Public Dialogue Workshops

Report prepared for the Health Research Authority

12 June 2013
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## Contents

### Executive Summary

### Chapter 1: Introduction & methodology

1.1 Background

1.2 Aims & objectives

1.3 Methodology

1.4 Report outline

1.5 Acknowledgements

### Chapter 2: Perceptions of health research and clinical trial, placebos and blinding

Key findings

2.1 Baseline knowledge of health research

2.2 Perceptions of Placebos

2.3 Perceptions of Blinding

### Chapter 3: Recruitment & consent

Key findings

3.1 Patient identification

3.2 Should participants have a mechanism for signaling a wish to participate?

3.3 Patient consent

3.4 Advising participants throughout the trial

### Chapter 4: Research Approvals Systems & Regulation

Key findings

4.2 Proposed streamlined system for approvals

4.3 Annual assurance and reporting

4.4 The researcher passport

4.5 Encouraging research publication

### Chapter 5: Public Patient Engagement

Key findings
5.1 Level of support........................................................................................................... 44
5.2 Who would best represent the ‘public’ perspective? .............................................. 45
5.3 Mechanisms for engagement....................................................................................... 46

Chapter 6: Increasing trust in the HRA and in health research 48

Key findings.......................................................................................................................... 48
6.1 Trust............................................................................................................................... 50
6.2 Perceptions of risk......................................................................................................... 54
6.3 Increasing trust in the HRA and the research process .............................................. 57

Chapter 7: Conclusions ...................................................................................................... 61

Appendix ............................................................................................................................. 62

Appendix 1: Table of participants (by demographic group) ........................................ 62
Appendix 2: Case studies .................................................................................................... 63
Appendix 2: Homework tasks............................................................................................. 66
Appendix 4: Discussion Guides.......................................................................................... 71
Executive Summary
Executive Summary

The Health Research Authority (HRA) has an ambitious programme of work to streamline and simplify the research approval process. The approval system covers all types of health research that involves patients across England including clinical trials. It is important for the HRA to understand what the implications of these proposed changes are for patients and the public and to understand the degree to which they feel protected or made at risk by the system for approving health research. The findings from this public dialogue activity are crucial in enabling the HRA and DH to make informed decisions on the strategy for the HRA and DH policy for the management of health research in the UK.

Ipsos MORI was commissioned to carry out public dialogue as part of a wider engagement exercise with HRA stakeholders, which also includes internal stakeholders, clinical researchers and delivery partners, and patients (via PPI networks). As well as providing the public’s view on the HRA’s proposals for streamlining the research approvals process a dialogue was chosen to explore how (and the extent to which) the HRA should engage the public with their strategic planning process in the future. The dialogue was co funded by the Sciencewise Expert Resource Centre (Sciencewise-ERC)\(^1\). Public dialogue was held in four locations, with each group of participants attending two evening workshops. In total 60 members of the public attended the first workshop, and 56 the second.

Participants had little knowledge about health research at the beginning of the workshops. As such, their initial views were mostly impressionistic and often incorrect, tending to be based on hearsay or some media coverage rather than fact or considered opinions. When ‘health research’ was explained by the facilitator(s) and by a multi-media presentation in the early plenary session, there was general surprise among participants about its broad scope and importance to medical advancements and treatment.

Most participants were comfortable about a range of health care professionals accessing their records, principally because of high levels of public trust in these professions and the perceived benefits of the work they do. A minority felt less comfortable about this and were concerned about the perceived impersonal nature of the approach taken to identifying potential research participants, or the embarrassment of personal information being shared.

Participants had mixed views on who should consent patients to take part in health research. Some suggested GPs, as they are seen as impartial and able to offer ‘trusted’ independent advice. Others felt the research team should consent given their specialist knowledge or an independent specialist who would have specialist knowledge and still be independent.

Participants did not hold strong views on the order in which shorter and longer patient information sheets (used as part of the consent process) should be provided. Most emphasised the importance of face to face information and many

\(^1\) The UK’s national centre for public dialogue in policy making involving science and technology issues
agreed that patients should have access to such support throughout the lifetime of the research project.

The current approvals system was acknowledged as providing appropriate safeguarding of patients. In contrast to this, the duplication of effort, inconsistency of approach and delays within the research governance strand were mostly seen as unnecessary and avoidable, and with the potential to discourage important research from being done.

Many participants believed the proposed streamlining of the research approvals process could tackle many of the problems identified with the current system. Most were enthusiastic about the HRA co-ordinating the process and believed this would improve efficiency without affecting patient safety. Some were more sceptical about the proposals suggesting that they might not work as well in practice as anticipated, or that they fail to address some of the concerns about the current arrangements.

Participants mostly supported the proposal to streamline the annual reporting system to one of regular ‘light-touch’ assurance with emphasis given to the final report. There was also some support for, but limited understanding of, the proposed changes to the researcher passport system.

Many cited research publication as the key issue for patients and members of the public. Some argued for the principle of publishing all research believing it to be the ethical duty of researchers to do so, and the duty of the HRA or the Research Ethics Committees to ensure that research is published.

Most participants were positive about the idea of public and patient engagement by the HRA as part of its strategic decision-making. As health research is of significant importance and potential benefit to individuals and society at large, the broad view is that there is something of an ethical imperative to involve the public in this work. Views were mixed concerning where the HRA’s emphasis should be in terms of who it engages with (the public, patients or people who have been involved in health research) and how patient engagement might work in practice.

The NHS and NHS staff are very highly regarded and trusted to protect public health and wellbeing above other considerations. In contrast, pharmaceutical companies are seen as having vested interests in the conduct of research, and as a consequence are not trusted to behave ethically.

Most participants agreed that health research benefits society. However, participants had mixed views around the personal risks that they might face in participating in research trials. Most believed they would make choices based on their perceptions of the potential costs and benefits of the trial to them as individuals, with the potential societal benefits being less important. They were therefore keen to eliminate or minimise safety risks, and ensure that the best care and information is available to those participating, both during and after the trial.

There is little knowledge of the HRA’s role as regulator for trials, though participants tended to assume upfront that regulation must exist. There is tacit support for the HRA as an independent body to hold researchers and funding organisations to account, so long as it has the regulatory powers, reach and capacity to monitor and
sanction where appropriate. As part of this, it is particularly important to maintain the independence of research ethics committees and the wider approvals process.

Evidence from the dialogue suggests that when informed about its value and conduct, there is a general call to **bridge the public’s knowledge gap** through **improved information and transparency**. Indeed, this is seen as an ethical imperative given its importance to society at large. Participants talked most about transparency when discussing patient information and the publication of results.
Chapter 1: Introduction & methodology

1.1 Background

The Health Research Authority (HRA) is an NHS organisation established on 1 December 2011 as a Special Health Authority. The purpose of the HRA is to protect and promote the interests of patients and the public in health research in order to support both their confidence and participation in health research, and improvements in the nation’s health.

The HRA is working closely with other bodies, including the Medicines and Healthcare Products Regulatory Agency (MHRA) and the National Institute of Health Research (NIHR), to develop a unified approval process policy for health research involving the public and to promote proportionate standards for compliance and inspection within a consistent national system of research governance. This aims to ensure that research involving members of the public is ethically reviewed and approved, that they are provided with the information they need to help them decide whether they wish to take part, and that their opportunity to do so is maximised by simplifying the processes by which high quality research is assessed.

In developing this policy approach the HRA is committed to making it easier to do good quality research in the NHS, and this will require a fundamental assessment of how the organisation reviews and manages research in the NHS. Therefore, in its initial six months the HRA set out an ambitious programme of work to improve the environment for health research in the UK. A feasibility study was announced, with key decisions on HRA strategy and business objectives produced in May 2013. The findings from this proposed public dialogue activity will be crucial in enabling the HRA and DH to make informed decisions on the strategy for the HRA and DH policy for the management of health research in the UK.

This public dialogue will therefore not only inform how the new HRA operates, but will also lead to updates in the current DH policies such as the Research Governance Framework and the Governance Arrangements for Research Ethics Committees (GAfREC), which, as proposed in the Care Bill 2013 will be the HRA’s responsibility pending its status changing from Special Health Authority to Non-Departmental Public Body. It is essential this policy work is grounded in the views of the public.

To this end, the HRA has conducted a wide engagement exercise incorporating dialogue with internal stakeholders, clinical researchers and delivery partners, patients (via PPI networks), and particular groups within the general public. The public and patient dialogue work received support from Sciencewise-ERC.²

² The Sciencewise Expert Resource Centre (Sciencewise-ERC) is funded by the Department for Business, Innovation and Skills (BIS). Sciencewise-ERC aims to improve policy making involving science and technology across Government by increasing the effectiveness with which public dialogue is used, and encouraging its wider use where appropriate to ensure public views are considered as part of the evidence base. www.sciencewise-erc.org.uk
Ipsos MORI was commissioned to facilitate a public dialogue as part of that process. The dialogue was also used to capture the public’s view on the HRA’s proposals for streamlining the research approvals process in line with its mandate to protect and promote the interests of the public in health research. This document presents Ipsos MORI’s analysis of the views expressed during the public dialogue.

1.2 Aims & objectives

The overall objectives of the general public dialogue were to:

- understand public expectations of the risks and benefits of clinical trials and research involving patients
- explore views of the ethical issues that might arise and the implications for the procedures required to protect individuals and society as a whole
- explore responses to some specific and detailed options for new procedures
- understand how the public feel they should be engaged and influence the HRA in future.

Detailed research questions under these aims are set out and addressed in each chapter of this report.

1.3 Methodology

Sciencewise-ERC, which is the UK’s national centre for public dialogue in policy making involving science and technology issues, defines public dialogue as “a process during which members of the public interact with scientists, stakeholders (for example, businesses and pressure groups) and policy makers to deliberate on issues likely to be important in future policies”.

Sciencewise-ERC’s approach places an emphasis on dialogue being:

**Informed** – participants are provided with information and access to experts;

**Two way** – participants, policy makers and experts all give something to and take something away from the process; dialogue is neither solely about informing the public nor extracting information from them;

**Facilitated** – the process is carefully structured to ensure that participants receive the right amount and detail of information, a diverse range of views are heard and taken into account and the discussion is not dominated by particular individuals or issues;

**Deliberative** – participants develop their views on an issue through conversation with other participants, policy makers and experts;

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**Diverse** – participants tend to be recruited to ensure they represent a diverse range of backgrounds and views (participants are not self-selecting);

**Purposeful** – dialogue engages the public at a stage in a decision-making process where the policy can be affected;

**Impartial** – public dialogues are often convened, designed, delivered and facilitated by independent individuals or organisations to help ensure the process is not biased in favour of a particular outcome; and

**Expansive** – public dialogue opens up conversations rather than closing them down.

In this case, members of the public were recruited and selected to reflect (but not represent) the demographic diversity of people living in England. The participants were asked to attend two evening workshops (from 6:30pm to 9:30pm) in one of four locations (Bristol, Newcastle, London and Manchester). Each workshop combined plenary sessions and break-out groups where more detailed discussions could take place. Each re-convened session was held one week after the first session allowing participants to reflect on the session and complete further research. Participants were given a task to complete between the two workshops to facilitate this.

Participants attending the public dialogues were informed about health research, the HRA and the proposed changed to the approvals system and encouraged to discuss and develop their views about HRA policy and engagement with each other and with clinical researchers who participated in the second event. The workshops were managed and facilitated by Ipsos MORI.

**Recruitment & Sample**

Sixteen adults aged 18+ were recruited in-street for each location with each agreeing to attend both workshop sessions.

People were excluded from participation if they were NHS employees, or working in another medical or clinical capacity, particularly clinical research in NHS, pharmaceutical companies or universities. They should also not have taken part in qualitative research in the past nine months.

Quotas were placed on gender, age, social grade and ethnicity to ensure a broad range of participants were recruited. Potential participants were also asked about their self-reported health and a series of questions to discern their general attitude and knowledge about science, clinical trials and health research ethics. Soft quotas were applied to these questions, with a view to ensuring a good mix of attitudes and knowledge within each workshop.

**Event structure**

A total of 60 participants attended the initial workshops (Workshop #1) and 56 the second (Workshop #2). In each session, participants were split into two groups, averaging 7-8 people per table and ensuring a good mix across demographic characteristics.
The event was mostly facilitated by a lead from Ipsos MORI, with support from a second facilitator who ran the second group discussion. In addition, two Ipsos MORI note takers were present at each event to record the dialogue as it happened.

The HRA client lead also attended several of the sessions, and provided additional input throughout the sessions. Clinical researchers were also invited to attend the Workshop #2 sessions to answer questions, raise issues and generate further dialogue among participants and at least two attended per session. Other observers were present at other sessions, including the Sciencewise lead evaluators from Cardiff University and HRA project Steering Group members.

Participants were asked to complete a post-task (homework task) after the first workshop (see appendix 3). These were used to encourage participants to consider and discuss the issues raised in the first workshop and to act as a warm up for the second workshop.

The table below provides an overview of attendance at each session. Further details of the demographic makeup of the groups are available in Appendix 1.

<table>
<thead>
<tr>
<th>Location</th>
<th>Workshop 1</th>
<th>Workshop 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Date</td>
<td>Attendees</td>
</tr>
<tr>
<td>Bristol</td>
<td>05/03/13</td>
<td>16</td>
</tr>
<tr>
<td>Newcastle</td>
<td>06/03/13</td>
<td>13</td>
</tr>
<tr>
<td>London</td>
<td>19/03/13</td>
<td>15</td>
</tr>
<tr>
<td>Manchester</td>
<td>20/03/13</td>
<td>16</td>
</tr>
</tbody>
</table>

The two sessions were structured along the basic premise of:

- **Workshop #1**: to inform and educate participants about health research in the UK. This used clinical research trials as a primary example of health research to illustrate many of the ethical and research governance issues that need to be addressed when evaluating health research proposals. In this workshop, participants were largely engaged in thinking about the issues presented from the perspective of being a ‘potential research participant’. They were given information about how health research is conducted. They were also asked to think about how they might respond to different research projects through the use of hypothetical case studies.

- **Workshop #2**: to engage participants and clinical researchers in an informed dialogue about the research approvals process. The initial focus was on the current approvals system, shifting to a discussion about the HRA’s proposals for streamlining the approvals process by taking a more central role in co-
ordination of research governance, and enhancing specific aspects of the process. In this workshop, participants were encouraged to think about the issues from a broader ‘citizen’ perspective and thus to consider the wider societal implications for health research and the strategic role of the HRA.

The workshop materials and discussion guides for both sessions are included in the appendices.

**Role of clinical researchers at the sessions**

In line with the principles of public dialogue set out by Sciencewise-ERC and others, clinical researchers were invited to Workshop #2 in each location, to enrich the dialogue and inform participants about what research looks like ‘on the ground’. The HRA located and invited relevant clinical researchers. They were briefed in advance (in writing from Ipsos MORI and on the day): to engage participants in discussion; to offer their own experiences of working in research as examples; and to ask questions of participants to open up the discussion. While they were asked to talk freely, they were also asked explicitly not to present themselves as the ultimate experts and not to correct participants even where their perceptions might not be correct. This was so that we could explore perceptions and where they came from, rather than closing down conversations early. We asked the clinical researchers to take care that their expertise was presented in an un-intimidating way, and to use lay person’s language, so that participants were able to follow the discussion. The facilitators also assisted in moderating the role of clinical researchers and their discussions on each table.

When working with scientists, clinical researchers or other experts in dialogue, the individuals we invite will of course bring their own experiences and personal approach to the event. In total ten clinical researchers attended the workshops with no clinical researchers attending more than two workshops. All the clinical researchers had a wealth of research experience, and the researchers had worked in a variety of research areas (including managing RCTs and qualitative studies), and had had different experiences of seeking approval for their work (for example, some conducted research over a greater number of sites than others). In addition, one of the clinical researchers invited to attend had a role in the development of the HRA’s new guidelines.

Some clinical researchers were very clearly supportive of the HRA’s proposals and as such effectively promoted these to their group, in other instances clinical researchers suggested changes to the current system that went beyond those proposed. Some were very forthcoming and some less so. Some participants were more forthcoming with questions than others. The clinical researcher contributors will inevitably have influenced the form and content of what was discussed in their own group. That said, only one clinical researcher attended more than one event and therefore participants were exposed to a wide range of professional experiences and opinions.

This meant that, as is normal for public dialogue, each workshop had a slightly different focus and covered off different themes and questions in different ways. Across the workshops as a whole, however, the key issues were all covered, and in analysis we were able to compare responses on a thematic level to
understand public perceptions (see data collection and analysis sections, immediately below). In analysis, we also bore in mind the interaction of clinical researchers and participants when drawing conclusions or evaluating the balance of opinion based on the weight of discussion.

**Data collection**

As mentioned above, note takers were present at each event to make detailed notes of everything heard and any notable observations throughout the session – including during plenary and the refreshment break. Sessions were also digitally recorded in their entirety, to further support analysis and quality assurance. Flipcharts were used to capture participant feedback for some exercises and facilitators took charge of noting summaries of the table’s views on these flip charts. They were also then used in-session to support both facilitators and participants. They were checked during the sessions and used to refer back to earlier thoughts and observations as the discussions progressed. A core team of facilitators attended the events, in most cases attending several locations, and each facilitator made their own field notes of reflections after the event. All of these sources of data have been utilised in the drafting of this report.

**Analysis**

Once the series of workshops were concluded, the Ipsos MORI workshop facilitators and the HRA client lead held an analysis session to explore the emerging themes when set against the research objectives and specific research questions we set out to address.

As a result of this session, the team arrived at a shared understanding of the range and depth of the data, and to agree a structure for this report that ensured coverage of all perspectives. With this structure as a basis, members of the team then conducted further detailed analysis of the workshop notes, flip charts and audio recordings.

The findings, as presented in this report, are based on this analysis. The report aims to provide a descriptive account of what was discussed, but also to provide some interpretation of the results taking into account what was said within the context of emergent underlying beliefs, values and social contexts which seemed to be driving discussions.

**Interpreting qualitative research**

Unlike quantitative surveys, qualitative investigation is not, by its nature, designed to be statistically representative. It is intended to be illustrative and to provide in-depth understanding around a topic. Therefore, claims cannot be made about the extent to which the conclusions may be generalised to the population. Instead, we present the broad range of views given by participants, and where appropriate make reference to overall balance of opinion or general consensus.

