberative and if not, why should they be compared to the deliberative comments from the face-to-face dialogue? Just because digital engagement can allow everyone who wants to respond the opportunity to do so, is it legitimate to do this or should there be filters and quotas for who can respond to provide robust digital engagement?

In future, we would recommend that expectations about the digital engagement findings in relation to the face-to-face findings are part of the Invitation to Tender. It is essential to be clear if the intention is for the digital engagement to match the high methodological and recruitment standards to which face-to-face dialogues are conducted, if the two channels are to be analysed together. Or, if the digital engagement element is intended to provide a different set of findings, then the purpose of the digital engagement element should be specified in the ITT.

## Appendix A - Summary of Views on Access to Patient Records

Do participants think they have access now?					
	Type of person	Liverpool	Nottingham	London	Cardiff
1	Your GP	Y Y Y Y	Y Y Y Y	Y Y Y Y	Y Y Y Y
2	A Practice Nurse who works with your GP	Y Y Y Y	D Y Y Y	D Y Y Y	Y Y Y Y
3	The Receptionist at your GP surgery	N D Y	D D D Y	D Y D D	D D D Y: some access
4	The Hospital Doctor who is responsible for your care	Y Y Y Y	Y Y Y Y	Y Y Y Y	Y Y Y Y
5	A Hospital nurse who cares for you	Y Y D	Y Y Yx2: some access	D Y Y Y: some access	Y Y Y Y: some access
6	Allied health professionals who are involved in delivering your care	D Y N	Y M Y Y: some access	D D Yx2: some access limited to condition treating	Y Y Yx2: some access limited to condition treating
7	Hospital admin staff	N N D Y: some access	D D D N	D Y D N	D D D N
9	A Research nurse based in your hospital, but who does not care for you	N D N N	N N N N	N N N N	N N N
10	A Hospital Doctor who works and does research in <u>the hospital that you attend</u> but who does not deliver your care and has never met you	N Y N N	N D D Y: only anonymous data	Y Y: some access	N N N N
11	A Hospital Doctor based at <u>another hospital</u> who conducts research across many NHS sites and does not deliver your care and has never met you	D N D N	N D Y Y: only anonymous data	N D	N N D N

Figure 15: Table showing participants views on whether each professional has access to patient records or not. Each letter represents the view of a table at each location.

Y = participants felt they have access

N = participants felt they did not have access

D = there was disagreement amongst participants on whether they have access

## 1. Summary matrix of views on what is included in a simplified information sheet

	Liverpool	Nottingham	London	Cardiff
Information	Simplified Information Sheet	Simplified Information Sheet	Simplified Information Sheet	Simplified Information Sheet
Invitation and brief summary	✓✓✓✓	✓✓✓✓	✓✓✓✓	✓✓✓✓
Purpose of and background to the research	✓✓✓✓	✓✓✓✓	✓✓✓✓	✓✓✓D
Why am I being asked to take part in this research?	✓✓✓✓	✓✓✓✓	✓✓✓✓	✓D✓D
What would taking part involve including name of drugs to be taken and for what conditions	✓✓✓✓	✓✓✓✓	✓✓✓✓	✓D✓X
What are the possible disadvantages and risks of taking part?	✓✓✓✓	✓✓✓✓	✓✓✓✓	✓D✓✓
Do I have to take part? Can I withdraw?	✓✓✓✓	✓✓✓✓	✓✓✓✓	✓✓✓✓
What if new information is found that might affect whether I would want to continue in the trial?	✓✓✓✓	✓✓✓✓	✓✓✓✓	✓✓✓X
What will happen if I don't want to carry on with the study?	✓✓✓✓	✓✓✓✓	✓✓✓✓	✓✓✓X

How will my information be kept confidential?	✓✓✓✓	✓✓✓✓	✓✓✓✓	✓✓✓✓
What will happen to the results of this study?	✓✓✓✓	✓✓✓✓	✓✓✓✓	✓✓✓✓
Who is organising and funding this study?	✓✓D✓	D✓✓✓	✓✓✓✓	✓✓✓✓
Contact details/website for further information	✓✓✓✓	✓✓✓✓	✓✓✓✓	✓✓✓✓
What are the alternatives?	✓✓D✓	X✓✓✓	✓✓✓✓	✓✓✓✓
What happens when the research study stops?	✓✓D✓	✓✓✓✓	✓✓✓✓	✓✓✓✓
How many participants will be involved in the study?	XXXX	XD✓X	XD	DXXX
Probability that you would receive either drug (e.g. 50 % chance of receiving either drug etc.)	XDDD	XDDX	XD	DXX
How long will it take?	D✓✓	✓D✓X	DDD	DX✓D
Insurance arrangements	XXX✓	DDDD	DD	DXXX
Circumstances in which the participant would be withdrawn from the trial	XD✓	XDX✓	DD	DD✓X