Anonymous verbatim comments made during the discussions by participants, and, where particularly relevant, clinical researchers, have been included throughout this report. These should not be interpreted as defining the views of all. Instead they give insight into how a particular issue or topic was addressed. Some issues were
discussed in one or the other of the groups, and this is indicated throughout; hence in some cases there will be a series of comments attributed to a particular location and not others, indicating this topic was more of an issue here than elsewhere.

Furthermore, it is important to acknowledge the influence of group dynamics on what is discussed and how (including the role of clinical researchers, as above). Participants inevitably discuss and build on the issues raised by others, so even when comments are discussed by a large number of people this does not necessarily mean that views held on these topics are the strongest. Similarly, issues touched on only briefly are not necessarily unimportant.

We have already drawn attention to the different roles we encouraged participants to embody in the discussions – from potential research participant to ethics committee member and citizen – and note that this is likely to have resulted in the same participant presenting conflicting perspectives at different phases of the discussion. This is no surprise and of value to our broader understanding of the issues. It is also worth mentioning here that individuals discussing health issues often have a tendency to conflate questions relevant to their own health and medical history with questions they are asked to address, relevant to the topic under discussion. This is something we notice in many dialogues, which we witnessed here, so we are mindful of this in our analysis.

While moderators made every effort to ensure that participants stayed on topic throughout, sometimes participants had discussions that did not directly address our specific research questions. While it is part of the facilitator’s role to manage such asides and quickly re-focus the group’s attention on the main issues, it is also important for the group dynamic to allow people to express themselves freely – albeit in a time-limited manner.

1.4 Report outline

This report mainly follows the same outline as the workshops themselves.

**Chapter 2. Perceptions of health research and clinical trial, placebos and blinding** considers the overarching themes framing participant understanding of and responses to the issues discussed in the dialogue with a particular emphasis on three topics that were introduced in the workshops (clinical trials, placebos and blinding).

**Chapter 3. Recruitment & Consent** considers the current system and new proposals for enhancing the process of patient identification and seeking patient consent. Participant views on patient information sheets and additional sources of advice are also considered here.

**Chapter 4. Research Approvals Systems & Regulation** considers whether participants felt sufficiently protected by the current approval system and their perceptions of new proposals for a more streamlined system for approvals. Among the specific proposals considered, annual reporting and assurance, the enhanced researcher passport and the HRA’s role in encouraging research publication are all explored.
Chapter 5. Future Public Engagement considers the ways in which participants thought the public should be included in further engagement with the HRA, and how far, and in what ways, the public should have influence.

Chapter 6. Increasing trust in the HRA and in health research considers some of the overarching themes driving participants’ views including their trust in health research and the organisations involved in funding, managing and approving the research, and their perceptions of individual and societal risk. In addition there is a consideration of things participants stated should be put in place to increase their trust in the HRA and in health research more widely.

1.5 Acknowledgements

Ipsos MORI would like to thank Amanda Hunn from HRA for her support throughout the project, Suzannah Lansdell from Sciencewise-ERC, and the members of the steering committee for their support. We would also like to thank all the clinical researchers who attended the workshops and the participants who took part.
Chapter 2: Perceptions of health research and clinical trial, placebos and blinding

Key findings

Participants had little knowledge about the conduct of health research in the UK at the beginning of the workshops. As such, their initial views were mostly impressionistic and often incorrect, tending to be based on hearsay or some media coverage rather than fact or considered opinions.

Many people equated the broad concept of ‘health research’ with clinical research trials. These were typically characterised as Phase 1 trials; convened to test a ‘new’ drug, involving healthy adult volunteers, recruited through newspaper advertisements, paid to take part and with the risk of serious adverse side effects.

When ‘health research’ was explained by the facilitator(s) and by a multi-media presentation in the early plenary session, there was general surprise among participants about its broad scope. Some participants had some concern about some aspects of the ways in which trials can work, such as the fact that vulnerable people and children can be asked to take part in research studies, although these concerns were allayed to some extent as more detailed evidence was presented. Most of the participants agreed that health research benefited society at an overall level.

There was some concern around the use of placebos in research, and there was some confusion around how and why they are used. Many participants were unfamiliar with the blinding process. The issue of blinding stimulated less discussion than placebos and participants in general were less concerned about this.

2.1 Baseline knowledge of health research

A consistent finding across all the groups is that the public has little knowledge about the conduct of health research in the UK. As such, participants’ initial views were mostly impressionistic and often incorrect, tending to be based on hearsay or some media coverage rather than fact or considered opinions. Around one or two participants in each workshop had themselves been approached to take part in research, however, or knew of a close family member who had.

Several in each workshop had undergone a variety of therapies for chronic conditions, accidents or illnesses through their lives. In some cases individuals conflated the treatment they received at different times in their lives (“My doctor tried me on X…”) with participating in a clinical trial. A minority, who had had a bad time with medical treatments in the past, found it hard to trust any medical authority and tended to be less trusting overall, whether they had taken part in trials or not. While these individuals did not dominate the groups, their vivid stories were a part of the discussion, and form a part of the backdrop to the other opinions expressed.

*I took part in trials…but I got nothing but contempt [from those running the trial]. The doctors said my nerve endings were sending wrong signals, said my brain was imagining things.*

Bristol #1
Overall, many people equated the broad concept of ‘health research’ with clinical research trials. These are typically characterised as Phase 1 trials; convened to test a ‘new’ drug, involving healthy adult volunteers, recruited through newspaper advertisements, paid to take part and with the risk of serious adverse side effects.

*It depends on how desperate you are. If you’re really down and out and need some financial incentive you might do it but it might be too risky*

London #1

As background to this, several people directly referred to high profile cases where there had been reported fatalities amongst volunteers. Most notably, several participants appeared to refer to the 2006 Northwick Park Study in which six healthy young men became seriously ill within minutes of being injected with a drug developed to fight autoimmune disease and leukemia, but references to this case were mostly non-specific and impressionistic.

When ‘health research’ was explained by the facilitator(s) and by a multi-media presentation in the early plenary session, there was general surprise among participants about its broad scope. For instance participants were mostly unaware and surprised that health research:

- has been an important element in all medical advancement
- covers all health disciplines from mental health interventions and natural remedies through to surgery – as well as drug trials
- encompasses a range of approaches and methodological designs; from qualitative interviews to Randomised Controlled Trials (RCTs)
- is highly regulated and that all interventions with patient involvement require consent. Many people were surprised for instance to learn that a doctor cannot use a blood sample taken from a patient for research purposes without first gaining their consent
- that direct consent may be sought from next of kin if the patient is vulnerable or in critical condition, and that consent is sought from very young children when they are potential research subjects, as well as from their parents.

Given participant’s initial focus on clinical trials of drugs, they were also surprised that RCTs specifically are:

- not confined to drug trials; and notably that surgical techniques are subject to testing via clinical trials
- undertaken with patients, including vulnerable groups. More specifically, that ill people and children can be involved in clinical trials. Participants were particularly shocked that people who were unable to consent for themselves might ever be able to participate in a clinical trial.
- designed to ensure random allocation of patients to control and test groups, via placebo and blinding protocols
and that the treatment or intervention being tested may be withdrawn from research subjects after a trial has ended, regardless of its impact.

In addition, participants were surprised that drugs trials are undertaken in four phases among humans, with animal testing always a prior stage.

Greater understanding of these areas tended to increase trust and lessen perception of risk around the overall concept of clinical trials. Overall, and once some of the basic elements of health research had been explained, most participants were generally supportive of health research and clinical trials, agreeing that they benefit society at an overall level.

*I don’t have any concerns about trials. They’re generally carried out in a responsible way*  

Newcastle #1

Participants were more likely to show scepticism or concern when discussing the potential impact of health research on individual patients taking part. Some participants were particularly concerned about the participation of children and other vulnerable people in trials, and the fact that informed consent might not always be sought in emergency situations.

Patients’ concerns around more vulnerable people taking part in research trials often related to their initial focus on phase 1 trials. Some participants were concerned that more vulnerable patients might be manipulated into taking part without fully understanding or considering the consequences. Participants were also concerned about children taking part for the same reasons. These concerns were allayed to some extent when it was explained that children’s and parental consent is always sought, and that research with children takes place because children and adults might respond different to an intervention.

Support for trials tended to be shaped by altruism: the more altruistic participants were very supportive of trials and more open to possibly taking part in them; others needed to understand “what’s in it for me”, and these participants were the most concerned about trials possibly capitalising on more vulnerable patients.

Participants were shown a clip from a video that explained why placebos and blinding were used in research trials. Participants discussed these issues further when considering the information that patients should be provided with before deciding whether to take part in a trial (workshop #1), and the questions that ethics committees should consider when deciding whether to approve a trial (workshop #1 and workshop #2). Participants’ views around these issues are discussed below.

4 [http://www.youtube.com/watch?v=wsFTgirKXHk](http://www.youtube.com/watch?v=wsFTgirKXHk)
2.2 Perceptions of Placebos

Many participants struggled to fully understand the purpose of placebos in trials. While some understood that placebos are often a necessary part of the trial process, others had concerns about their use.

*Why do we have drugs at all if we can just be sugared pills?*  
Newcastle #1

*“If my child was ill and I found out they were using placebo, I don’t know how I’d feel.”*  
Manchester #1

In particular, some participants suggested that:

- patients who do not understand placebos could be mislead into taking part in a trial (believing they are receiving the test treatment)
- placebos are unfair as some patients will not be able to access new treatments while others would not
- placebos would only help “gullible patients” or those who had “made up” their medical problem
- placebos are used to mislead or confuse patients
- trials might be used to test placebos rather than the efficacy of new treatments against a placebo treatment.

Even people who had close relatives with serious conditions demonstrated a lack of understanding of the role of the placebo:

*My son is really sick (with cystic fibrosis). He was running out of treatment. They said there’s this new clinical trial but it might be placebo. I don’t want to waste time ‘cos he’s so sick if it’s only placebo. I said I’m happy to put him on it as long as it’s not …It’s more to test placebo than to test the drug – testing two different things.*  
London #1

The same participant went on to say:

*If I had more information at the time maybe I would have made a different choice. I didn’t even know what placebo meant.*  
London #1

Participants who were most concerned about placebos also tended to be amongst the most sceptical about the benefits and risks of health research.

Those who understood and supported the use of placebos often felt reassured by the fact that patients participating in a trial would often continue to receive the current treatment in addition to any placebo treatment.

*I don’t think anything is particularly wrong with placebos. They’d never take you off your medication.*  
Newcastle #1
2.3 Perceptions of Blinding

The concept of blinding in studies was new to many participants. Most participants had assumed that their doctor would always know whether or not they are taking a placebo or not.

*Interesting when the doctor doesn’t know, I thought they always did know*  
London #1

The issue of blinding stimulated less discussion than placebos and participants in general had fewer concerns about the process. Participants were largely reassured when it was explained that the information around whether a patient had been receiving a test or placebo would be available to health professionals if there was a relevant medical concern. Some participants in Newcastle described blinding as an important quality issue.

*It’s a good idea that blind tests are done to verify whether the drug is effective.*  
Newcastle #1
Chapter 3: Recruitment & consent

Key findings

Patient Identification:

Who should be able to trawl through patients records to identify suitable patients for inclusion in trials?

- Participants had little initial understanding of how their records can be accessed and who might have access to them.

- There is a common assumption that health services are more joined-up than they actually are, with all NHS health professionals able to easily access patient records using an NHS computer system. Following from this, some believe that private organisations would be able to easily access patients' records should they wish.

- Other participants emphasise the need for confidentiality of patient records, particularly when it concerns the potential sharing of highly personal information in their medical history (such as sexual health issues).

- This view is predicated on the assumption that health professionals would have access to named rather than anonymised records.

- A small number of participants were uncomfortable about the perceived impersonal approach to identifying potential research participants by trawling through patients records. An associated concern is that such an approach might be insufficient to assess the suitability of patients for the trial (if it were the only way such an assessment was made).

- Most participants were comfortable about a range of health professionals accessing their records, principally because of high levels of public trust in these professions and the perceived benefits of the work they do. The public, charity and academic sectors were seen as broadly synonymous.

Some GPs are not interested in research and may not pass information on about research studies to patients. Should there be a way for patients to show that they are interested in participating in a clinical trial?

- Participants who commented were keen to ensure that patients are given the opportunity to take part in health research, although the underlying assumption here was that taking part would afford them access to new drugs and treatments. GPs were seen as an important link between patients and appropriate research trials, but it was also recognised that GPs may lack the time and resources to manage this additional role.
Consent

Who should consent patients and how? It is currently restricted to the care team, should it be wider? E.g. a research nurse?

- Participants had mixed views on who should consent patients to take part in health research. GPs were again identified for this role, as they are seen as impartial and able to offer ‘trusted’ independent advice. Several people were concerned that GPs could be paid by pharmaceutical companies to promote their research, however. In addition, concerns were expressed about GP’s lack of specialist knowledge though for some this would be counter-balanced by knowledge of the individual’s patient history.

- Other participants felt consent should be taken by the research team given their specialist knowledge. Whether this was a research nurse or other member of the team was not considered to be important.

- Having access to an independent specialist was suggested by some as a way to overcome the drawbacks of seeking consent via GP or a researcher involved in the trial.

In seeking consent patients are given a patient information sheet to read (PIS). Current practice is to give patients a short one to read first and longer version to read later. It is thought that giving out the long version at first would deter people from reading it all. Is this a correct perception or is this patronising?

- Participants provided only top of mind views about the long and short information sheets, which were shaped by people’s personal preferences regarding detail: some people tended to prefer lots of detail from the outset, while others would rather get the gist of something before wanting to get a better understanding of it. In addition, participant’s explained that their preferences would depend on the context and their prior level of knowledge. In general, those who were most positive about taking part in research favoured less information than those who were more concerned about the risks.

- Participants did not hold strong views on the order in which the information sheets should be provided. While many of those preferring a shorter information sheet stated that they might not read a longer sheet, some of those preferring a longer sheet stated that they would not read a shorter sheet, as it would not have sufficient information for them to make a decision.

Who should they turn to for advice about a clinical trial? To what extent do the public trust the views of their doctor in advising them if they should participate?

- Participants agreed that in addition to the patient information sheets and detailed conversations with their doctor, they would expect to have a face-to-
face conversation with a professional with sufficient knowledge to answer any questions about the research.

- Some would also like to be able to talk to patients who have been through similar research programmes.
- In addition to pre-consent advice and information, some participants emphasised the need for patients to also have access to such support throughout the lifetime of the project.

Methods note

Ipsos MORI facilitators introduced these issues using a combination of PowerPoint presentations (describing the consent process), and handout slides (with prompts showing the different professionals being discussed and some example patient information sheets). In addition, participants were asked to look at some case studies (see appendix 2) that encouraged them to explore participants’ views of the consent process and patient information (as well as other issues) in greater levels of detail. The advantage of using case studies is that they allowed participants to consider how health research can work in practice. Participants’ discussions of the case studies are included throughout this chapter where they are appropriate to the issues being discussed.

It is important to note that these discussions all took place in the first workshop when participants had had fewer opportunities to develop their understanding around health research. The initial workshops were not attended by clinical researchers. At this stage participants tended to consider these issues from the perspective of a potential patient rather than a citizen.

3.1 Patient identification

Participants were asked to consider who they think should be able trawl patient records to find patients for a trial. Participants were asked to consider various professionals who could access patient data such as;

- a patients’ GP;
- members of their care team;
- a clinical nurse and research team; and
- a charity supporting the trial.

The Health Research Authority was particularly interested in exploring the issue of whether participants were happy with a clinical nurse from the research team trawling patient records.

Professional and researcher access to records

Professional and researcher access to records was discussed in the Bristol and Newcastle workshops but not in the workshops in London and Manchester. This was to allow sufficient time in subsequent workshops to discuss the other topics in more detail.
It was clear from the discussions that the issue of how patient records can be accessed and who might have access to them did not initially have a great deal of saliency amongst workshop participants. There were a number of reasons for this confusion. Firstly, participants had limited prior knowledge and understanding of these issues, perhaps because many had good health and had had limited interactions with medical professionals. Secondly, as we often find in qualitative public sector research, participants assumed that health services are more joined-up than they are, with some suggesting that any healthcare professional could easily access patient records. Following this assumption some participants thought a wide variety of healthcare professionals were already accessing their records.

*Anybody can get hold of your medical information. Everything about you is on computers*

Newcastle #1

Finally, participants were often unaware that the healthcare team already looking after them might also be conducting the research.

Once the subject was explained in more detail most participants were happy with the option to allow members of the research team, as well as other groups, to trawl patient data. The key reason for this was that participants trusted healthcare professionals working within the NHS and felt they could all be trusted to prioritise the interests of the patients.

*Everybody in the hospital is concerned about my wellbeing and getting well: doctors, nurses and [pharmaceuticals]*

Newcastle #1

Participants were also reassured by the fact that patients always have the option of choosing whether or not they would like to take part in any research.

*I'd be happy [about people looking through my records] as long as I had the right to decline*

Newcastle #1

Finally, some participants felt that the ability of researchers and care teams to share information would ensure that patients’ care was more joined-up throughout the course of a trial.

Those participants who disagreed with the proposal did so because they were uncomfortable about their records being seen by anybody but their GP. In particular, there were concerned about too many people being able to access the more personal or embarrassing information that might be on patients’ records (such as their sexual health). They believed that a patient’s GP should only allow other professionals (such as members of the research team) to access their records if it was in the interests of the patients. Participants’ concerns around this issue may relate to a mistaken belief that health professionals would be looking at named rather than anonymised records as part of their trawl of patients’ records.
Unless your GP has recommended you, then I believe all this information should be held confidentially

Bristol #1

A small number of participants were uncomfortable about the impersonality of trawling through patients’ records. One participant was concerned that such a process would not involve “looking at patients as individuals”.

Participants were also concerned that a cursory investigation of patients’ records might not be sufficient to ensure that trial participants are healthy enough to take part. Participants were particularly concerned about trial participants’ mental health and wellbeing, with some suggesting that more nervous or vulnerable patients could be more easily manipulated into agreeing to take part in a trial that they do not feel comfortable with (see perceptions of vulnerable groups in Chapter 2 above). This view is likely to be based on the fact that many participants’ image of a typical trial was one that is high-risk (with the potential for a significant break-through), and only involving healthy patients (phase 1). Many participants were surprised to be told that trials can involve unhealthy patients, and may involve testing relatively small amendments to accepted practice as well as more high-risk studies.

Some participants were concerned about pharmaceutical companies accessing records: it was explained that this does not currently happen and there are no plans for this to happen.

3.2 Should participants have a mechanism for signalling a wish to participate?

Many participants, particularly in the Newcastle workshop, were keen to ensure that patients should have the opportunity to take part in trials that could potentially help them by allowing them to have access to new drugs and treatments. They believed that this could be managed by making GPs responsible for informing participants about any trials that they might be able to take part in.

Maybe the doctor should be responsible to make patients' aware of clinical trials as part of their remit

Newcastle #1

Others, particularly in Bristol, suggested that it would not be difficult for anyone (who was online) to find out about trials which were going on and so the onus could remain on individuals for finding out. Some participants had been asked to research trials in the gap between workshops 1 and 2 and reported back that they had not found it difficult to find some trials in their area. However, they had not searched for trials in particularly specific areas of medicine.

Some felt that there was already a process in place for matching potential participants with trials, but were hazy about who organised it or the details.

You get letters through the door if you have a specific illness from different companies offering you to test this or that

Newcastle #1
Some participants felt that the GP should certainly remain in the loop, because if they were to find out about trials from elsewhere they had little faith that their interests would be protected.

If I was sick maybe Alzheimers or something like that I wouldn’t like to hear someone just walk in my room and say hi there there’s a new drug blah blah blah. I would like to hear it from a doctor

London #1

One risk of placing the onus on GPs to recommend trials is that GPs may not have the time and resources available to manage this additional role.

3.3 Patient consent

Who should consent patients?

Participants had mixed views on who should consent patients to take part in health research. Some argued that GPs should take on this role, while others felt it should be managed by the research team. Those participants who favoured consent via GPs often had very positive and long-standing relationship with their GP. In contrast, some of the patients who disagreed with this view explained that they did not have a regular doctor but were assigned a different doctor every time they visited their local practice.

The principle reason for arguing that GPs should consent patients was the assumption that GPs are independent and impartial (assuming that they are not involved in the research themselves) and less likely than members of the research team to try to persuade patients to take a particular decision.

Doctors are more likely to give you impartial advice about the trial as they won’t benefit from the trial

Bristol #1

While many participants shared this view, one participant was concerned that GPs might be paid by pharmaceutical companies to promote their research, while others were concerned that GPs may have particular opinions about their patients taking part in health research that could make them more biased when giving advice.

Participants suggested that the fact that most people trust their GP meant that the GP would be well-placed to introduce the research to them, and reassure them that the research was legitimate and managed and funded by a reputable organisation\(^5\).

I would like my GP to be the first person and the last person I see personally. Not just some random person with a briefcase

London #1

\(^5\) It is worth noting that this discussion took place before the approvals system was explained to participants.
While GPs might not have specialist knowledge of the specific research area being investigated, many participants felt that their understanding of patients’ own health history and background would be advantageous as they would be able to consider the patient’s specific needs and background when advising them about the research.

Other participants suggested the research team should manage consent believing that they would have the expertise needed to provide participants with all the information required to make a decision.

**How should consent be sought?**

Participants were asked to look at typical patient information sheets that patients would see if they were asked to take part in a trial. The standard approach is to use a short summary sheet initially and if the patient is interested, they can be given a longer version with more detail. Some participants in each group were given a longer version of the information sheet while others were given the shorter version so that each break-out group could compare the advantages and disadvantages of each. It is worth noting that there was not sufficient time to allow participants to read the information sheets in detail. Instead, participants were asked to skim read the sheets and comment on their ‘top of mind’ thoughts about the sheet.

Participants’ views on the sheets varied considerably with some seeking very in-depth information and others stating they would be happy with a short summary. In addition, participants explained that their preference would depend on the context and their prior level of knowledge. In general, those who were most positive about taking part in research favoured less information than those who were more concerned about the risks.

> Assuming everything is OK I would not read the terms and conditions like on iTunes. I’d accept it all. There should be a summary “we don’t think you’re going to die”.

  Bristol #1

> I’ve actually done a study for a science park. I preferred the longer version to a shorter version. I prefer more info than less. I don’t think I would have done it if I got the shorter version

  Manchester #1

Most participants agreed that the information sheets were well designed and answered most or all of the questions that they might ask if they were taking part in a trial. They also explained that they thought that the information sheets were fair and did not appear to be hiding any information – although some would have liked to have seen more information before making a decision.

> It’s quite fair about some of the things that could go wrong

  Bristol #1

Some younger participants felt that the sheets could be formatted in a clearer way with a greater use of colour and pictures. There was also some demand for information to be available in different formats such as a DVD. The disadvantage with this is that additional formats would cost money.

Some participants explained that they would not agree to take part in any research unless they had been provided with full details of the research including summaries
of previous research similar research projects to help them consider the risks and develop their understanding of the importance of the research.

*If you had a real problem, you'd want to read everything even if it [seems] irrelevant*

Bristol #1

Participants did not hold strong views on the order in which the information sheets should be provided. While many of those preferring a shorter information sheet stated that they might not read a longer sheet, some of those preferring a longer sheet stated that they would not read a shorter sheet, as it would not be sufficient for them to make a decision.

**Who should advise participants about the trial?**

Participants did agree that the information sheets would need to be supplemented by a face-to-face conversation with a professional who could answer any questions that patients had about the research. Some suggested that the sheets could include or be supplemented by a document where GPs or other professionals could write up their answers to any questions that patients had raised in their conversations about the research. This would help the patients to remember and reflect on the answers they had been given in any previous conversations.

Some participants also explained that they would like to talk to patients who have been through similar research programmes. This would help them to understand more about what the trial is likely to be like in practice, and to consider whether they have any other questions that they would like to ask in advance of the trial.

*It’s more personal to have a discussion, the paper is more impersonal*

Manchester #1

**What information did participants want to see?**

Participants suggested a number of things they would like to be told about before agreeing to take part in a trial (see Chapter 2 for more details). In particular they suggested that they would like to know about any potential risks and side effects. Other issues included:

- practical details such as the timings and any expenses payments or incentives;
- methodological details such as whether a placebo is being used, and the chances of receiving a placebo treatment;
- whether a help-line or any other support would be available to patients;
- what is happening after the trial, and the length of time it might take for any new intervention to be used in the NHS
- how the results are likely to be used; and
- whether the results are likely to be published

Many of the suggestion were raised as a response to participants’ consideration of the three case studies. For example, participants raised a number of practical details when discussing Sam (who may have found the trial difficult to manage his school
work) and suggested that a help-line could be helpful in a counselling intervention (Sophie and Simon).

Some of this information is unlikely to be available at the time when consent is sought the UK’s national centre for public dialogue in policy making involving science and technology issues.

3.4 Advising participants throughout the trial

Some participants emphasised the need for patients to have access to information before providing consent and throughout the lifetime of the project. Patients were concerned that further information might be needed if patients were to make a decision about whether to continue participating in the research.

Some participants suggested that patients might need further reassurance at any time throughout the trial period. Some participants suggested that help-lines should be used so that patients could easily access help and information if they had any concerns. In addition, participants in Manchester suggested that patients taking part in the same trial could meet-up to share their experiences. This could help their own wellbeing and recovery and could reduce the risk of patients feeling “alone” throughout the trial period. This was considered to be particularly important for psychological interventions which might have an impact on research participants’ wellbeing.

There was some debate about whether a doctor who knows a patient and their medical history or the research team who knows more about the trial would be the best port of call for help and support, but most agreed there should be somebody.

You would need somebody who is actively involved in the trial so I know I'm getting all the information I need” - opposing the previous point about asking questions

Bristol #1

However, the more cynical participants called for an independent source of advice and support while deciding whether to take part in a trial, and for ongoing advice. One participant suggested a GP should refer patients to independent specialist professionals who would understand the specific research area whilst not being actively involved in that particular research project. Participants in Manchester suggested that an independent specialist should be available to fulfil this role. The advantage of these suggestions is that they could potentially ensure that research participants are able to talk to somebody who is has the knowledge to provide detailed information whilst still being independent from the research study.

You could ask a doctor if they know someone in the field for impartial advice

Bristol #1

An independent government advice service would be less inclined to have an interest in the research

Manchester #1
Chapter 4: Research Approvals Systems & Regulation

Key findings

Views on the current system

Do patients/public feel sufficiently protected by the current approval system?

- The current system was generally acknowledged as providing appropriate safeguarding of patients and there was some surprise about the degree to which patient safety is embedded in the system. The work of research ethics committees was also praised, although there was some debate about the ability of [uninformed] lay members to contribute effectively in this arena. In contrast to this, the duplication of effort, inconsistency of approach and delays within the research governance strand were mostly seen as unnecessary and avoidable, and with the potential to discourage important research from being done.

- Some participants did feel that there could of course be benefits to the currently bespoke approach to research governance, allowing for greater scrutiny at the local level and providing a second, frontline, opinion on research ethics. Clinical researchers mostly disagreed with this view, suggesting that such delays were typically a consequence of internal bureaucracy and administrative problems rather than a more considered approach to scrutiny.

What are public views on proposals to streamline the system for research approval?

Current system leads to considerable duplication of review and forcing researchers back though the system due to inconsistencies in responses. Proposed change is a single national review with an early assessment to identify problems

- The majority of participants believed the proposed streamlining of the research approvals process has the potential to tackle many of the problems identified with the current system noted above. Furthermore, most were enthusiastic about the HRA co-ordinating the process and believed this would improve efficiency without affecting patient safety. Most participants were also supportive of placing a time-limit on sites for research governance approval.

- A minority were sceptical about the streamlined proposal, however, suggesting that it might not work as well in practice as anticipated, or that it still fails to address some of the concerns about the current arrangements.

- The early assessment proposal in particular received mixed views. Supporters felt it would achieve the aim of freeing up Research Ethics Committees by reducing the time they spend considering poorly written research proposals where elementary mistakes have been made. It was also thought this has
potential to introduce further delay if the HRA is unable to dedicate sufficient resource to deal with applications swiftly. Clinical researchers typically thought this would be of little benefit to them, since the primary problem is poor quality student applications which should rather be dealt with by the academic institution before reaching the REC.

Annual reporting of research back to the ethics committee – proposed changes to reduce this but to put greater emphasis on the final report back to the ethics committee.

- Despite little prior or in-depth knowledge of the current reporting system, participants mostly supported the proposal to streamline the annual reporting system to one of regular ‘light-touch’ assurance with emphasis given to the final report. This was based on the perception that the proposals would reduce what is said to be unnecessary administrative burden and duplication, without loss of transparency and accountability.

- Participant suggestions for the annual assurance reporting included a combined Research Ethic Committee and local site report and more flexibility around the timings/ frequency of reporting depending on the research taking place.

- Participants agreed that the emphasis should be on the final report as this was the most important and the most likely to be read.

Researcher Passport – under current system researchers are assessed repeatedly. Proposed system would take account of a researcher’s track record

- Some participants were initially concerned that this would introduce a form of ‘elitism’, creating barriers for less experienced researchers to manage projects but this view was countered by clinical researchers. It was also felt important that those holding a passport would be re-assessed periodically and that accreditation could be withdrawn for ‘poor performance’. Views on administration of the scheme and criteria for evaluating researchers were beyond participants’ understanding of the issues within the dialogue setting.

What happens when a study is finished? HRA would like to see all studies published. They cannot insist on this but could put greater effort into chasing researchers for publications.

- For many participants research publication is seen as the key issue for patients and members of the public. Some argued for the principle of publishing all research believing it to be the ethical duty of researchers to do so, and the duty of the HRA or the Research Ethics Committees to ensure that research is published.

- In particular, it was variously felt that publication would improve transparency and accountability in research, encourage higher research standards, and lead to improved relationships between patients and the public on one side and researchers on the other.
• While many acknowledged that few members of the public would read published reports, there was still a call for publication so they can be read. Some called for audience-specific versions of each report so research findings are accessible to public and professionals alike.

• A minority did agree that it is not appropriate to publish all research. Those excluded could be very small studies and some student research with little potential public benefit associated with publication.

• Furthermore, some clinical researchers were concerned that universal publishing could have potential consequences for public health where data is misrepresented or poorly reported, such as the MMR vaccine scare which resulted in a decline in vaccination of children and subsequent rise in the incidence of these diseases.

• There was general support for the HRA having the responsibility [and enforcement powers] to encourage/ensure appropriate publication of research findings.

Methods Note:

This chapter describes the participants’ discussions in the reconvened workshop, which focussed on a series of proposals for amending the research approvals system and regulations.

Ipsos MORI facilitators introduced these issues using a combination of PowerPoint presentations (describing the current and proposed new approval systems), and handout slides (with slides describing the researcher passport, annual reporting and the publication of report findings). Each of the eight break-out groups discussed the current and proposed new approval systems and the publication of research findings. The researcher passport and annual reporting were both discussed in four break-out groups with each topic was addressed once in each workshop; this was to ensure there was enough time to discuss each issue in sufficient depth.

The clinical researchers were involved in each of these discussions and played an important role in bringing the facts to life by providing examples of their own experiences, explaining and clarifying issues, and providing their own thoughts on how some of the proposed changes could work in practice. The clinical researchers contributed to the dialogue and allowed participants to develop their views and understandings of the proposed changes and the current systems in place, and how these work in theory and in practice. Inevitably, clinical researchers’ accounts and explanations had a major impact on participants’ understanding of the different issues discussed. As a result, participants’ views were often directly based on the anecdotes they had heard. For this reason clinical researchers’ own views and experiences are discussed throughout this chapter alongside those of the participants.
4.1 The current system

Participants had very different starting points as a result of their own prior interest in, experiences with, and understanding of health research. While some took very little time to understand and discuss the merits and shortcoming of the current system and proposed changes, others struggled to fully understand these.

There were a range of views represented in each of the four workshops. Participants in London tended to be the most sceptical about the proposed amendments, while participants in Manchester and Newcastle were amongst the most positive. Bristol lay somewhere in-between.

In general, participants from all four areas believed that the current system safeguards patients and some explained that they were surprised by the extent to which the safety of patients is embedded in the current system. Participants were particularly positive about the work Research Ethics Committees do although there was some discussion around the involvement of lay members.

In contrast to this, most felt that the current delays and duplications inherent in the current system were unacceptable, with many believing that the current system is likely to be discouraging research. Some participants, particularly those in London, felt that the delays currently occurring may have some benefits as a slower process may allow for further scrutiny because they thought that a longer period to reach a decision implied a longer and therefore in-depth review. Clinical researchers disagreed with this view and suggested that in their experience delays in the current system happen as a result of bureaucratic and administrative problems rather than as a result of some local sites considering proposals more carefully than others.

Research Ethics Committees’ role in safeguarding patients

Participants generally had little or no prior awareness of Research Ethics Committees and the work that they do and were reliant on the information provided in the presentation, and verified by facilitators and clinical researchers within the event. The ethics committees were seen as having a vital role in protecting patients. All of the clinical researchers agreed that the committees played an important role in safeguarding patients and improving the quality of their research.

Some participants were concerned that there is a risk that committees and sites could be influenced by pharmaceutical companies who (like all researchers) have an interest in gaining approval for their research. Some of the participants in London (who were amongst the most sceptical about health research) were alarmed at the number of Research Ethics Committees in the country (76 at the time of the project) believing that the existence of so many might encourage researchers to seek to use those committees that are most likely to grant them approval. The clinical researchers involved in the research explained that this did not happen in their experience. Those participants concerned by this issue were largely reassured when it was explained that researchers would ordinarily use their local committee or be
allocated a committee by the HRA, and that the HRA has a role in ensuring that different committees require the same approval standards from researchers\(^6\).

There was some discussion around the use of lay members in ethics committees. Many participants did not know that lay members attended ethics committees, and expressed surprise. Upon being informed of this issue some participants were initially concerned about the use of lay members suggesting that lay people may not have the expertise to make decisions.

*It is a waste of time having lay people rather than people who know what they are talking about.*

Bristol #2

Participants’ concerns about lay people were based on the assumption that lay people would not have the experience and qualifications of professionals, and would consequently feel uncomfortable about taking part and becoming involved in the discussions. This view may have been influenced by the difficulties participants faced in learning a great deal of information in a relatively short period of time. Clinical researchers explained that in practice, many lay members of committees do have a particular interest in research ethics, and consequently may have greater levels of expertise than many members of the public.

Clinical researchers from all the groups were enthusiastic about the involvement of lay members in ethics committees and the wider research process and in some cases highlighted the practical benefits of having lay people involved. In particular, clinical researchers felt that lay members were often able to improve the quality of patient information sheets by confirming what patients are likely to understand. The positive experiences of clinical researchers reassured participants about the use of lay people on ethics committees.

*They* improved everything by thinking about how to explain things

Clinical researcher

Participants seemed to become more positive about the use of lay people in Research Ethics Committees when considering the ways in which the public can become more involved in the process of regulating health research (see chapter 5 for more details).

**Local research governance arrangement role in safeguarding patients**

Many participants commented on the existence of local research governance arrangements stating that this additional level of approval could provide further reassurance that the approval would only be given if research proposals were of a high standard. This view was based on the assumption that local sites currently check for similar things as the Research Ethics Committees.

*I really like the local approval sites because you have to go to the hospital and there is an extra check*

\(^6\) The role of the HRA was described in the presentation, but some participants asked for further clarification.
This view was (to some extent) supported by some clinical researchers who suggested that the local approval process could improve the quality of their proposals. One clinical researcher explained that she would like the channels of communication between sites and researchers to remain open while the approval process was taking place so that the expertise that exists in some local sites could be used to improve the quality of research proposals.

_Some local sites are very good … the research managers in some of the hospitals provide good advice_

Clinical researcher

Some of the more sceptical participants were particularly concerned that research could begin in one site when another had not given their approval as officers in the latter site could notice something that needs to be investigated.

Some clinical researchers and participants suggested that the fact that R&D approval is managed at a local level could be an advantage as the R&D managers involved may have specific knowledge about local circumstances that might not be available at a national level.

_It's still good to have local level input… things are different at a local level_

Manchester #2

While most participants were happy about the R&D approval process some sites were surprised that R&D approval was given at a local level and concerned that this could result in some sites having stricter criteria than others. Participants holding this view expected the NHS to work in a more centralised way.

Problems with the current system

While participants generally felt that patients were safeguarded by the current system they were concerned about the bureaucratic and administrative difficulties clinical researchers could have in seeking site approval.