Who has reviewed this study? (e.g. a research ethics committee)	XD✓✓	XDX	XX	✓XXX
How have patients and the public been involved in this study? (e.g. in its design, not just by taking part)	XXXX	XX	XX	DXX
Details of the drug(s) to be used in the research				
Name of the drug	✓✓✓✓	✓✓✓✓		✓✓✓✓
What medical conditions is the drug used for?	✓✓✓✓	✓✓✓✓		✓✓✓✓
Information necessary before taking the medicine	XXXX	X✓DX		XXXX
Dosage to be taken and how to take it	XXXX	XXX		XXXX
Possible side effects	XXXX	XXX		XXXX

Figure 16: Table showing participants' views on what should be included in a simplified information sheet. Each symbol represents a table.

✓ = participants felt it should be included in the information sheet

D = participants disagreed

X = participants did not think it was necessary to be contained in the information sheet

# Appendix B - Online Survey

## Issue 1: Access to Patient Data

*Clinical trials have lengthy inclusion and exclusion criteria to see if a person has the right characteristics to enter a study. Clinical trials may use patient records as a starting point to find participants for research. This involves looking through patient records to identify suitable candidates that fit the study's criteria. The suitable candidates are then contacted to see if they would like to participate in the clinical trial.*

*For more information, click here [links to relevant page of RPHR.org.uk].*

***How do you feel about the following considerations being used to decide whether a researcher should have access to medical records to identify people who might want to take part in a trial?***

- They already know the patient concerned (e.g. they are the patient's doctor or nurse)
- The researcher is an NHS employee
- The researcher has an honorary contract with the hospital or the GP surgery
- The person has a confidentiality clause in their contract of employment
- The research might give the patient access to new improved treatments
- Patients should be able to opt-out of the process
- They work at the same hospital or GP surgery that the patient goes to, but might not know the patient
- They work in the same department as the patient's doctor but don't provide direct care for the patient

Participants rated each of these options on a four point scale: 'This would be essential', 'This would be desirable', 'This is not of great importance', 'This would be undesirable'. Participants also had a 'Not sure' option.

Participants were also given the chance to provide open responses if they wished to.



## Issue 2: Developing lists of people who are willing to be approached about potential studies

*One way of increasing the opportunity for patients to be involved in health research is what is sometimes called 'consent to be approached'. This is where groups of people are asked in advance if they would be happy to be approached if a health research study came up that they would be eligible to take part in. To make it possible for researchers to identify who might be eligible, these patients make some or all of their medical information available to researchers.*

*These lists mean that if researchers find someone that might be eligible for a study, the researcher is often able to approach the person directly, rather than having to make this approach through the patient's doctor.*

For more information click here [links to relevant page of RPHR.org.uk].

### ***How comfortable would you feel about the following approaches to finding out whether you would be happy to be contacted about studies that they are eligible to take part in?***

- A member of staff approaches you in a GP or hospital waiting room to ask you if you would be happy to be contacted about future studies.
- A request is sent to you by post or email to ask if you would be happy to be contacted about future studies. You reply if you **do** want to be informed of relevant studies.
- A request is sent to you by post or email to ask if you would be happy to be contacted about future studies. You reply if you **do not** want to be informed of relevant studies. Otherwise you will be informed.
- A poster is prominently displayed in a waiting room, with details of who to contact if you **do** want to be informed of relevant studies.
- A poster is prominently displayed in a waiting room, with details of who to contact if you **do not** want to be informed. Otherwise you will be informed if a relevant study comes up

Participants rated each of these options on a four point scale: 'This would be appropriate', 'This would probably be appropriate, but I have some concerns', 'This might be appropriate, but I have quite a few concerns', 'This would be inappropriate'.

Participants were also given the opportunity to provide other suggestions about how people should be approached.

## Background

*The following questions are optional, but will really help us to understand the responses to this questionnaire better.*

### ***How did you find the RPHR website?***

*Web search*

*Via twitter*

*Other social media*

*Recommended by a friend*

*Attended one of the public workshops*

*Other (please specify)*

### ***How much time did you spend reading the RPHR website?***

*I read most of it in detail*

*I read parts of it*

*I briefly skimmed some sections*

*I have not looked at the website*

### ***How useful did you find the RPHR website?***

*Very useful*

*Quite useful*

*Not very useful*

*Not sure*

### ***If you wish to provide feedback on the website, please do so here:***

*[participants were given space to provide additional comments]*

## About you

*The following questions are optional but answering them will help us to understand more about the range of people responding to this survey.*

### ***Please tick the box that best describes you.***

*General public, not an active patient*

*Patient who frequently uses the NHS*

*Patient who rarely uses the NHS*

*Carer*

*Representing a patient organisation*

*NHS staff*

*Researchers*

*R&D function*

*Member(s) of an ethics committee/ethicist*

*Professional body*

*Regulatory body*

*Industry*

*University*

*Research Council*

*Social Care services*

*Other (please specify)*

***Please indicate if these are your own views or if you are representing an organisation or group:***

*My own views only*

*The views of my organisation*

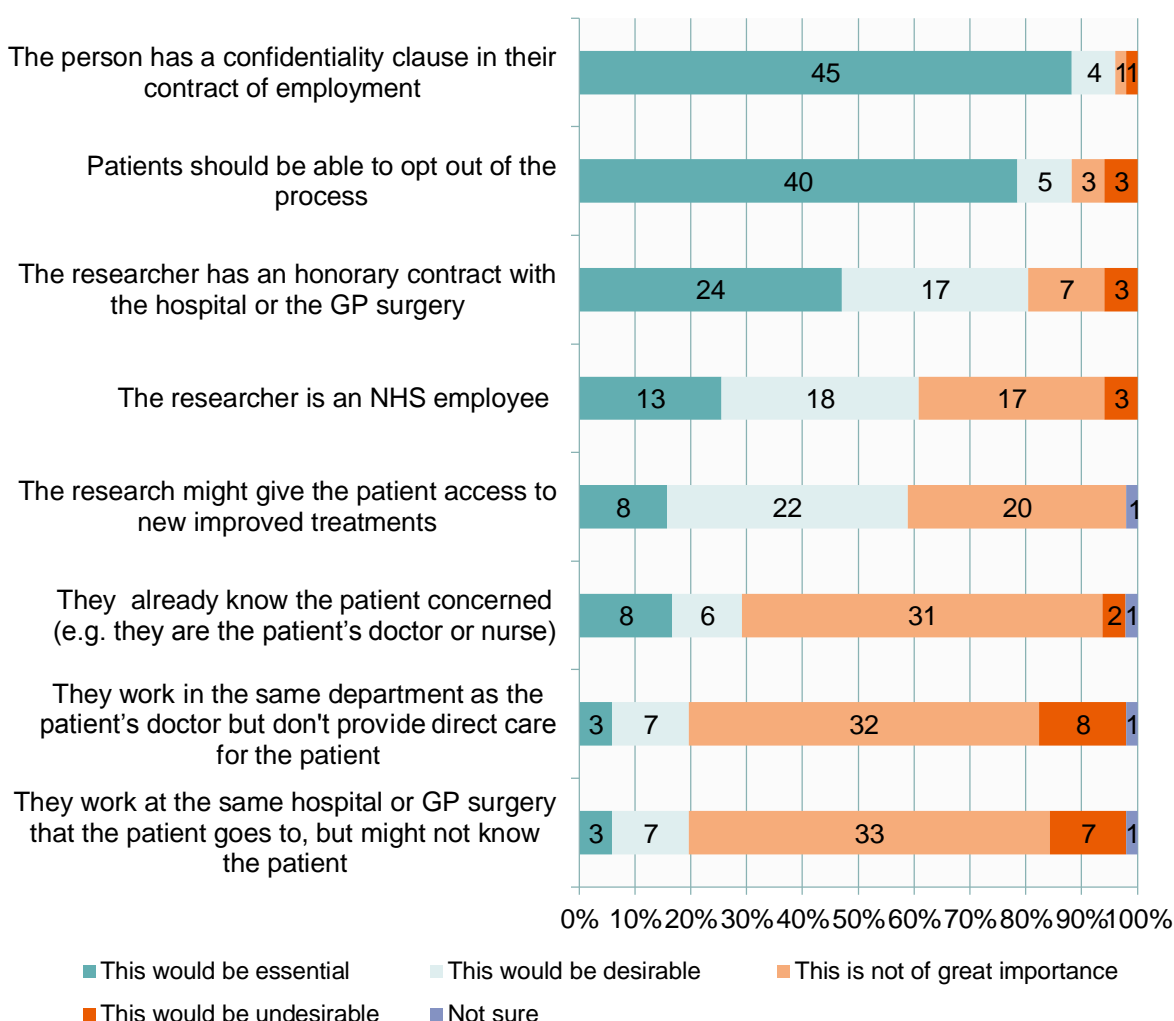
***If you are representing an organisation, please state which one below:***