_Sometimes it can take 5 years and sometimes it can take 5 months. It is a very haphazard process at the moment and very frustrating_

Clinical researcher

_Every time we went to look at something in more detail we had to go back to the main committee and down to local level_

Clinical researcher

Participants were often surprised about these problems and most were concerned that these may adversely affect patients (as potential new treatments may be delayed) researchers (as new research might be costly, slow and difficult to manage) and the British economy (as researchers might decide to conduct their studies elsewhere). In addition, some participants suggested that more junior researchers (in particular) may struggle to conduct research as a result of the complexity of the research governance process.

_It’s delaying potential life saving medications_

London #1
I feel relatively assured but the delay in the development of the drug concerns me
Newcastle #1

Participants were also concerned about the risk that the current system can result in researchers having to repeat administrative tasks by providing the same information in different formats due to the varied demands of sites across the country. Many were generally surprised that a single system was not already in place that would avoid the risk of this problem occurring, and some explained that they were disappointed when clinical researchers’ described the diversity that can exist between Trusts operating in the NHS.

Participants suggested a number of potential solutions for this problem including structural changes (such as the use of time-limits), an increased standardisation of the information that researchers have to submit to local sites, and representatives from local sites attending Research Ethics Committee meetings so that the ethics and governance arrangement could be managed together. Clinical researchers suggested the latter suggestion would be impractical, while the former suggestions have been included as part of the proposed new approvals system.

Efficiency, effectiveness and speed of approvals

Some participants, particularly those who were most sceptical about health research, suggested that the length of time needed to approve some research projects could be seen as a positive aspect of the current system, as it could help to ensure that the research proposals are thoroughly scrutinised and that no short-cuts are taken. This view was based on participants’ initial assumption that the additional time taken in some sites was a result of the site’s own higher levels of scrutiny, rather than the result of administrative or bureaucratic delays.

There could be good reasons for slowing things down, what about Thalidomide?
London #2

The clinical researchers disagreed with this view and provided participants with a range of examples highlighting the bureaucratic problems they had experienced including being asked for inappropriate safeguards, or finding that hospitals did not have sufficient resources to provide approval in a timely fashion.

It gets buried under a pile of paper and there is no regulation to get it signed
Clinical researcher

4.2 Proposed streamlined system for approvals

The HRA has proposed to streamline the approvals system with the aim of making it more effective. The key changes in the new system include;

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7 This is a common finding in qualitative health research as well as in our wider research within the public sector.
• an early assessment process to identify any problems in researchers applications;
• the HRA co-ordination of the process (including local site approval) with ethical approval and governance approval taking place sequentially rather than simultaneously; and
• a potential time-limit placed on local sites and the development of shared systems for gaining site approval.

The proposed streamlined system for approvals was discussed after the participants had the opportunity to discuss the current system and think about the benefits and drawbacks of the way that it works in practice.

Support for the proposed system

Most participants in Bristol, Newcastle and Manchester and some in London demonstrated some support for the streamlined system. These participants suggested that it has the potential to tackle many of the problems identified with the current system such as the delays and financial costs that can occur when seeking local site approval.

In particular, participants suggested that the new system could;

• be faster and easier to navigate;
• be less costly;
• allow for a greater differentiation between the roles of the Research Ethics Committees and Local Approval; and
• increase accountability.

They suggested that these changes would improve the approvals system and encourage more research to be conducted. Participants who supported the changes to the system believed that patient safeguarding would not be affected by the changes.

Scepticism around the proposed system

While no participants stated that the proposed system would be worse than the current one, a minority were sceptical about the proposal suggesting that it might not work well in practice or that it does not address some of the concerns participants had about the current arrangements.

In particular, more sceptical participants suggested that;

• a lack of sufficient resources in the HRA or at local sites could produce delays and bottlenecks;
• cultural change will be needed if local sites are to change the way in which they work;
• infrastructure problems (such as different IT systems) might make it difficult for sites to co-ordinate and streamline their approval systems;
• the proposed new system does not reflect their own priorities around increasing transparency and reporting research; and
- that the new system could lead to short-cuts being taken if there was insufficient time to consider proposals.

Participants in London were amongst the most likely to be sceptical about the proposal and many had mixed or negative overall views. Those who were most sceptical about the proposed system often considered the risks to individual patients as being more important than the potential wider benefits that the research could bring to society.

The following sections consider participants’ views of specific aspects of the proposed system.

**An early assessment**

The proposal suggests that a trained officer should consider each research proposal before it is shown to the full committee.

Participants had mixed views about this proposal. Those supporting it suggested that it could take pressure away from the Research Ethics Committees by reducing the time they spend considering poorly written research proposals where elementary mistakes have been made. Participants suggested that this would also allow committee members to use their time more effectively as all the proposals they look at would be of a good standard. Some clinical researchers supported this view arguing that the early assessment could potentially reduce the time spent managing the small proportion of submissions (6%) that get an unfavourable response.

Other clinical researchers did not support an early assessment process as (from their experience) there was no need for this additional step to be implemented as most researchers submit high quality proposals. When it was suggested that students and less experienced researchers might not always manage this, clinical researchers suggested that in their experience university supervisors would not allow poorly designed proposals to be taken to Research Ethics Committees.

Clinical researchers’ views and experiences of the early assessment had a significant impact on the views of some participants who were more sceptical about this recommended change than the others. Some participants were concerned that the early assessment placed a significant amount of pressure on the person who had the role of managing the early assessment.

> *It would [put] a lot of pressure to put on one person*  
>  
> London #2

Some participants were concerned that the person managing this job may not have the training or ability to manage the variety of different research proposals that are regularly presented to committees, or the time to look at each proposal in detail. For this reason, some felt the proposal could lead to bottle-necks. In addition, some participants suggested there would be a bigger risk of bias if a single person is looking at a proposal at the early stage of the approvals process rather than a full committee.

> *I don’t want just one person there saying what is fair and what is not*  
>  
> Bristol #2
Both of these concerns could be said to relate to a perception that the person giving the assessment would be making value judgements about the proposal rather than simply providing more practical recommendations for improving the paperwork and forms being sent to the committee. The precise role and remit of the person making the early assessment has a significant impact on participants’ views.

**HRA co-ordination**

The proposal includes an increased role for the HRA who would co-ordinate responses from local sites and any other approvals that might be needed. The ethical approval and local site approval would take place sequentially rather than simultaneously.

Many participants agreed that the ethical and local site reviews should take place in sequence rather than at the same time as this could reduce the risk of time-delays occurring if there were disagreements between the two bodies. Some suggested that this change could slow down the process for more straightforward proposals although this was not considered a significant issue.

Participants were generally more enthusiastic about the HRA co-ordinating the process of gaining local site approval believing that this could speed-up local site approval; particularly in the case of larger and more complex studies using a number of sites.

> [I like the] co-ordination of HRA over local sites [so they are] time-regulated and managed by the HRA

London #2

Some participants suggested that the HRA would encourage local sites to share best-practice and integrate their local site approval systems, consequently reducing waste and the duplication of effort.

Participants also suggested that this element of the process would help increase the differentiation between the roles of the Research Ethics Committees and local sites as ethics committees would be able to insist that the sites only look at governance issues rather than ethical issues.

> It's a lot clearer to local sites approval that they are not involved in the ethics at a local level which is good

Manchester #2

It was argued that this change could in turn increase accountability as there will be more clarity over the Research Ethics Committee’s and local sites’ responsibilities.

> It gives patients a clear body to go to in terms of ethics, there aren't local variations

Manchester #2

Those participants who were more sceptical of the proposed changes suggested that the HRA would need to have the resources in place to manage this additional role. If this did not happen a bottle-neck could occur with the HRA struggling to approve proposals on time.
I'm negative because of the [risk of] bottle-necks

Some believed that the proposals would not go far enough, and the continued existence of a local site approval process would mean that the problems with the current system would still remain as long as local site approval was sought.

The end problem is still the local site problem

A time-limit on local sites

The facilitators explained that a time-limit could be imposed on local sites to ensure that they check proposals on time. Many participants were in favour of this approach as long as local sites had the resources they needed to manage these additional demands. Some of the participants who approved the time-limit in principle were concerned that in practice it might take some time for local sites to be able to manage these new demands.

The paper model is perfect but there might be stuff to iron out

The implementation of the new system

Participants had some suggestions around the implementation of the new system.

Some of the more sceptical participants suggested that the proposed system should be trialed in some areas so that any teething problems could be rectified before the system is fully introduced.

Some believed that the proposed system should require researchers to publish all their results. The participants believed in not tackling this problem the proposed system did not respond to their greatest concern about the current system.

Some participants felt that the new system could go further in ensuring the local site agreement is not an impediment to research taking place. This would involve more centralised decision making. This view was made by those who were concerned about the differences that occur between different NHS trusts.

4.3 Annual assurance and reporting

At the present time researchers have to send annual reports to the Research Ethics Committees and the local sites where they are working. These reports are not always read and provide limited information. They also place an administrative burden on researchers. The HRA proposals include:

- a simple annual assurance system;
- reporting through a single online portal or email; and
- a greater emphasis on the final report.
The proposals were presented by the facilitators and hand-outs were given to participants to help explain the changes. The clinical researchers provided information on how these changes would work in practice. It is worth noting that participants had little understanding of how research is reported and the different mechanisms that are in place to report and monitor research. This meant that some participants may have had different assumptions around what the reports look like and how they are written.

In general, participants supported this proposal on the basis that it would reduce the administrative burden that researchers, sites and the Research Ethics Committee will have to face without reducing the transparency of the research.

Participants suggested that a combined Research Ethics Committee and local site report was a “common sense” solution that would be quicker to read, write and disseminate. Some suggested that patients might find this report more helpful if it was made publicly available.

Some participants suggested that introducing more flexibility around the timings of the report might be sensible. It was suggested that the frequency of the report could change depending on the research taking place. This view was suggested by clinical researchers who stated there was no particular need for reports to always be annual when other time periods might be appropriate;

*It shouldn’t [necessarily] be every year, just every period*

Bristol #2

Some participants felt the reports should all be public. Others suggested they should not necessarily be public if this placed an additional burden on the research team, and if there was a risk that the public could be confused by the report.

*By making it public… [and] opening it up to public scrutiny it might slow the process even more*

Manchester #2

Participants agreed that the emphasis should be on the final report as this was the most important of the reports to be published and the most likely to be read. The timings of the workshop did not allow a great deal of explanation around the different forms of publication that could potentially take place. This meant that participants had limited understanding around what would be published and the format and details likely to be published using different media.

### 4.4 The researcher passport

The HRA are considering centralising the existing researcher passport system for lead researchers who are involved in a number of studies. At the current time a researcher passport system is sometimes used at a local level and is not always accepted by other Trusts. Researchers with a passport may not need to be scrutinised as closely as those without as they would have a track record of high quality research. Participants were asked to comment on this approach.
Some participants were initially concerned that researcher passports could be ‘elitist’ as they could make it difficult for less experienced researchers to manage projects. Clinical researchers disagreed with this view suggesting that the passport would increase the efficiency of research proposals but would not be considered something that would be used to establish how experienced or good a researcher is. A clinical researcher explained that researchers working on larger projects would have less experience so might not have a passport but would still have a good reputation.

*I see it as something that facilitates rather than to boast about, you wouldn’t put it on your CV*

Clinical researcher

After some consideration, clinical researchers and participants supported the idea of a passport on the assumption that it was regularly renewed, so that poorly performing researchers could lose their passports, and would not act as a barrier to less experienced researchers managing projects. They believed that the passport could save time and a duplication of effort when research proposals are going through the approvals system.

*It would be good as long as it's continually reviewed*

Manchester #2

Participants’ lack of prior knowledge and experience meant that they had few ideas about how the passports would work in practice. Participants did not suggest a timeframe for renewing the passports but agreed with the suggestion made by a clinical researcher that a five year renewal period could work.

*I like it as long as they update it regularly like a 5 year as most projects take about 4 years*

Clinical researcher

One clinical researcher suggested that the passports should include some space to enclose continual professional development indicators that could be considered over time, and the group agreed that this also seemed sensible.

4.5 Encouraging research publication

Participants were asked to discuss whether all research should be published and how this should be encouraged or facilitated by the HRA, if at all. Facilitators and clinical researchers explained how publication has traditionally been managed in peer-reviewed journals, and how it can now been shared more easily online. It is important to note that many participants struggled to fully understand this subject as they had little prior understanding of how research could be published. As a result of this some participants tended mix up the concepts of releasing findings to participants, releasing findings to the general public, and of releasing findings to other researchers.

For many participants research publication was seen as the key issue for patients and members of the public. Some argued for the principle of publishing all research
believing it to be the ethical duty of researchers to publish their results, and the duty of the HRA or the Research Ethics Committees to ensure that research is published.

Research should all be published: because that would be the right ethical thing to do
London #2

Could you say that not publishing results is a violation of ethics because the whole process is making sure you protect people? If you have drug Y and it's not published that it failed for some reason and then you test it again and it harms people again
Newcastle #2

Shouldn't it be an ethical responsibility by the ethical association (RECs) to disseminate and share that information?
Newcastle #2

One of the key arguments for publication was that it would improve transparency and accountability in research. Participants suggested that asking researchers to publish their results would encourage higher research standards as more people would be able to consider the work that they had done.

Publication would make them have a better standard. If they published they would have someone to answer to
London #2

Patients and clinical researchers also felt that the publication of research would improve the relationships between patients and the public on one side and researchers on the other. One clinical researcher suggested that patients and the public should have access to all NHS research as in most cases they will have funded at least some elements of the research process through general taxation.

It helps the relationship between patients and the public
Clinical researcher

While many acknowledged that few members of the public would read published reports, most felt they should be published so they can be read if needed. In particular, some participants felt they would like to look up the available health research on a topic if they had been asked to take part in a trial.

If somebody in your family was unwell you would want all the details
London #2

For this reason, participants and clinical researchers in some groups suggested that two reports should be published for each piece of research; one that could be understood by the lay person, and a more technical report for professionals.

[you need] one that is geared to the average person, and … the next level up
London #2

Clinical researchers had mixed views about this; some were concerned about the administrative burden this would place on researchers, while others argued that it was already considered good practice to send an easy to understand summary of the report to any patients who have been involved in any trial.
Participants supporting the publication of all research suggested that with more research being published there would be less of a risk of research studies being unnecessarily repeated. This was a particular concern to those participants who were most worried about the risk that research might have on patients.

*It would stop duplication down the line*  
Manchester #2

If you are only publishing the positive results you are not giving the bigger picture  
Manchester #2

Some participants (particularly in London) believed that research publication would significantly improve their trust in health research and the approval system in a way that other proposals would not. When asked to discuss the proposed changes to the approval process participants argued that the new system would have limited impact (from their perspective) if the new system did not include a demand that all research is published so it can be read by the public.

*The issue of publication is more important*  
London #2

Other participants were less passionate about this issue. These participants felt that most research should be published in principle but were more likely to agree that some research should not be published if there was a good reason for this. One example where some felt publication should not be necessary is if the act of publication would be too bureaucratic compared to the potential benefit of publication. Participants felt that for small studies and some student studies there might be little public benefit associated with publication and the researchers may find that publication could take time.

*It would slow things down if researchers had to publish everything*  
London #2

In contrast, clinical researchers suggested that they would encourage their students to seek publication whenever possible as it would help them in their career.

Some clinical researchers were concerned that the publication of some research could mislead the public who may misunderstand the findings. They were concerned that patients and the public could misunderstand the research and this could lead to poor decision making. The scare stories that were published about the MMR vaccine were cited as an example of this.

*There are nuances in the way you display facts. You can put up results that show a tiny difference and make it look massive*  
Clinical researcher

Some participants agreed with this view while others suggested this reason was not sufficient to stop publication.

*It should be all published because information is knowledge; if you are educated you can make an informed decision*
Despite this reservation most participants were in favour of publication and believed that a government body such as the HRA should have a role to ensure that is happens.
Chapter 5: Public and Patient Engagement

Key findings

The HRA is tasked to protect and promote the interests of patients and the public in health research, what therefore should the HRA’s engagement with the public look like? To what extent should the HRA engage directly with the public/patients/participants in studies? How should the public influence the role of the HRA?

- A large majority of participants were positive about the idea of public and patient engagement by the HRA as part of its strategic decision-making. As health research is of significant importance and potential benefit to individuals and society at large, the broad view is that there is something of an ethical imperative to involve the public in this work.

- Additionally, people recognise there is currently a gap between public knowledge about health research – and trials specifically – which affects the extent to which people trust the system and would be willing to participate in research. Wider engagement by the HRA is seen as one way to bridge this gap.

- Views were mixed concerning where the HRA’s emphasis should be in terms of who it engages with – the public, patients or people who have been involved in health research.

- There was very limited discussion about the mechanisms for engagement people would prefer or support. Even when pressed and given examples such as the proposal for a panel, participants could not sufficiently conceptualise what this might look like.

- While generally the view was that a cross section of society should be engaged, there was also mention of the importance of involving people with experience of trials.

- A small minority said that for them, the lay members on Research Ethics Committees were adequate representatives of the public perspective and could continue to provide public opinion by proxy.

- Overall, a large majority of participants were positive about the idea of public and patient engagement by the HRA and felt this would inform and communicate the work done around clinical trials, as well as increase transparency and trust in the system.

- It is worth noting that while participants see engagement as important, they were unsure whether they, or others, would ultimately make the time to attend – with some suggesting that expenses should be paid while others suggesting a ‘jury system’
Methods note:
In moving on to this part of the discussion Ipsos MORI facilitators summarised the HRAs approach to public and patient engagement. It was explained that part of the HRA’s remit is to ‘protect and promote the interests of patients and public health research’. The HRA has a limited history of engagement with patients and the public but does have some contact with members of the public through the organisation’s relationship with the lay membership of the Research Ethics Committees.

The HRA would like to engage with patients and the public on an ongoing basis to inform the development of future policies. Participants discussed the option of there being a panel of patients and members of the public who they can draw on to work with the HRA at different points as the need arises. This was presented to participants who were then asked their views on the extent to which it is appropriate for the HRA to engage directly with the public, and what they think the HRA’s engagement with the public should look like.

5.1 Level of support
A large majority of participants were positive about the idea of public and patient engagement by the HRA as part of its strategic decision-making. As health research is of significant importance and potential benefit to individuals and society at large, the broad view is that there is something of an ethical imperative to involve the public in this work.