*[respondents were provided with as pace to write this in]*

## Appendix C – Survey findings

### How do you feel about the following considerations being used to decide whether a researcher should have access to medical records to identify people who might want to take part in a trial?

Respondents were asked how important they thought eight different considerations were, and were also given the opportunity to provide additional comments. In the chart below, the responses have been ordered with the options that were felt to be important by most participants at the top, and those felt to be less important lower down.



*These questions were all answered by 51 respondents, apart from 'They already know the patient concerned (e.g. they are the patient's doctor or nurse)' which was answered by 48.*

This data shows that confidentiality clauses, the ability to opt-out, and having an honorary contract with the hospital or GP surgery were of high importance to most respondents, when considering who should have access to medical records to identify trial participants. Views on other issues were more mixed. There was greatest

ambivalence about whether they should work in the same department as the patient's doctor, and whether they should work in the hospital that the patient goes to.

It is interesting to note that already knowing the patient concerned was not widely felt to be of high importance. Of 48 respondents who answered this question, only 14 thought that it would be essential or desirable, while most (31) thought that this was of no great importance.

Respondents were given the opportunity to provide open responses to clarify their answers to these considerations.

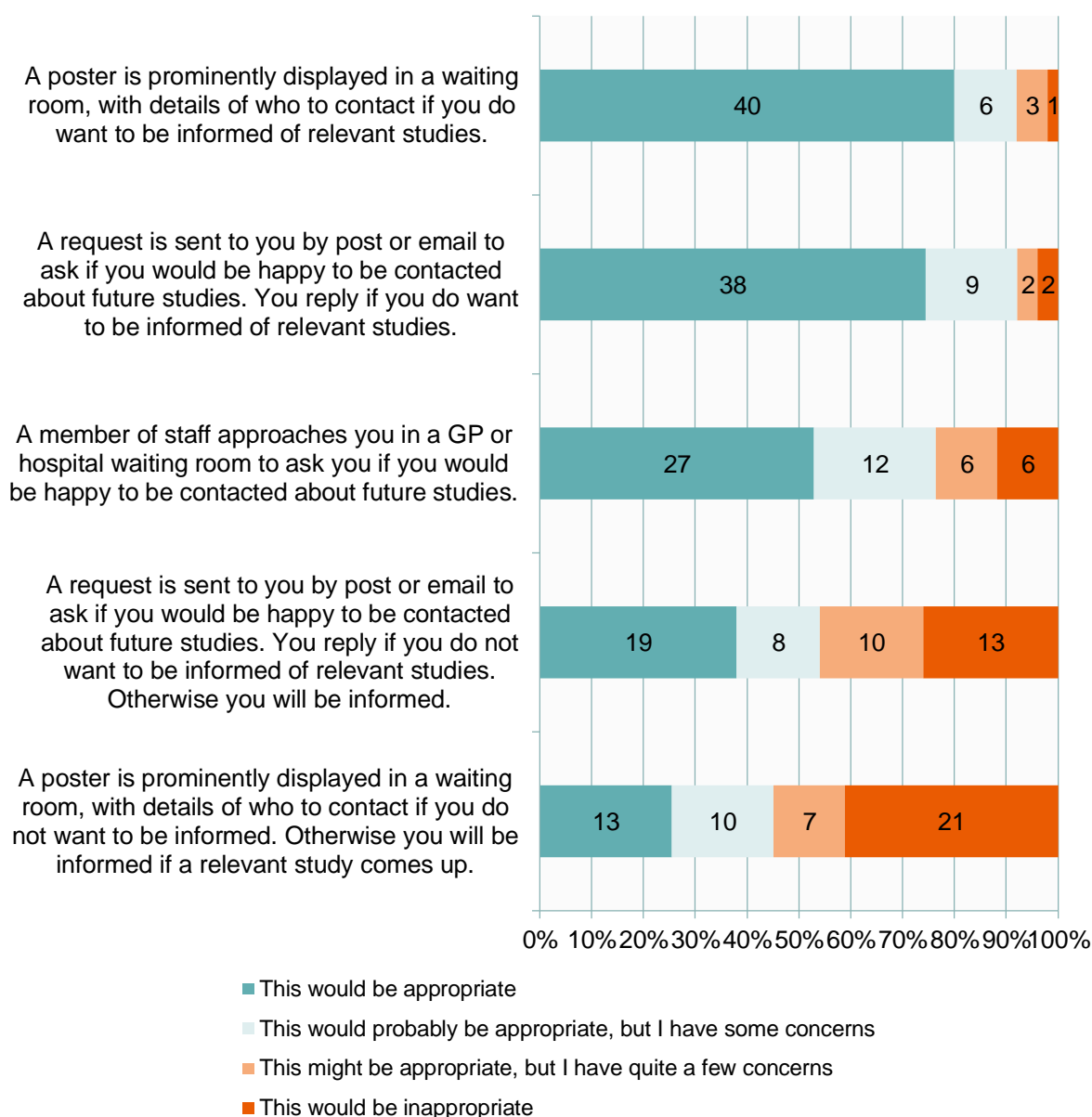
Sixteen open responses were submitted:

- Six respondents discussed the importance of data confidentiality. They built on the idea that researchers should have confidentiality clauses, but added to this in various ways. For example one commented that there should be the possibility for professional repercussions on them if they break confidentiality. Another argued that trust in the NHS is well placed, and that the work should be kept in house.
- Five respondents said that the background of the researcher is another important consideration. They variously argued that researchers from certain backgrounds should not have access. For example, one respondent said that academics from universities would be acceptable, but they would be much more concerned about researchers from pharmaceutical companies having access. Another two argued that accessing records should be restricted to NHS staff.
- Four respondents argued that there should be much easier access to medical records for researchers, or access should be available to any accredited researcher so long as consent has been given.
- Two respondents argued that records should only ever be looked at with a patient's consent.
- Other comments included one respondent saying that they did not fully understand the question, and another said that they thought "a lot of this work would be done under the banner of audit".

### **How comfortable would you feel about the following approaches to finding out whether you would be happy to be contacted about studies that you are eligible to take part in?**

Respondents were given five scenarios to consider, and for each one, they indicated how appropriate they thought the approach used was.

In the chart below, the data has been organised with the scenario considered appropriate by most respondents at the top, and the scenario considered appropriate by fewest respondents at the bottom.



*These questions were each answered by 51 respondents, apart from “A request is sent to you by post or email to ask if you would be happy to be contacted about future studies. You reply if you do not want to be informed of relevant studies. Otherwise you will be informed.” and “A poster is prominently displayed in a waiting room, with details of who to contact if you do want to be informed of relevant studies.”, which were each answered by 50 respondents.*

One clear trend in these results is that scenarios in which patients actively give their approval for records to be looked at (opt-in) were consistently rated as being more appropriate than scenarios in which use an opt-out approach. Of the two opt-out

scenarios, more participants preferred to be contacted by post or email, rather than rely on a poster to give them this information.

It might be surmised from these observations that the more directly respondents are involved in having a say about how their records are used, the more likely they are to consider this appropriate.