*They should use the public because it affects the public so therefore the public should be used*  
Newcastle #2

*Yes because we are paying for it …and we’re the guinea pig*  
Bristol #2

Additionally, people recognised there is currently a gap between public knowledge about health research – and trials specifically – which affects the extent to which people are perhaps willing to participate in research.

*You always get people saying ‘we’re left in the dark and we never knew’ so it’s good to get people involved*  
Manchester #2

*It’s useful to publicise … to inform … talk to people directly…in a language they understand … and communicate it’s not all about side effects*  
Manchester #2

*You get better ideas about communicating it to the general public and socialising people of the street*
It was also felt that greater engagement of the public and patients by the HRA would help to inform and communicate the work done around clinical trials, and would thus increase general transparency and trust in the system.

*It's actually showing there is a system. The more people who get educated about it the better*

Newcastle #2

*It would make me trust it more*

Bristol #2

*It builds trust in the system and the NHS. And it would make people feel that the NHS is working for the public*

Manchester #2

### 5.2 Who would best represent the ‘public’ perspective?

**Public, patients or research participants?**

Views were mixed concerning where the HRA’s emphasis should be in terms of who it engages with – the public, patients or people who have been involved in health research. While generally the view was that a cross section of society should be engaged, there was also mention of the importance and greater relevance of people with experience of trials.

*All walks of society*

Bristol #2

*They could get the opinion of the man in the street*

Newcastle #2

*I think that patients who have been through a research trial could also offer useful insights, they could identify weaknesses in the system better … I feel as though I wouldn’t be able to comment*

Manchester #2

*Patients who’ve been in research studies would bring a different dynamic*

London #2

*Wouldn’t you want someone with experience of disease to be on a panel?*

Manchester #2

*… especially people who have been in hospital for extended periods*

Bristol #2
I think it’s important to have people who are not medically trained... they have tunnel vision. We need to have other people who can think outside the box

London #2

A small minority said that for them, the lay members on Research Ethics Committees were adequate representatives of the public perspective and could continue to provide public opinion by proxy. One or two preferred delegation to experts in this specialised field.

Normal people will not have so much weight where knowledge is concerned

London #2

5.3 Mechanisms for engagement

There was very limited discussion about the mechanisms for engagement people would prefer or support. Even when pressed and given examples such as the proposal for a Panel, participants could not sufficiently conceptualise what this might look like.

Patients are important and maybe different panels for different types of medicine

Newcastle #2

Panels of people is difficult on a regular basis. But maybe a questionnaire would be better

Newcastle #2

However most were not clear what a panel would actually be like, and asked numerous questions of facilitators concerning what this might constitute in terms of numbers, subject matter, required knowledge, frequency of contact, types of involvement and so on. This suggests that the detail will be important in driving involvement. Few were overtly supportive of participation in deliberative workshops similar to that they had taken part in, though most acknowledged they had enjoyed the process and learned a lot. Some were concerned that even long, reconvened sessions were not enough to give an informed view on a subject.

Furthermore, while participants see engagement as important, they were unsure whether they, or others, would ultimately make the time and effort required to participate if voluntary and unpaid. On this basis, some suggested that expenses should be paid while others suggested a ‘jury-style system’.

With a voluntary system people will always find that they don’t have time – they have to do babysitting instead or something

Newcastle #2

There was some debate in Manchester as to whether those involved should get some form of expense payment. While some participants wondered if this may bias views, others thought it would be necessary to get people to attend.
If you pay someone are you going to get the true views or are they just doing it for the money?

... People would have to take a day off for it

... Reality of life is that you have to pay people for it

Ipsos MORI’s wider research into the publics’ attitudes and behaviours around involvement in policy decisions suggests that only a small proportion of those who show an interest in becoming involved attend events. On a national level this can still equate to a large number of people getting involved.
Chapter 6: Increasing trust in the HRA and in health research

This chapter considers the public' perceptions of trust and risk in the HRA and in health research more generally before considering the things that need to be in place to increase patients' trust in the organisation and the way that health research is managed. The chapter draws on findings from each stage of the workshop.

Key findings

To what degree do the public and others trust their doctor, charities, NHS, Academia, Pharma to protect their interests in research?

- The public currently does not understand the interconnected relationships between those funding research and those undertaking research. In other words, there is currently no substantive recognition that regardless of whether research is funded by the NHS or a pharmaceutical company, or a health charity, most of the research is done within the NHS by NHS staff.

- The NHS and NHS staff are very highly regarded and are trusted to protect public health and well-being above other considerations. Overwhelmingly, participants want to take the advice of their doctor in deciding whether to participate and trust him or her to protect their interests. This trust extends to a wider NHS care team.

- In contrast, pharmaceutical companies are seen as having vested interests in the conduct of research, and as a consequence cannot be trusted to behave ethically. Making a profit is often seen to be mutually exclusive to the aim of benefiting patients or advancing long-term healthcare.

- Few participants are aware of the role of charities and academia in health research, even when prompted for their views on these. It is worth saying, however, that charities and academic institutions are not distrusted, unlike pharma.

What are the perceived risks for individuals agreeing to participate in research? (Differentiating between different types of research)

- Most participants acknowledged that society benefits from most, if not all, health research. In this sense, most agreed that health research should be supported and encouraged.

- As individuals, participants had mixed views around the personal risks that they might face in participating in research trials. Most participants believed they would make choices based on their perceptions of the potential costs and benefits of the trial to them as individuals, with the potential societal benefits being a less important factor. They were therefore keen to eliminate or minimise safety risks, and ensure that the best care and information is available to those participating, both during and after the trial.

- For some groups in society, health research is perceived to be particularly risky. The most vulnerable groups are perceived to need protection;
especially where a trial could be seen as a ‘last chance’ for effective treatment for the terminally ill, or where a currently effective therapy is withdrawn in favour of a ‘less tested’ one. In these cases, safeguarding of participants is felt to be important.

- Spontaneously, most participants’ top of mind concept of clinical trials were mostly Phase 1 RCTs of new drugs. When presented with a range of other options and types of trials, participants felt that other trials (qualitative studies for example) were less risky. Trials which involved adding something new to an existing course of treatment were also not seen as risky. Surgical trials could be perceived as risky but this was largely because the mechanisms behind these trials were not well understood.

- Broadly, the more invasive the trial and the more lasting the side-effects or consequences of failure could be, the more risky it was perceived to be.

- Different individuals based their judgements of risk on differing criteria. The HRA may need to understand, respond to and reassure different constituencies within its key audiences.

- There is little knowledge of the HRA’s role as regulator for trials, though participants tended to assume upfront that regulation must exist.

- Trust is also affected by where participants get information from (personal experiences and the media) and can be increased when accountability for trials is given to a particular body. Perception of risk therefore decreases. There is tacit support for the HRA as an independent body to hold researchers and funding organisations to account, so long as it has the regulatory powers, reach and capacity to monitor and sanction where appropriate. As part of this, it is particularly important to maintain the independence of research ethics committees and the wider approvals process.

What would increase the public’s trust in the HRA and in health research?

- Evidence from the dialogue suggests that when informed about its value and conduct, there is a general call to bridge the public’s knowledge gap through improved information and transparency. Indeed, this is seen as an ethical imperative given its importance to society at large. Participants talked most about transparency when discussing patient information and the publication of results. Some participants suggested that the publication of results was key to increasing participants’ trust.

- Other important things that could maintain and increase the public’s trust in the HRA and research more widely included the HRA being held accountable for research standards and fully independent of research organisations. Participants suggested that patient wellbeing should be a key consideration at each stage of the research process and for all organisations involved in health research.
6.1 Trust

There is no universal definition of trust, but in the context of public services it can be linked with ‘confidence’ and ‘satisfaction’ in those services. In an Ipsos MORI report on the subject in 2004\(^8\), the point was made that the value of trust in public and professional life can scarcely be over-estimated:

*The establishment of trust amongst the public gives politicians a licence to govern; affords businesses loyal customers, employees and investors; journalists the chance to influence; charities the opportunity to raise money and so on. In short, it is a keystone of success.*

Seen in a more personal way, ‘trust’ can be construed also as a foundation of personal security and contentment.

*A complete absence of trust would prevent one even getting up in the morning*  
Niklas Luhmann\(^9\)

We need trust to feel comfortable about the people we live and work alongside, what we purchase, whose advice we listen to and who we vote for. It is no surprise then that different institutions and professions inspire varying levels of trust among the public. The chart below shows a recent poll of public trust in different institutions.

<table>
<thead>
<tr>
<th>Public trust in different professions/organisations</th>
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<tbody>
<tr>
<td>I’m going to read out some different types of organisations and professions. On a scale of 0-10 where 10 means you trust them completely and 0 means you don’t trust them at all, please tell me how much trust and confidence you have in each?</td>
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<table>
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<tr>
<th></th>
<th>2010 Mean Score</th>
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<tbody>
<tr>
<td>Doctors</td>
<td>7.7</td>
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<tr>
<td>Police</td>
<td>7.1</td>
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<tr>
<td>Charities</td>
<td>6.6</td>
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<tr>
<td>Social Services</td>
<td>5.9</td>
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<tr>
<td>Ordinary man/woman in street</td>
<td>5.6</td>
</tr>
<tr>
<td>Private companies</td>
<td>5.3</td>
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<tr>
<td>Banks</td>
<td>5.0</td>
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<tr>
<td>Your local council</td>
<td>4.8</td>
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<tr>
<td>Newspapers</td>
<td>4.0</td>
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<tr>
<td>MPs</td>
<td>4.0</td>
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<tr>
<td>Government Ministers</td>
<td>3.9</td>
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In our workshops, participants’ views broadly align with this overview. Though we did not ask specific questions about all these different types of organisations, our workshops reflect the poll. We found very high levels of trust in doctors and other health professionals in the NHS, more ambivalence about charities and academics (perhaps as a function of little understanding of their role in research) and overt

\(^8\) In Search Of Lost Trust. MORI 2004

\(^9\) Niklas Luhmann. Trust and Power(1979); John Wiley & Sons; Chichester. Accessed via online search April 2013
scepticism and even fear of pharmaceutical companies. Although the opinion poll data does not specifically identify pharmaceutical companies, private companies are undoubtedly viewed less positively than public services.

One of the key issues for the HRA in addressing public understanding and trust in health research is that the public currently does not understand the interconnected relationships between those funding research and those undertaking research. In other words, there is currently no substantive recognition that regardless of whether research is funded by the NHS or a pharmaceutical company, or a health charity, most of the research is done within the NHS by NHS staff. There is also little or no recognition for the ethical procedures they have to adhere to, or any positive role in the advancement of medicine.

If it’s run by a pharmaceutical company and not your doctors, I wouldn’t really want that

London #1

If there’s a pharmaceutical company involved… it’s like corruption

Manchester #2

There’s a difference between your doctor offering you a drug and a pharmaceutical company – they are trying to test the drug more than the doctor, who’s trying to get you better.

London #1

However, a small minority of participants did understand this relationship.

When you test new drugs and methods to make people better, I think that pharmaceuticals and doctors work hand in hand

Manchester #1

Furthermore, participants’ views on many of the detailed aspects of health research, particularly relating to informed consent and whether or not they would wish to be associated with a particular research study, but also access to personal data and publication of results, were very much shaped by the [perceived] involvement of different organisations; primarily NHS and pharma, but also charities and academia.

The average person has a lot more trust in the NHS than pharmaceutical companies [All participants in this group note their agreement]. ... The pharmaceutical companies are in business to make money. The NHS is just plodding along.

Bristol #1

Views on the NHS and its staff

Positive views on the NHS as a national institution and at the local level are well documented, so it is no surprise that participants spoke highly of the NHS throughout the discussions.

It’s an institution. No one has an NHS like ours. Greatest social achievement of the modern world

Bristol #1
GPs were particularly well trusted, but the public also trust their wider care teams at hospitals.

Many participants expressed the belief that above all the NHS exists to protect public health and well being, and that it is inherently protected from financial and commercial interests. Therefore, most people believed that doing a clinical trial under the auspices of the NHS would mean that the patient’s interests would be automatically protected.

*Hospitals have so many regulations. They wouldn’t put the public in danger to get a few quid*

Newcastle #2

However, there was seen to be some overlap between the NHS and pharmaceutical companies and a feeling that pharma has too close links with GPs. Consequently, despite generally positive views of GPs’ approach to patient welfare, for some participants GPs are not seen as untainted by financial motives.

*It’s a confusing situation. Is he [GP] in it for money? Can you still trust him?*

Manchester #1

*A lot of these doctors are getting under-the counter incentives to prescribe particular drugs. E.g. pharmaceutical companies were giving out holidays to Las Vegas!*

Bristol #1

*Most GPs have pens and penknives from the pharmas*

Newcastle #1

This gives rise to a reflection that the recent shift in Government policy to local commissioning of health services through Clinical Commissioning Groups (CCGs) has the potential to exacerbate the perception of too close-ties between GPs and pharmaceutical companies and therefore to undermine GPs’ ‘trustworthiness’ in respect of patient access to clinical research trials and treatment options.

Overall, many participants expressed the view that the NHS should be ‘run as one organisation’ and protected from any financial considerations which, they feel, could potentially clash with the best interests of patients. So, all of their views on trust in any healthcare regulation system are mediated by this wider belief.

*I just feel disappointed that I can’t regard the NHS as unified.*

Bristol #2

**Trust in patient confidentiality**

There were mixed views about the level of trust participants had concerning patient confidentiality in the NHS, particularly as it relates to identification of patients via their records for possible participation in health research.

*Patient confidentiality is very strict in the NHS. I’m confident that my treatment is kept confidential*

Newcastle #1
Similarly, several participants reflected on local GPs’ or the NHS care teams’ knowledge in relation to potential new drugs that may be trialled. Some felt that they might not be best placed to provide appropriate advice and information to patients.

\[
\text{How much do NHS teams know about new drugs? That would be a problem as they won't necessarily be up-to-date, so that might not help} \\
\text{Newcastle #1}
\]

\[
\text{I would see my GP for general advice - about the general process of a clinical trial – but would need a specialist to find out about specific information} \\
\text{Newcastle #1}
\]

**Views on the pharmaceutical industry**

In contrast to the NHS, pharmaceutical companies are seen as having vested interests in the conduct of research, and as a consequence cannot be trusted to behave ethically. Indeed, making a profit is often seen to be mutually exclusive to the aim of benefiting patients or advancing long-term healthcare. This view was not just expressed by participants, but underlined by at least one of the clinical researchers.

\[
\text{Medical trials shouldn't just be for making money, but for the future health of people} \\
\text{London #1}
\]

\[
\text{What is happening is that the pharmaceutical companies will [do a lot of research abroad], because it's all about the money} \\
\text{Clinical researcher}
\]

Even if charities or the NHS were to be involved, the fact that a commercial company might be providing the actual [drug] therapy to be tested was seen as not being in the interests of patients.

\[
\text{I don’t think that they’re making the drugs themselves. There’s like a company that’s providing the pills for them or making them. So whoever is involved they will be incentivised by the pharmaceutical companies to make the drugs.} \\
\text{London #1}
\]

Participants noted a range of unethical practices they believed could be a consequence of participating in a ‘pharma-led’ research study as opposed to an ‘NHS-led’ one, such as cheating the system:

\[
\text{Could a drug company try and spot something [referring to loophole or weakness in the approvals process] to push something through an easy way?} \\
\text{[A Clinical researcher then agreed with this perception] Yes ... it’s worrying} \\
\text{Manchester #2}
\]

or biasing research findings to hide ‘bad’ data:

\[
\text{I was worried that if it is funded by a company, that would have an influence on the research} \\
\text{Manchester #1}
\]

\[
\text{Pharmaceutical companies just need to protect their own interests.} \\
\text{Bristol #2}
\]
Some participants did become more conciliatory towards pharmaceutical companies as the discussion progressed and participants became more knowledgeable about the ways that pharma and NHS can work together. However, this remained a minority view.

*It doesn’t matter who is funding the research if you’re dealing with the NHS day-to-day. It depends on the reputation of the company. If it’s good, it doesn’t matter*

London #1

That said, people do not necessarily consider efficiency to be a crucial consideration. In their final summations, participants drew a distinction between the supposed efficient new process, and the current process, questioning the loss of local input and rigour as a consequence of ‘streamlining’. This again reflects what we know about public trust in organisations more generally; that irrespective of perceived inefficiencies, people tend to trust public bodies more because of their public focus and greater perceived accountability, whereas the potentially more efficient private sector are seen as less publicly accountable but instead governed by the needs of shareholders.

**Views on large medical charities and academics**

In contrast to well formed, (though often inaccurate) views on the NHS and pharmaceutical companies, few participants understood or commented on the role of large medical charities in health research.

*Charities supporting trials have no need to know any details ... about the participants of the trial, even in selection*

Newcastle #1

*I didn’t even know charities did research. What research would they do?*

Bristol #1

There was also minimum discussion around the involvement of academics in research, with participants struggling to differentiate between academics and the public sector.

**6.2 Perceptions of risk**

Perception of risk is a challenging area to debate and recent behavioural theory reveals that individuals are often bad at calculating and discussing personal risk as it pertains to themselves and others.

In these workshops, participant views on the risks of participating in trials were somewhat contradictory and often changed over the course of discussion. Dialogue participants were challenged throughout to offer their personal view of ethical considerations and expectations of the approvals process, and at other times to take the position of informed citizen and consider the benefits for society. Often, these different perceptions of risk contradicted one another.
Many people could see the value of health research at the societal level, and felt it was broadly not risky, irrespective of the potential risks to the research subjects.

> Whether negative or positive, the result is good in the end as the whole point is to know what happens... Even if it ends in the death of a patient, it might benefit people going forward

Newcastle #1

However, some groups were seen as particularly vulnerable, especially the elderly, those with serious or critical conditions, or children who were ill. For these groups trials were seen as more risky.

> There does seem to be a crisis now in older people just swallowing pills willy nilly which is making their condition even worse if they’re not monitored. I am a bit suspicious about who is to gain from all these pills being given to old vulnerable people in the community

London #1

Participants refined their ideas around risks when considering the three case studies. Some suggested that older patients (such as Karen in the case studies used in the discussions and which are appended) might be pressured in to taking part in a research trial. Participants were also concerned that patients with mental health problems or who had suffered from a traumatic event (such as Sophie and Simon) might be too vulnerable to take part in a qualitative research project.