Respondents were given the opportunity to add open comments to their answers to this question:

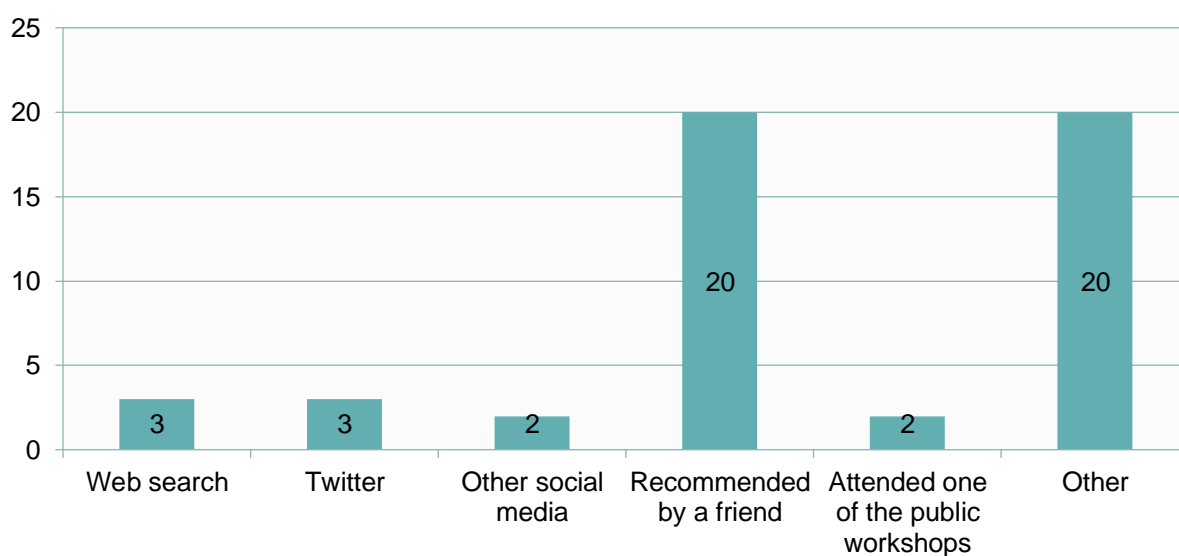
- Seven respondents raised concerns about approaching patients in a waiting room. A lot of these related to the fact that patients might feel pressured to opt-in in this situation, possibly because of making the decision in front of other people. Some were also concerned that this approach could lead to accidental confidentiality breaches as people may wish to discuss personal issues when considering whether to take part.
- Six respondents suggested that communications about consent to approach could be most effective if combined with other NHS communications, for example you could be asked at the same time as registering at a clinic, or while you meet your GP.
- Four respondents stated their support for an opt-out approach. Arguments given to support this included that research is an essential part of the NHS, and that an opt-in approach might lead to biased samples.
- Another four respondents stated their support for an opt-in approach. An argument given for this view was that information should not be shared about people without their consent, and the communications are unlikely to be sufficient to inform everyone.
- Three respondents felt that it would be important for the first contact to be made in person by health care professionals.
- Three respondents argued that a poster would be insufficient as a way to inform people of changes, as it may not be read.
- Two respondents suggested other communication methods that could be used, such as social media and text.
- Two respondents suggested that people who have already shown an interest in trials or taken part could be contacted as a way to enlarge the lists.
- The remaining responses covered various topics including the suggestion of publishing a list of upcoming studies on line for interested people to sign up to, and the concern that anyone approaching people should be trained to make a judgement about whether that patient has sufficient capacity to make an informed decision.



- One interesting response related to a concern that if people are approached by email or letter, unscrupulous organisations might take advantage of this to try to harvest people's contact details and personal information.