There was some contradiction here, as many believed that very ill people should do trials (“it’s a benefit to people with incurable diseases to be in a trial, and a benefit to the rest of society”) but, being very ill, they might be more vulnerable and take a decision against their best interests (“It’s unacceptable to offer people trials at the moment when they are most desperate for help with their illnesses”).

When weighing up the risks to them personally, participants focused on the costs and the benefits to themselves. Most imagined that they would be well placed to weigh up theses costs and benefits, thus making the decision process not risky. The onus here was on eliminating/minimising safety risks and ensuring the best care is available to those participating.

> If you’re ill you want to get better and you’ll try whatever it is to get better. You trust your doctor to tell you the information if you’re fit and healthy … you wouldn’t risk your health unless there is a reward

Bristol #1

Some participants stated that they would never take part in a research trial unless they believed that their life was at risk. This may be partly a result of participants’ image of research as being high risk.

> If you’re talking about a life threatening illness, I would take any opportunity. Everything else is irrelevant. If someone gets offered a trial, I think they’d be very lucky. They’d be foolish not to take it.

Bristol #1
Unless it’s a life-or-death situation I wouldn’t want to take part. I really believe in it. It’s great if somebody else does it, if it’s for medical advancement, but I wouldn’t do it.

Manchester #1

I wouldn’t do a trial unless I was going to die, then I might.

London #1

Participants considered the following areas of personal risk, about which they felt they needed to be informed in order to judge the riskiness of a trial.

- Taking up time – how long will the trial last?
- Payment – how much will I get, and will this compensate me if there are any side effects?
- Opportunity cost – what other effective therapies are available for my condition?

Newcastle #1

Asthma is relatively well controlled unless you’re chronic. To enter into a trial may not be beneficial and actually make your particular illness deteriorate.

London #1

- Expertise and experience of the trial team
- Performance of the therapy or drug in previous trials – how many previous trials have there been, and what are the sample sizes?

Newcastle #1

I’d ask “Is this the first trial you’ve done?”

- Risk of being left out on a limb without being treated for any side effects or mistakes – whose care am I under? What aftercare is there?
- Risk of benefiting from a therapy, then the therapy is withdrawn after the trial – risk of being in a worse position than before.

When considering different types of trials, those trials which involved adding something new to an existing course of treatment were not seen as risky. Surgical trials could be perceived as risky but this was largely because the mechanisms behind these trials were not well understood.

Bristol #2

Hang on, surgical trials? The surgeon would have to just pretend to operate. Well I’ve had a replacement hip – are you saying that maybe I didn’t have one after all and it was just a placebo hip?

Qualitative studies were seen as potentially upsetting to participants particularly if they included sensitive subject matter (such as bereavement) or involved vulnerable audiences (such as those with mental health problems or who had suffered from trauma). In contrast, drugs trials were seen as being risky in a different way. Broadly, the more physically invasive the trial and the more lasting the side-effects or consequences of failure could be, the more risky it was perceived to be.
As noted above, while some criteria are universal when considering personal risk it is also important to note that different people, and different sections of society, will base their judgements of risk on different criteria. Consequently, a secondary challenge for the HRA is to understand, respond and reassure different constituencies within its key audiences.

6.3 Increasing trust in the HRA and the research process

Participants suggested a number of things that could be done to increase the publics’ knowledge of and trust in the HRA and health research generally.

Information provision

It is clear from this research that the public is under-informed about health research and the HRA both in terms of how research is managed and the ethics and approvals systems used.

Participant’s initial knowledge of health research was largely based on their own experiences and those of their friends and media stories. Those who had some experience of taking part in research studies often had greater knowledge about the processes involved but in some cases were still confused about specific elements of the research such as the use of placebos. Participants also recognised that the media can often exaggerate stories or only present the more headline grabbing stories in a way that can distort the public’s understanding of health research and regulations.

*I’m very concerned about the poor quality of health and science reporting in the news which prevents people from understanding clinical trials. Attention grabbing headlines with lack of evidence to back up could put people off from taking part*

Newcastle #2

When discussing health research in general and before introducing the HRA, there was no spontaneous knowledge of the HRA’s role as regulator for trials. However, some participants did assume that regulation must exist.

*Surely there’s a government briefing on safety of trials, there must be a set standard*

London #1

*I would assume there would be safeguards*

Newcastle #1

Others still needed reassurance and were surprised by the extent of safeguarding currently in place, particularly around approving research proposals.

*Are the doctors involved fully qualified and of good calibre? Not struck off doctors!!*

London #1

*It’s very thorough*

Newcastle #1
Evidence from the dialogue suggests that when informed about its value and conduct, the public recognises the need to bridge the gap between low levels of knowledge as a way to encourage people to participate as research subjects. Furthermore, enhancing public knowledge about health research is seen as an ethical imperative given its importance to society at large. More information and openness at every level is seen as key.

When talking specifically about engaging potential participants in research, again communication is seen as vital. In this respect, the basic aspects of communication such as source, tone, style and presentation of patient information sheets can be significant. Given varying needs and expectations among different people, these nuances will be important yet most likely difficult to get right.

Transparency

Participants considered transparency to be an important element in building public trust in health research as there is a reliance of members of the public to take part in research, and the public often has a role in funding research, and will be affected by the results. Some of the more sceptical participants suggested that their own lack of knowledge around health research had made them less likely to trust health research.

*I think by not giving people information it does breed suspicion.*

London #2

Participants discussed transparency in terms of enabling potential research participants to make the correct choices when deciding whether or not to participate in a trial. While some participants were happy to initially receive summary information, others explained that they would like to have full details of the trial provided in a format that they could understand. For example, some participants explained that they would want to know about the background and history of the trial, details of the research team managing the trial and the results of any similar trials that had taken place in the past. Participants also explained they would like information about what would happen to them on the trial and what potential side-effects they might expect. As participants became more informed about health research the amount of information that they believed should be available increased.

*People who would want to do [research] might want to look at past projects and their findings before they get involved.*

London #2

Most participants supported the publication of all or most health research (with some discussion around the practicalities of publishing smaller projects such as those managed by students). While there was some confusion around how reports could be published participants agreed that the publication of research could increase accountability in the research process by demonstrating transparency.

*I don’t know if many people would want to read it, but I am sure some would. It is about trust.*

Manchester #1
I am quite sceptical at the moment [about research] if there is transparency [publication of the results] I will trust it more.

Manchester #1

Accountability

Participants considered transparency to be an important element in building public trust in health research as there is a reliance of members of the public to take part in research, and the public often have a role in funding research, and will be affected by the results from all the workshops emphasised the importance of accountability in the research approvals process. In particular, participants’ trust in health research was largely based on the assumption that an organisation (the HRA) would continue to be responsible and accountable for overseeing health research.

When discussing the new proposals around regulation, participants were keen to understand how the HRA would implement and enforce elements of the proposals for the new system. Particular examples include:

- enforcing governance decisions in the 30 day time frame
- fining those not compliant with requirements for publishing
- monitoring and revoking the proposed researcher passport
- deciding whether or not to progress an application overall, or to demand further revision.

Some participants felt that the HRA’s enhanced role in the proposed new system could increase accountability as a result of there being more clarity around the role of the research ethics boards and local R&D approval. On the other hand, some participants were concerned that the HRA might not have the resources needed to manage this enhanced role. In particular, participants and clinical researchers were concerned that the early assessment, co-ordination of local site approval and enforcement of approval deadlines could be resource intensive. Several clinical researchers raised the question of whether the HRA can enforce local health authorities or whether they rather needed to play a persuasive role in managing the process and developing best practice.

Protecting patient well being

Throughout the workshops participants were concerned that the system places patient well being at its core. While there was a great deal of trust for research funded by the NHS, participants suggested that there was potential conflict of interest between a research team wanting to get the best results and patients on board and what is the best thing for patients, particularly the more vulnerable or more seriously ill.

In some cases participants’ suggestions went further than current practice. For example, some suggested that potential research participants should have access to independent advice from a qualified specialist not working on the project to enable them to come to an informed decision about consent. In addition, the public would be
reassured by measures to ensure the personalisation of care where appropriate. In the workshops, suggestions were made for research participants to have access to a ‘helpline’ or support group who could support them throughout the process. Participants also stressed the HRAs role in reassuring research participants about their well-being during and following a trial. It seems that while people accept there may be consequences to participating in a trial, be it negative side effects or psychological impacts, they need to know there would be adequate redress and support post-trial if they needed it.

**HRA has got a role and a responsibility to the participant**

Bristol #2

*It’s important that they are told that there will be aftercare whether you’re on the placebo or the trial drug*

London #1

**Independence**

Independence is another important facet of public trust in health research and the HRA. As such, there is tacit support for the HRA as an independent body to hold researchers and funding organisations to account, so long as it has the regulatory powers, reach and capacity to monitor and sanction where appropriate. As part of this it is important to maintain the independence of research ethics committees and the wider approvals process. Participants were particular concerned that the HRA (and the approvals process) remains independent of pharmaceutical companies reflecting their concerns that pharma might not always put the interests of patients first.

It is interesting to note, however, that while participants valued the role that an independent regulator could play, they were not concerned that it was an organisation that they had necessarily heard of. To a degree there was a blind faith that if the HRA were to perform this role they would do it properly.

**Consistency of approach**

Another overall duty of the HRA is to ensure *consistency of approach* across the system. This would be reflected in several ways, not least through its main proposal to streamline the research governance process and protocols by taking a central co-ordination role for seeking site-specific approvals and enforcing the time limit for such approvals.
Chapter 7: Conclusions

It is clear from this research that the public is under-informed about health research. However, evidence from the dialogue suggests that the when informed about its value and conduct, the public recognises the need to bridge the gap between low levels of knowledge as a way to encourage people to participate as research subjects. Furthermore, enhancing public knowledge about health research is seen as an ethical imperative given its importance to society at large.

To have trust in the approval system, the public expects patient well-being to be at its core. The current system is seen as providing many aspects of safeguarding that the public expects, however, there is a desire for greater access to independent and knowledgeable advice for patients throughout the process.

Participants consider another primary duty of the HRA to be ensuring consistency of approach across the system, and as such there is broad support for the proposals put forward to streamline the research governance process. Three out of four groups were broadly supportive of the concept of early assessment but one group were concerned that it would create another potential delay in the approvals process.

While most participants believe that the current system provides appropriate safeguarding of patients, many are concerned about the duplication of effort, inconsistency of approach and delays that can occur. For this reason there is support for many of the proposed changes based on the assumption that they would streamline the system without putting patients’ safety and wellbeing at risk.

The HRA’s task to protect and promote the interests of patients and the public in health research is an objective wholly supported by the public. Views are mixed however in terms of the extent to which the HRA can and should engage with the public about its strategic agenda, and then how this might be achieved.
# Appendix

## Appendix 1: Table of participants (by demographic group)

<table>
<thead>
<tr>
<th>Location</th>
<th>Attendees</th>
<th>Gender</th>
<th>Age</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>Bristol</td>
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</tr>
<tr>
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<td>London</td>
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</tr>
<tr>
<td>Manchester</td>
<td>16</td>
<td>9</td>
<td>7</td>
</tr>
</tbody>
</table>
Appendix 2: Case studies

**Case Study: Karen**

- Karen is 60 years old and has arthritis. This means that she is often in serious pain and can find it difficult to move around. Her painkillers have stopped working effectively, and she is looking for a treatment that is more effective.

- Her specialist at the local NHS hospital asked her to take part in a clinical trial to test a treatment that has not been tested in England before. She may be given a new form of medication or she may be provided with her usual medication and a placebo. Her doctor will not know whether she is receiving the new treatment or a placebo.

- The trial is going to take 2 years to complete. During this time she will have visit the hospital for regular check-ups. Her health will be carefully monitored throughout the trial period.

- She has been told that even if she feels better on the medication after the trial she will have to stop taking it until the medication is licensed.

---

Q. Should Karen take part? Why? Why not?

Q. What concerns would you have about the trial?

Q. What questions would Karen ask before deciding whether or not to take part?

Q. How would Karen feel if she is given a placebo treatment?

Q. How would she feel if the new treatment works but is not immediately available on the NHS?
Case Study: Sophie & Simon

- Sophie gave birth to a baby in Liverpool in 2007 but she had experienced problems in her pregnancy and the birth itself was difficult. The baby was ‘stillborn’.
- This was Sophie’s first child. She and her husband Simon were very shocked. Relatives helped them to organise a service for their baby’s funeral and every year Sophie and Simon attend a memorial service at the hospital to celebrate their child.
- In 2010 a local Psychologist employed by the maternity hospital is doing a PhD on the ‘Grieving process’ and would like to interview Sophie and Simon. The research would take the form of a qualitative interview, possibly up to 2 hours long to take place in their home.
- The Psychologist would write to Sophie and Simon in the first instance asking if they would be agree to be interviewed. He is planning on interviewing 20 other couples who have also lost a baby.

Case Study: Sophie & Simon

Q. Who should make the initial approach to Sophie and Sam? Who would have access to their records?

Q. If you were Sophie/Sam, how would you want that initial approach to be made?

Q. What consent process should be used for qualitative research?

Q. What are the risks of such a study?

Q. What are the benefits?
Case Study: Sam and his parents

- Sam is 13 years old and has had problems with re-occurring migraines. His doctor explained that while a number of drugs for migraines have been tested on adults, none of these drugs have been tested on children so doctors don’t know if they work as well in children, if they are as safe and what would be the right dose for children of different ages. So whilst the doctor can prescribe any of these drugs for Sam, they would like to find out more about the use of this particular drug in children.
- As part of the trial he might be given the drug being tested or another drug that is already on the market.
- The family have been told that Sam will have to take some two tablets a day over a six month period. He will also have to fill in a form so that the medical team know how he is feeling throughout the trial period. Sam will also have to attend the hospital several times to see how he is progressing. This might be difficult to manage around Sam’s school work.
- Sam and his parents have been told that the trial is being managed by a pharmaceutical company who manufacture the treatment.

Sam and his parents: Questions to think about

Q. Should Sam (and his parents) take part? Why? Why not?
Q. What concerns would you have about the trial?
Q. What questions would Sam and his parents ask before deciding whether or not to take part?
Q. How would Sam and his parents feel if he is given a placebo treatment?
Q. Does the organisation managing and funding the research matter or not? Why?
Appendix 2: Homework tasks

The homework tasks are enclosed overleaf.
Homework task 1

You’re the researcher!

Your name: (Please Print)

We know that the issue of health research – and in particular regulation of clinical research trials – has been a hot topic in the news recently. There have been articles on the TV news, on the radio as well as in daily newspapers and online.

Using the Internet, or any other resources you would like, find one or two news stories that have talked about health research and which interest you.

Tell us about one news story or programme you found interesting here.

- What did the headline say?
- Where did you find it? (e.g. Daily Mail online, BBC Radio 4 website, Metro newspaper)
- What were the main points in the article?
- What did it say, if anything, about the way the research had been regulated or approved?

Did you mostly agree or disagree with what the article or programme was saying? CIRCLE ONE ANSWER BELOW

MOSTLY AGREE
DISAGREE
NO OPINION EITHER WAY
MOSTLY

What did you agree with?

What did you disagree with?

Thinking about everything we have talked about in the session, make a list of any questions about the research you thought of when you were reading the article
If you found more than one article or news programme and would also like to tell us about that, please do that here.

Tell us about another news story or programme you found interesting here.

- What did the headline say?
- Where did you find it? (e.g. Daily Mail online, BBC Radio 4 website, Metro newspaper)
- What were the main points in the article?
- What did it say, if anything about the way the research had been regulated or been approved?

Did you agree or disagree with what the article was saying?

MAINLY AGREE NO OPINION EITHER WAY MAINLY DISAGREE

What did you agree with?

What did you disagree with?

Thinking about everything we have talked about in the session, make a list of any questions about the research you thought of when you were reading the article

Thank you!

Please hand this in to your facilitator at your next session
Homework task 2

You’re the Interviewer!
Your name: (Please Print)

We would like you to talk to a member of your family or a friend about their views on health research. We have written out some questions for you to ask them, but this is an opportunity for you to share what you know and also to find out what they know and think about it. It will be interesting to see if you have the same views or if they are different!

1. Do you know anything about health research that is done in England to test new drugs and new treatments with patients and members of the public?

CIRCLE ONE OF THE ANSWERS BELOW

- YES – A LOT
- YES – A BIT
- NO - NOTHING

If they don’t know anything or not much why not explain in your own words the main things you remember from Workshop 1, about what health research is and see what they make of it?

2. What do you think about this type of health research that is done with patients and the public to test new drugs and new treatments? What are the benefits? What are the drawbacks? Why do you say that?

Benfits ....

Drawbacks …
2. If you were asked to take part in a health research trial, what would you want to know about it before deciding if you want to take part or not?

Write down anything they say here, even if you disagree. Single words or phrases are fine.

I would like to know

3. Who would you trust to tell you about the pros and cons of taking part in a health research trial? Can they think of anyone other than their Doctor or Nurse?

Write down everyone they can think of even if you disagree.

I would trust...

4. Thinking about what you have been talking about, what do you and your friend or family member agree about when you are talking about health research trials?

We agree on ...

5. And what do you disagree about?

We disagree about

PLEASE COMPLETE THIS BEFORE THE NEXT SESSION AND HAND IT IN TO YOUR FACILITATOR
Appendix 4: Discussion Guides

Patient & Public Engagement in the Research Trial Approval Process
EVENT 1     Bristol/ Newcastle

<table>
<thead>
<tr>
<th>ATTENDEES</th>
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<tbody>
<tr>
<td>X 16 dialogue participants</td>
</tr>
<tr>
<td>X Ipsos MORI facilitators and note takers</td>
</tr>
<tr>
<td>X Observers &amp; evaluators</td>
</tr>
</tbody>
</table>

AIMS / DESIRED OUTCOMES OF EVENT
1. Participants acquire enough of an understanding of the research trials approvals process to discuss and form a view
2. Indication of their expectations, concerns and relative acceptability of core elements ('touch points') of the process
3. Setting the scene for more strategically focused discussion at workshop 2

BRIEFING PAPERS / MATERIALS ON THE DAY AS HANDOUTS
Delegate pack - badge, agenda, Clinical trials leaflet
Quiz questions
Quiz answers
Case studies

OTHER MATERIALS
Flip charts - 1 per room/ table
PowerPoint/ Multimedia
Signage
Participant incentives
Consent forms
Further information for facilitators - case study notes for facilitators and map (opposite)

Colour key
Lead facilitator task - usually in Plenary
Group working
Important note!
<table>
<thead>
<tr>
<th>Time</th>
<th>Task</th>
<th>Details</th>
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<tbody>
<tr>
<td>6:00</td>
<td>Arrivals and registration</td>
<td>PLENARY – LEAD FACILITATOR &amp; HRA</td>
</tr>
<tr>
<td>6:30</td>
<td>Opening session</td>
<td><strong>PLENARY</strong> – LEAD FACILITATOR &amp; HRA &lt;br&gt;  o Welcomes everyone, thanks for coming. &lt;br&gt;  o Housekeeping (toilets, fire, mobiles, most of us starting with minimal knowledge and everyone’s opinions valid and important)  &lt;br&gt;  o Introductions – Sciencewise, Steering Group, Evaluators, facilitators, then at tables  &lt;br&gt;  o Intro Presentation – why we are here today - framed in terms of approvals process and the balance between protecting patients/public and encouraging research; role of HRA, broad aims and objectives &lt;br&gt; Run through the <strong>agenda and how we will work today</strong> – important that you understand the topic so don’t be afraid to ask questions. This is a sensitive topic which touches us at a very personal level, so all need to be aware of people’s feelings.</td>
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</tbody>
</table>
| 6:45   | Quiz answers and discussion of topics covered | PLENARY **PARTICIPANTS TO WORK THROUGH QUIZ QUESTIONS IN PAIRS (APPX 5-8 MINS)** <br>  **LEAD FACILITATOR PROVIDES QUIZ ANSWERS AND ENCOURAGES SPONTANEOUS COMMENTS & FEEDBACK FROM PARTICIPANTS TO EACH**<br>  - Q1 ...[we don’t expect anyone to get this wrong. No follow up except answer B]  
  - Q2 Was anyone surprised by the range of treatments covered by clinical trials? What surprised you? Why? What do you think about this?  
  - Q3 Was anyone surprised by the fact that all of these people [except Dr Who, who is not human] .... What surprised you? Why? What do you think about this?  
  - Q4 Was anyone surprised by the fact that different types of organisation might be funding research that takes place in the NHS? What surprised you? Why? What do you think about this?  
  - Q5. Was anyone surprised by the fact that .... being tested as part of a research trial will not always be better than a treatment that is already being used to treat patients with the same illness? What did you think about the fact that isn’t always the case?  
  - Q6 Was anyone surprised by the fact that in a clinical trial your doctor will not know which treatment you would be given? What surprised you? What did you think about this? |
**What are clinical research trials and why important?**

7:05

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<tbody>
<tr>
<td><strong>PLENARY</strong></td>
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<tr>
<td><strong>GROUP WORKING</strong></td>
</tr>
<tr>
<td>Discuss with a neighbour for a couple of minutes, then as a whole group. Facilitator develops discussion -</td>
</tr>
<tr>
<td>o Do you know much about clinical research trials before today? If so, what? Where from?</td>
</tr>
<tr>
<td>o What did you think about them? Where did you get your impressions from?</td>
</tr>
<tr>
<td>o What came to mind when you were watching that film clip? What did you know? What was new?</td>
</tr>
<tr>
<td>o What surprised you?</td>
</tr>
<tr>
<td>o Was there anything you heard that made you worry? About yourself? About anyone else you know or think about?</td>
</tr>
<tr>
<td>o Do you feel you have any more questions so far?</td>
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<tr>
<td><strong>Facilitator:</strong> Make sure you capture their reasoning as well as answers to the question – why do they think certain things?</td>
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**Feedback and discussion**

7:20

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<tr>
<td><strong>PLENARY</strong></td>
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**Introduction to process**

7:30

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<tr>
<td><strong>PLENARY</strong></td>
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<tr>
<td>Here’s a reminder of the simplified outline of the trial process. For each step we’ll be explaining what’s involved and asking you to think about what you think needs to happen in order to safeguard patients without compromising the effectiveness and rigour of the trial. For this you’ll be working in 2 groups, each with a facilitator and a note taker at your separate tables</td>
</tr>
<tr>
<td><strong>HAND OUT LAMINATED PROCESS FLOW CHART</strong></td>
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**Step 1: Identifying patients to be approached to**

7:35

<table>
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<tr>
<td><strong>LEAD FACILITATOR INTRODUCES GROUP DISCUSSIONS</strong></td>
</tr>
<tr>
<td><strong>GROUP WORKING 1. PRACTICE OF IDENTIFYING POTENTIAL RESEARCH PARTICIPANTS THROUGH TRAWL OF PATIENT RECORDS TO IDENTIFY SUITABLE CANDIDATES</strong> – NOTE WE WANT SPONTANEOUS COMMENTS FIRST!</td>
</tr>
<tr>
<td>Spontaneous views on how people think this process currently works – ask them to work in pairs and feedback</td>
</tr>
</tbody>
</table>
take part in a research trial

- Who do you think takes part in trials?
- How do you think they are identified?
- Who do you think currently has access to patient information to assess who should be asked to take part in a trial?
- Which types of organisation are allowed access to patient information if they want to carry out a research trial?
- Who should be able to do this? Individual professional groups? Organisations?

Feedback and discuss around table

Currently anyone in a patient’s care team can access their records and identify suitable participants. A research nurse is not included as a member of the care team.

FACILITATOR PRESENTS OPTION CARDS DESCRIBING PROFESSIONAL GROUPS/ ORGANISATIONS WHO ARE/ COULD BE GIVEN ACCESS TO PATIENT INFORMATION TO IDENTIFY POSSIBLE RESEARCH PARTICIPANTS: NHS CARE TEAM; CLINICAL TRIAL NURSE/TEAM; PHARMA TEAM; ACADEMICS; CHARITIES 

NOTE: PHARMA TEAM CANNOT & WILL NOT BE ABLE TO DO THIS. DO NOT USE THE STIMULUS CARD HERE!

PARTICIPANTS CONSIDER IN PAIRS EACH TYPE. WOULD THEY BE HAPPY FOR THAT TYPE OF PERSON/ORGANISATION TO HAVE ACCESS TO THEIR RECORDS? WHAT SAFEGUARDS DO THEY EXPECT? UNDER WHAT CIRCUMSTANCES IS IT OK/ NOT OK FOR THESE GROUPS TO ACCESS PATIENT INFORMATION? CONCERNS ABOUT ANY OF THESE?

- For each one in turn, would it be acceptable or not for these people to be given access to patient information for the purpose of identifying potential research trial participants?
- Is there a preferred option or are some/all equally acceptable?
- Is there any group(s) who definitely should not have access to patient information? Why do you say that?
- Generally – when professionals are allowed access to patient information for this purpose, what safeguards do they think need to be in place?
- What would be your main concerns or questions about this process?

GROUP FACILITATOR: PROMPT IF NEEDED WITH KEY ISSUES: Trust; Patient confidentiality; Counter factual example – What if a patient had another unrelated illness or condition they would not wanted shared with anyone other than their GP/specialist?

GROUP SUMMARISES KEY POINTS OF CONSENSUS / DIVERGENCE TO FACILITATOR

7.50 15

Step 2: Placebo and

PLENARY LEAD FACILITATOR INTRODUCES THAT WILL NOW THINK ABOUT THE PLACEBO EFFECT AND BLINDING. THAT THIS IS AN IMPORTANT PART OF ENSURING RIGOUR OF THE TRIALS.
blinding

**PLAY VIDEO: THE PLACEBO EFFECT – STOP AT 3:20**

SHORT PRESENTATION TO CONSOLIDATE UNDERSTANDING OF PLACEBO & BLINDING

- Any questions?

**GROUP WORKING:** Discuss with a neighbour for a couple of minutes, then as a whole group.

Participants to discuss with each other their understanding of placebo, blinding, randomisation

- What do these terms mean? What do participants understand to be the reasons for/benefits of these?

**Facilitator develops discussion**

- What do these terms mean?

**PROMPT:** Do they understand that roughly half of all the people in a trial will not get the new drug/treatment and that the allocation to these 2 arms of the study is entirely random?

**PROMPT:** Do they understand that allocation is not up to the discretion of their doctor? How do they feel about that?

- What do participants understand to be the reasons for/benefits of these?

- What concerns do they have about the use of these?

**PROMPT:** Consider views on the ethics of whether or not the use of placebo might deprive someone of normal treatment OR whether a placebo could be used to show a new drug in a better light than existing normal treatment (these could happen without the role of REC)

**ALSO NOTE:** PLACEBO/BLINDING/RANDOMISATION ARE NON NEGOTIABLE ELEMENTS IN CLINICAL TRIAL DESIGN SO WE DO NOT WANT PARTICIPANTS DEBATING THIS PER SE.

DISCUSSION PICKED UP AFTER COFFEE BREAK IN INFORMED CONSENT/PATIENT INFORMATION SHEET
spontaneous
(appx 10 mins)

CASE STUDIES TO LAST 35 MINUTES. SESSION MUST END AT 9PM FOR PLENARY OUTPUT IS 5-POINT SUMMARY OF DISCUSSION TO HIGHLIGHT THEIR MAIN CONCERNS AND EXPECTATIONS RELATING TO INFORMED CONSENT ISSUES
- **KEY QUESTION FOR THIS SEGMENT** Who would you trust to answer questions/ give advice?
  - PROMPT Use show cards again if helpful
  - PROBE Why/ not?
  - **What would you expect to be told if you were being asked to take part in a trial? What would give you confidence? What would make you feel safe?**
    - PROBE: Expectations/ Needs/ Would like to have
    - PROMPT: Randomisation/Blinding/Placebo
    - PROMPT: Who’s funding
    - PROMPT: How long for/ What level/ Frequency of commitment/ Monitoring
    - PROMPT: Potential risks, side effects/ What happens after the trial
    - PROMPT: Do they expect it to be regulated? Is it important for them to know who would do this?
    - PROMPT: Other types of support (expenses)/ information (how many other people taking part)
      - **What if you couldn’t be told about X? Would you still trust the process?**
      - PROBE Why/ not?
      - **Would the consent process need to be different for different types of people or patients with different illness?**
      - PROBE Who would need a different type of approach? Why?

b. Patient
information forms
(appx 8 mins)

**FACILITATOR INTRODUCES SHORT PRESENTATION ON INFORMED CONSENT AS IT IS CURRENTLY INCLUDING BRIEF 'SHOW' OF PATIENT INFORMATION SHEETS (SHORT AND LONG VERSIONS)**

<table>
<thead>
<tr>
<th>session starts</th>
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<tbody>
<tr>
<td><strong>KEY QUESTION FOR THIS SEGMENT</strong> Here is a short/ long version of a typical consent form.</td>
</tr>
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</table>

**IN PAIRS CONSIDER AND DISCUSS EITHER LONG OR SHORT VERSION** [SPLIT ACROSS TABLE] TICK/ CROSS UNDERLINE ASPECTS THEY LIKE OR DON’T LIKE. SCRIBBLE NOTES BRIEF FEEDBACK TO GROUP. FACILITATOR TO COLLECT IN MARKED-UP SHEETS. **KEY QUESTION FOR THIS SEGMENT** |

| Facilitator introduces short presentation on informed consent as it is currently including brief ‘show’ of patient information sheets (short and long versions) |
| INSTANCES OF DIFFERENT TYPES OF SUPPORT AND INFORMATION (How many other people taking part) |

**FACILITATOR COLLECTS MARKED-UP SHEETS.**

**IN PAIRS CONSIDER AND DISCUSS EITHER LONG OR SHORT VERSION** [SPLIT ACROSS TABLE] TICK/ CROSS UNDERLINE ASPECTS THEY LIKE OR DON’T LIKE. SCRIBBLE NOTES BRIEF FEEDBACK TO GROUP.
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<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Description</th>
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<tbody>
<tr>
<td>9:00</td>
<td>All back to plenary</td>
<td></td>
</tr>
<tr>
<td>9:05</td>
<td>Summary of discussions so far – participant led</td>
<td>EACH GROUP PRESENTS BACK FIVE KEY THOUGHTS FROM THE PREVIOUS SESSION</td>
</tr>
<tr>
<td>9:15</td>
<td>Summary of discussions so far – facilitator led</td>
<td>LEAD FACILITATOR TO DRAW LINKS BETWEEN CONSENSUS / DIVERGENCE</td>
</tr>
<tr>
<td>9:20</td>
<td>Closing session</td>
<td>Run through the between session task – don’t refer to this as ‘Homework’ say instead <em>Now it’s your turn to do some research!</em> Complete final questionnaire</td>
</tr>
<tr>
<td>9:30PM</td>
<td>Session ends</td>
<td>Incentives</td>
</tr>
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</table>

Incentives
Participants depart
Patient & Public Engagement in the Research Trial Approval Process
 EVENT 1   Manchester/ London

ATTENDEES
X 16 dialogue participants
X Ipsos MORI facilitators and note takers
X Observers & evaluators

AIMS / DESIRED OUTCOMES OF EVENT
4. Participants acquire enough of an understanding of the research trials approvals process to discuss and form a view
5. Indication of their expectations, concerns and relative acceptability of core elements (‘touch points’) of the process
6. Setting the scene for more strategically focused discussion at workshop 2

BRIEFING PAPERS / MATERIALS ON THE DAY AS HANDOUTS
Delegate pack - badge, agenda, clinical trials leaflet
Quiz questions
Quiz answers
Case studies

OTHER MATERIALS
Flip charts - 1 per room/ table
PowerPoint/ Multimedia
Signage
Participant incentives
Consent forms
Further information for facilitators - case study notes for facilitators and map (opposite)

Colour key
Lead facilitator task - usually in Plenary
Group working
Important note
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<tr>
<td>6:00 pm</td>
<td>Arrivals and registration</td>
<td>Refreshments and fill in quiz</td>
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<td><strong>PLENARY – LEAD FACILITATOR &amp; HRA</strong>&lt;br&gt;  o Welcomes everyone, thanks for coming.&lt;br&gt;  o Housekeeping (toilets, fire, mobiles, most of us starting with minimal knowledge and everyone’s opinions valid and important)&lt;br&gt;  o Introductions – Sciencewise, Steering Group, Evaluators, facilitators, then at tables&lt;br&gt;  o INTRO PRESENTATION (SLIDES 1-8) – why we are here today - framed in terms of approvals process and the balance between protecting patients/public and encouraging research; role of HRA, broad aims and objectives&lt;br&gt;  Run through the agenda and how we will work today – important that you understand the topic so don’t be afraid to ask questions. This is a sensitive topic which touches us at a very personal level, so all need to be aware of people’s feelings.</td>
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<tr>
<td>6:45</td>
<td>Quiz answers and discussion of topics covered</td>
<td><strong>TABLE INTROS. INTRODUCE EACH OTHER TO TABLE IN PAIRS. THEN SWAP QUIZ ANSWERS IN PAIRS TO MARK FOR ANSWERS.</strong>&lt;br&gt;  <strong>LEAD FACILITATOR PROVIDES QUIZ ANSWERS AND ENCOURAGES SPONTANEOUS COMMENTS &amp; FEEDBACK FROM PARTICIPANTS TO EACH</strong>&lt;br&gt;  • Q1  …[we don’t expect anyone to get this wrong. No follow up except answer B]&lt;br&gt;  • Q2 Was anyone surprised by the range of treatments covered by health researchs? What surprised you? Why? What do you think about this?&lt;br&gt;  • Q3 Was anyone surprised by the fact that all of these people [except Dr Who, who is not human ] .... What surprised you? Why? What do you think about this?&lt;br&gt;  • Q4 Was anyone surprised by the fact that different types of organisation might be funding research that takes place in the NHS? What surprised you? Why? What do you think about this?&lt;br&gt;  • Q5. Was anyone surprised by the fact that  .... being tested as part of a research trial will not always be better than a treatment that is already being used to treat patients with the same illness? What did you think about the fact that isn’t always the case?</td>
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</table>
What are clinical research trials and why important?

PLenary video clip to be shown provides a very simple & gentle introduction to clinical research, then a slide of the four phases of a trial.

1. Lead facilitator presents the schematic participation process flow chart. Here it is shown very much in overview, with detail provided at each key point.

Use this flowchart to locate participant discussion in the approvals process as the session progresses.

Here's an overview of a simplified outline of a clinical trial process.

One of the most complicated things to think about is what happens to people when they take part in a trial, particularly whether they are in the control group or not and how that might effect them.

2. Placebo effect and blinding - short presentation of placebo & blinding

Play video: The placebo effect – Stop at 3:20

Any questions?

Group working

Facilitator: Make sure you capture their reasoning as well as answers to the question – why do they think certain things?

Reaction to trial process

Placebo and blinding

Group working

What are your ‘top of mind’ thoughts about what you’ve just been told? What did you already know? What surprised you? What concerns does it raise?

Discuss with a neighbour for a couple of minutes, then as a whole group. Facilitator develops discussion -

- What came to mind when you were watching the film clip? What was new? What did you already know? How did you know that? What experience have you had of trials?
- What surprised you?
- Was there anything you heard that made you worry? About yourself? About anyone else you know or think about?
- Do you feel you have any more questions so far?
- What do these terms mean? What do participants understand to be the reasons for/benefits of these?

If not already done so focus the deliberation on placebo and blinding

- What do participants understand to be the reasons for/benefits of these?
- Key question: What concerns do they have about the use of these? ***
- Key question: If your doctor suggests you go on a trial is he doing it to get you the best treatment available?
**KEY QUESTION:** how about if he doesn’t even know what treatment you would receive?

- PROMPT If you go in a trial and are given a placebo instead of the current treatment do you think that your doctor is still giving you the best available treatment? **NOTE A LOT OF TRIALS USE BEST CURRENT TREATMENT RATHER THAN PLACEBO.**

- Is there a risk to you as participant? What safeguards do you need/ would you want?**

- PROBE FOR participant views on the ethics of whether or not the use of placebo might deprive someone of normal treatment OR whether a placebo could be used to show a new drug in a better light than existing normal treatment **(these could happen without the role of REC)**

**ALSO NOTE:** PLACEBO/BLINDED/RANDOMISATION ARE NON NEGOTIABLE ELEMENTS IN CLINICAL TRIAL DESIGN **SO WE DO NOT WANT PARTICIPANTS DEBATING THIS PER SE.**

GROUP SUMMARISES KEY POINTS OF CONSENSUS / DIVERGENCE TO FACILITATOR

### Deciding whether to take part

- **Spontaneous** (approx 10 mins)

**Feedback and discussion**

**PLENARY:** LEAD FACILITATOR TAKES A FEW THOUGHTS FROM EACH TABLE ***** See if there is any consensus on anything, but without pushing for it. Reflect back the factors people are weighing up.