## Demographic information on respondents

### *How did you find the RPHR website?*

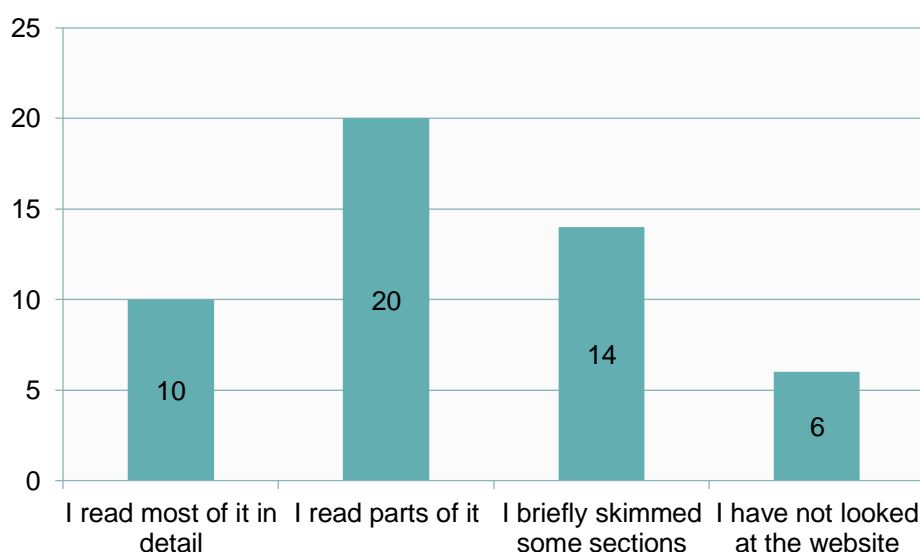


*This question was answered by 50 respondents.*

A key finding of this data is that few respondents filled in the survey because they had attended one of the public workshops. This indicates that the survey data can be treated as additional evidence in addition to the workshops, rather than being a reinterpretation of the same individuals' opinions.

20 respondents gave an 'other' response. Eight of these said that they had been directed to the website by a colleague. Five said that they had arrived at it via the HRA, for example because they had been browsing the HRA website or via other communication with the HRA. Two said that they had heard about it via an organisation called Biobank. The remainder had various reasons such as finding it by accident or via another website.

### *How much time did you spend reading the RPHR website?*

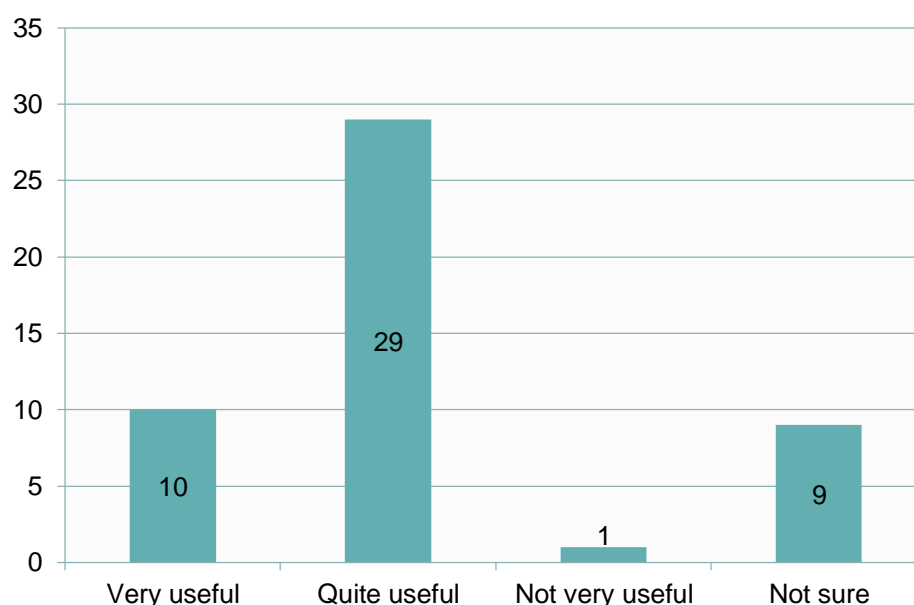


*This question was answered by 50 respondents.*

This question shows that most respondents read parts or most of the website before filling in the survey. This suggests that the responses received will be based on at least a basic understanding of the relevant issues, and can therefore be understood as considered responses, rather than simply being initial reactions to the questions.

One caveat to this finding is that it is plausible that there may have been a response bias, in which respondents indicated that that they have read more than they had, either in order to give their response more perceived validity, or to conform to social norms. While it is hard to estimate the size of this effect (or indeed whether it happened at all) it is unlikely that this will have had an overly large impact on the results. Data from the website analytics suggests that the average number of pages per view on the website was four, which provides some support for this. This data is based on all website visitors, not just those who completed the survey.