### Deciding whether to take part

**PLENARY:** LEAD FACILITATOR INTRODUCES CONCEPT OF INFORMED CONSENT – HERE WE WILL CALL THIS ‘DECIDING WHETHER TO TAKE PART IN RESEARCH’. **LOCATE IN THE OVERALL PROCESS USING PROCESS FLOWCHART.**

Based on what we have told you so far, I’m sure you are getting a sense of how much to think about there is for people who are asked to take part in health research.

**TASK IN PAIRS:** IMAGINE YOU HAVE A HEALTH CONDITION THAT RESEARCHERS ARE INTERESTED IN. WRITE ON A SHEET WHAT ARE THE 3 OR 4 MOST IMPORTANT THINGS THAT YOU WOULD NEED TO BE TOLD ABOUT SO YOU COULD DECIDE WHETHER TO TAKE PART OR NOT

**WHO WOULD YOU MOST WANT/TRUST TO TELL YOU THIS INFORMATION IN GROUPS FEEDBACK AND FACILITATOR TO FLIPCHART RESPONSES**

- What would you expect to be told if you were being asked to take part in a trial?

- What would give you confidence? What would make you feel safe?

**PROMPT:** Randomisation/Blinding/Placebo

**PROMPT:** Who’s funding

**PROMPT:** How long for/ What level/Frequency of commitment/ Monitoring
<table>
<thead>
<tr>
<th><strong>b. Patient information forms</strong></th>
<th><strong>appx 10 mins</strong></th>
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<tbody>
<tr>
<td>PROMPT: Potential risks, side effects/ What happens after the trial</td>
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<td>PROMPT: Other types of support (expenses)/ information (how many other people taking part)</td>
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<tr>
<td>o <strong>KEY QUESTION FOR THIS SEGMENT</strong> Who would you trust to answer questions/ give advice?</td>
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<tr>
<td>o Who would you want to go to advice for?</td>
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<tr>
<td>o <strong>Is your GP a good source of advice about a trial? Who do you trust more to guide you in a decision</strong> PROMPT YOUR GP/ SOMEONE INDEPENDENT OF THE RESEARCH TEAM / CARE TEAM/ RESEARCH TEAM / ANYONE ELSE</td>
<td></td>
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<tr>
<td>PROMPT What if your GP wasn’t an expert in that area? What if GP not interested in telling patients?</td>
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</tr>
<tr>
<td><strong>GROUP FACILITATOR INTRODUCES PATIENT INFORMATION SHEETS (SHORT AND LONG VERSIONS)</strong></td>
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</tr>
<tr>
<td>Currently a short patient information sheet is given out to a patient to tell him/her about the research. If the patient is interested in finding out more the longer one is sent to them. What do people think of this?</td>
<td></td>
</tr>
</tbody>
</table>
| **IN PAIRS CONSIDER AND DISCUSS EITHER LONG OR SHORT VERSION** [SPLIT ACROSS TABLE]
| TICK/ CROSS UNDERLINE ASPECTS THEY LIKE OR DON’T LIKE. SCRIBBLE NOTES |
| BRIEF FEEDBACK TO GROUP. FACILITATOR TO COLLECT IN MARKED-UP SHEETS. |
| **KEY QUESTION FOR THIS SEGMENT** |
| o Here is a short/ long version of a typical consent form. |
| o What do you make of it? |
| o What works about it? Why do you say that? |
| o What doesn’t work? What’s missing if anything? Why do you say that? |
| **KEY QUESTION** Should the long one be sent out straight away or might it put someone off taking part in a trial? |
| Or is the short one off putting as not enough information so would stop you from looking into it further? |
| **GROUP FACILITATOR INTRODUCES CHALLENGE TO DISCUSSION USING CASE STUDIES – AIM FOR TWO** |
| CASE STUDY A: ADULTABLE TO GIVE INFORMED CONSENT (Karen) |
| CASE STUDY B: QUALITATIVE CASE STUDY (Sophie & Simon) – BOTH NEWCASTLE GROUPS TO DO |
| Studies (apx 20 mins) | CASE STUDY C: CHILD WHOSE PARENTS GIVE CONSENT (Sam)  
- For each, do you think you would want to take part?  
- What questions would you have?  
- Would they change their opinions/ expectations?  
- What would be different? Why?  
- What are the risks for these people?  
- Would anything else affect their thinking? E.g. another condition or type of person? |
| d. Perceived Risks (apx 10 mins) | GROUP FACILITATOR ASKS PARTICIPANTS TO WRITE 2 KEY RISKS PER PAIR ON POST IT NOTES FOR THE THREE PROMPTS BELOW. Intention exercise to summarise key issues arising from informed consent and case studies above  
- What are the perceived risks for individuals agreeing to participate in research?  
- How about different types of research?  
- What needs to happen to counteract those risks?  
GROUP FACILITATOR TO COMPLETE THREE SUMMARY POSTERS WORKING WITH THE GROUP |
| 8:50 | 10 | Summary of discussions so far – facilitator led  
EACH GROUP TO SUMMARISE IN PLENARY THEIR 3 X GROUP SUMMARY SHEETS FROM DISCUSSION ON INFORMED CONSENT  
LEAD FACILITATOR TO SUPPORT BY DRAWING LINKS BETWEEN THEM; CONSENSUS / DIVERGENCE  
Recap of any queries about the process which were raised and answered in the groups  
Questions and clarification |
| 9:00 | 20 | Introduction of REC and the approval process  
PLENARY: LEAD FACILITATOR TO PRESENT ROLE OF RESEARCH ETHICS COMMITTEE (REC) – WHO THEY ARE AND WHAT THEY DO  
We are going to be considering the role of Research Ethics Committees in the research approvals process in more detail next week. Before then, given all that we have discussed this evening, we would like you to start thinking about what a Research Ethics Committee does, and specifically the kinds of questions you think they ought to be asking researchers.  
GROUP TASK  
- Taking one of the Case Studies you were discussing just now (Sam, Sophie and Simon or Karen), and think –  
  - IF YOU WERE A MEMBER OF THE RESEARCH ETHICS COMMITTEE, WHAT WOULD YOU WANT TO KNOW FROM THE RESEARCHER?  
  - TO HELP YOUR THINKING, YOU MIGHT WANT TO PUT YOURSELF IN THE PATIENT’S SHOES – WHAT WOULD THEY NEED OR WANT TO KNOW? |
WHAT ABOUT THE ORGANISATIONAL ASPECTS OF THE PROJECT?
WHAT WOULD HELP YOU TO TRUST THAT THE RESEARCH WOULD BE DONE SAFELY AND WELL?
WHAT ELSE IS IMPORTANT TO KNOW?
IF YOU LIKE YOU CAN DO SOME RESEARCH ONLINE TO SEE WHAT IS REALLY CONSIDERED BY RESEARCH ETHICS COMMITTEES

EXPLAIN WE WILL REVISIT THESE POINTS NEXT WEEK

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:20</td>
<td>Closing session</td>
<td>Introduce homework task</td>
</tr>
<tr>
<td></td>
<td></td>
<td>COMPLETE FINAL EVALUATION QUESTIONNAIRE AND CONSENT FORM</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thanks and see you on [date of next event]</td>
</tr>
<tr>
<td>9:30</td>
<td>Session ends</td>
<td>Incentives</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Participants depart</td>
</tr>
</tbody>
</table>
Patient & Public Engagement in the Research Study Approval Process

EVENT 2:

ATTENDEES
X 16 dialogue participants reconvened
X Ipsos MORI facilitators and note takers
X Observers & evaluators

AIMS / DESIRED OUTCOMES OF EVENT
7. Recap on what learned / tasks
8. Debate around current and proposed system
9. Feedback on propositions
10. Levels of engagement required

BRIEFING PAPERS / MATERIALS ON THE DAY AS HANDOUTS
These are highlighted in the plan
Delegate pack - badge, agenda, clinical trials leaflet, glossary
End questionnaire to be handed out
Case studies
Posters

OTHER MATERIALS
Flip charts - 1 per room/ table
PowerPoint/ Multimedia
Signage
Participant incentives
Consent forms
Further information for facilitators - case study notes for facilitators and map (opposite)

Colour key
Lead facilitator task - usually in Plenary
Group working
All to consider viability/ usefulness
HRA to provide more information/ advice
Dialogue with clinical researcher

85
<table>
<thead>
<tr>
<th>Time</th>
<th>Task</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>6:00 pm</td>
<td>30 Arrivals and registration</td>
<td>Participants complete post its about key things learnt during their own research tasks</td>
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| 6:30  | 15 Opening session            | PLENUM – LEAD FACILITATOR  
- Welcome back everyone, thanks for coming back.  
  - Housekeeping (quick reminder: toilets, fire, mobiles, everyone’s opinions valid and important)  
  - Introductions – facilitators, Sciencewise, HRA, Clinical researchers, Evaluators, others present, then at tables  
  - INTRO PRESENTATION – reminder of the dilemma we are here to address – the big questions posed by HRA.  
  Run through the agenda and how we will work today – again is important that you understand the topic so don’t be afraid to ask questions. Again, will be asked to fill in questionnaire at end to see how you felt about this evening, and ask if you are happy to be recontacted again so that we can let you know what happened as a result of this evening. |
| 6:45  | 20 Findings from task discussed Run through of approval system | PLENUM LEAD FACILITATOR GROUPS POST ITS INTO THEMES AND FEEDS BACK KEY LEARNINGS FROM THE PARTICIPANTS’ RESEARCH TASK AND ENCOURAGES SPONTANEOUS COMMENTS & FEEDBACK FROM PARTICIPANTS TO EACH  
PLENUM REVISIT THE KEY ASPECTS PARTICIPANTS THOUGHT NEEDED TO BE ADDRESSED BY ETHICS COMMITTEES. As you have had time to think about what we’ve learnt, and you have found out more doing your tasks, do you still agree with these? What might you want to change?  
PRESENTATION, overview of the basics behind the approvals process. What an ethical committee is, site approval, etc. Presents current system, and set up how we are going to talk about it – signposting ‘chapters’.  
You are now going to have the chance to talk to the researchers about how this works in practice. They will tell you about the types of studies they conduct, and their experiences of the approvals system, and you can ask them questions. After these discussions in our tables we are going to work out what we think are the strengths and weaknesses of the current system, so you might want to jot down notes on the pad while we go along that you can refer to later. |
| 7:05  | 20 Identifying strengths and weaknesses of | GROUP WORKING  
Discuss the current system with your neighbour for a couple of minutes, thinking about what the benefits and what the drawbacks might be of such a system? What looks as if it would work well? What looks like it might not work as well?  
Clinical researcher to share examples of how the process has worked for them in the past. Ideally outlining both an example |
<table>
<thead>
<tr>
<th>Time</th>
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<tr>
<td>7:25</td>
<td><strong>Feedback and discussion</strong></td>
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<td></td>
<td>PLENARY LEAD FACILITATOR TAKES A FEW THOUGHTS FROM EACH TABLE: What are</td>
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<td>the key strengths and weaknesses of the current system? See if there is</td>
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<td>any consensus on anything, but without pushing for it. Reflect back the</td>
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<td>factors people are weighing up.</td>
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<td>Is it effective in safeguarding patients?</td>
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<td>Does it instil trust?</td>
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<td>7:40</td>
<td><strong>COFFEE – MIX UP TABLES THROUGH MOVE ABOUT GAME</strong></td>
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<td>7.55</td>
<td><strong>Discussion on streamlined proposal</strong></td>
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<td>PLENARY LEAD FACILITATOR PRESENTS THE PROPOSED STREAMLINE SYSTEM</td>
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<td>Here is a streamlined system, where there is one key process, via the HRA.</td>
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<td>Only one application would be submitted to the HRA via an Ethics Officer.</td>
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<td>It would undergo an early assessment to identify any problems. Often that</td>
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<td>is just a quality check of the document (such as badly written or</td>
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<td>documents missing), or where there are issues arising that clearly need</td>
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<td>more consideration. This advice would be given before presented to the</td>
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<td>Ethics Committee. The HRA would also oversee any other approval needed</td>
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<td>from partners. Only after approval by the Ethics Committee would local</td>
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<td>site approval be sought.</td>
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<td><strong>HAND OUT LAMINATED PROCESS FLOW CHART</strong></td>
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<td><strong>GROUP WORKING</strong></td>
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<td>Spontaneous views, and how this fits in with the core principles they</td>
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<td>designed — ask them to work in pairs and when</td>
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mins) ready discuss with clinical researcher
  o What would be the strengths of this approach? What would be gained?
  o And what would be the weaknesses? What would be lost from previous approach
  o SPECIFICALLY PROMPT ON:
    o What if the HRA miss something?
    o What happens if the local site spots something that the HRA misses? How can they feed that back?

NOTE ON LAMINATED POSTER – WHICH BITS HAVE TICKS, CROSSES AND QUESTION MARKS
  o What would be the strengths of this approach? What would be gained?
  o And what would be the weaknesses? What would be lost from previous approach

Key question: Does this process safeguard participants? How? Or how could it do it better?
Key question: Which elements most make you feel trust in the system? Which less so?
Discuss thoughts with clinical researcher so can see how this fits with his/her experiences.
  o Another aspect is the accreditation of a professional researcher. HRA are proposing a researcher passport so that they do not need to be accredited on a study by study basis once they are accredited as a professional researcher. The idea is that the same researcher does not need his/her ability reviewed several times over. HRA could develop an investigator profile based on the previous track record showing numbers of studies submitted, publications and compliance with standards. Researchers with an established track record would not require constant review for each separate research submission.
    o In pairs, how would this work? What would an 'established track record' look like? How would it be regulated? Who would hold this data? What would need to happen to lose accreditation? What would be the advantages and disadvantages.
    o Discuss with clinical researcher, how do your views sit with their experiences of getting accredited for a research study? What do they need to do to get accredited?

PLENARY
LEAD FACILITATOR TAKES A FEW THOUGHTS FROM EACH TABLE. What are the key points for consideration when streamlining the process? Do a washing line of support exercise (2 points on a wall, one is strongly support the revised proposal, one is strongly oppose, people to take a stand on where they are. Ask people at different points of the washing line why they are standing where they are, and what would move them further towards the support end.
LEAD FACILITATOR: As we discussed last week, health research studies are the cornerstone of medical advancement. It is therefore very important that people trust them.

GROUP WORKING
Spontaneous views on what elements need to be present in a research study – ask them to work in pairs and feedback. Facilitator with the groups to pull together a list of key things, and discuss why they are important. (IF NOT MENTIONED PROMPT FOR MONITORING AND REPORTING RESEARCH STUDIES).

- Monitoring research: PRESENT SLIDE ON ANNUAL REPORTING
  - What are the clinical researchers’ experiences? Do they see annual reporting as useful or a waste of resource?
  - single online portal for people to access if want/need?
  - Which options would make you trust the research studies more or less? Why?
  - DISCUSS OPTIONS WITH CLINICAL RESEARCHERS
  - Who should receive the monitoring information?

Feedback and discuss around table with clinical researchers
Research findings: OUTLINE CURRENT REPORTING IN TABLES Currently all study results should be published but they aren’t always. Traditionally when they are published it is in academic Journals, which are subject to peer review. But they are not always published, for example when negative results are found, or student or small scale research. Academic journals tend to want to publish positive results. Prior to the internet researchers were entirely dependent on academic journals to publish their findings and of course it was difficult for them to influence that. Now with the web there are ways of displaying your findings for all to see at almost no cost and not dependent upon peer review by an academic journal.

  - Should all studies be made to publish the results? What are the consequences of always publishing? And the consequences for not always publishing? Discuss with clinical researchers
  - Not all studies are suitable for publication, some are small scale, some are student studies, some are just poor quality
  - Should the HRA have a formal mechanism for chasing for reports of studies/ trials? Or should researchers be trusted to publish themselves?
Pressure to publish needs to be appropriate, some studies are very small so publishing results could be costly or research might not be effective, run by students, been stopped – what is the difference by these types?

Some pharma companies (GlaxoSmithKline) publish all their results on their website now

**Feedback and discuss around table with clinical researcher**

Prioritise key elements needed to encourage high levels of trust in studies?

GROUP SUMMARISES KEY POINTS OF CONSENSUS / DIVERGENCE TO FACILITATOR

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**GROUP EXERCISE ON TRUST:**

**IN PAIRS:**

What do you think the risks are of taking part in a research study or trial?

Thinking about everything we’ve been talking about, what needs to be in place in order to have confidence in health research?

That it is the best it can be and is safeguarding participants?

TABLE TO PRIORITISE LIST ON FLIPCHARTS. How does this change by type of sponsor of the study? NHS / CHARITY / PHARMA.

Are there specific things needed for each type of sponsor?

**PLENARY**

LEAD FACILITATOR TO SUMMARISE 3-4 MAIN THINGS FROM EACH TABLE.

PLENARY DISCUSSION How does the streamlined process fit with your requirements?

ASK CLINICAL RESEARCHERS FOR THEIR REACTION / RESPONSES / IDEAS.

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Historically there hasn’t been much public involvement in these processes but the HRA are proposing to consult more with patients and the public, using a patient / public panel as a pool to consult on at a strategic level. This might include surveys, discussions like this, etc

What do you think about this idea?

Is it important to involve the public / patients or not? Why is it important or not? Is it relevant?

Which groups of people in particular? People who haven’t been involved in research studies? People who have? Patients with particular illnesses?

How would this fit with the role of safeguarding patients?

What effect would that have on overall levels of trust in research studies?
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<th>Time</th>
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<tr>
<td>9:10</td>
<td>All back to plenary</td>
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</table>
| 9:10  | Summary of discussions so far – facilitator led | **LEAD FACILITATOR TO SUMMARISE ALL**  
Recap of any queries about the process which were raised and answered in the groups  
Questions and clarification |
| 9:20  | Closing session                    | **Complete final Evaluation form**  
Consent for further research and use of data  
Thanks |
| 9:30  | Session ends                       | Incentives  
Participants depart |