### *How useful did you find the RPHR website?*



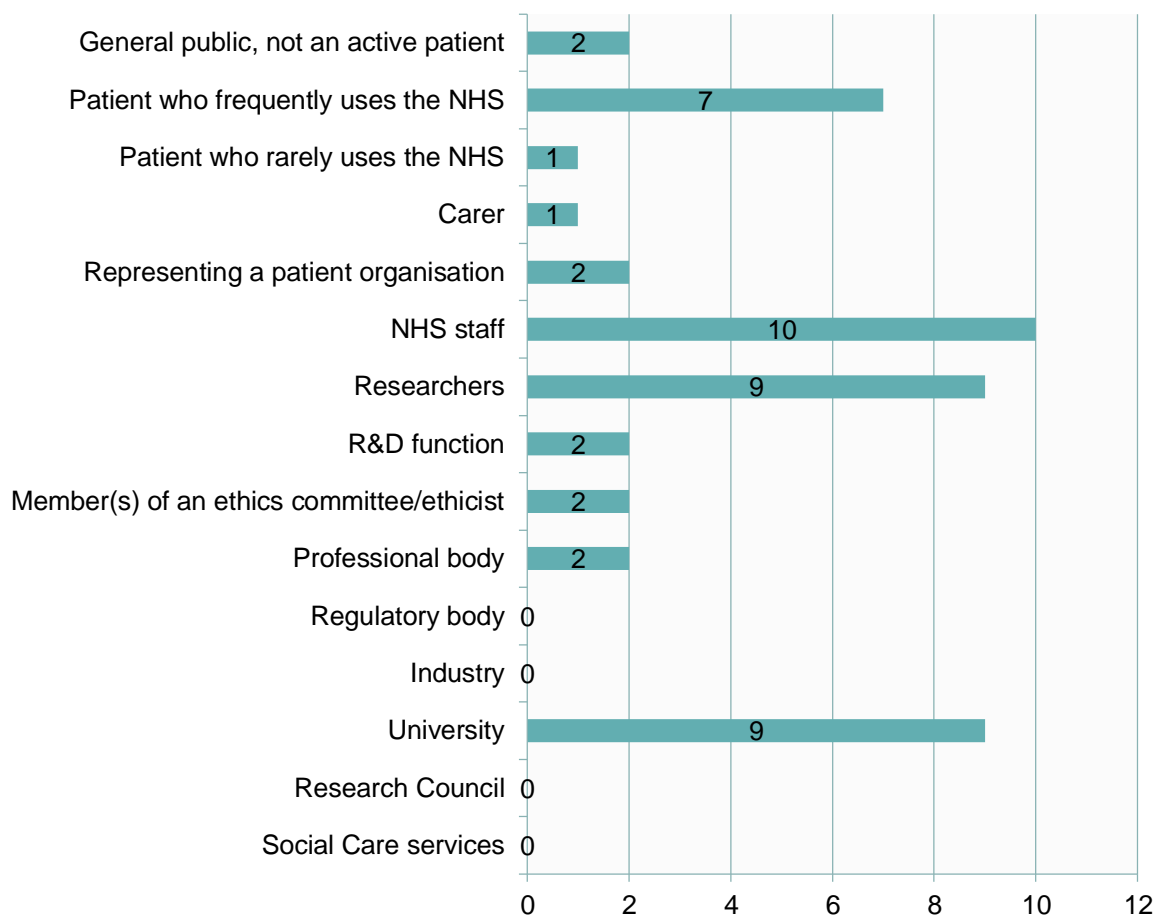
*This question was answered by 49 respondents.*

This question shows that most respondents found the website to be at least quite useful. This adds further weight to the possibility that respondents were able to find enough information to meaningfully answer the questions presented in the survey. If they were not able to find the information that they needed, it is likely that more would have described the website as 'not very useful'.

Looking at individuals' responses between questions, 5 of the 9 of the 'not sure' answers come from individuals who previously said that they have not looked at the website, which explains why they were not sure how useful it is.

### *Please tick the box that best describes you*

Respondents were asked to choose from a number of options to describe themselves. Their answers are shown below:



*This question was answered by 47 respondents.*

These responses show that many of the respondents to the survey were from a background that might indicate a higher than average level of knowledge about relevant issues (e.g. NHS staff, researchers). Only 10 out of 47 respondents to this question said that they were patients or general members of the public.

This indicates that the survey should not be interpreted as representing the general population, but more indicative of the views of a particular group of more interested and aware individuals.

***Please indicate if these are your own views or if you are representing an organisation or group***

All 48 respondents who answered this question indicated that they were sharing their own views.

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