



*National Institute for
Health Research*

Public involvement in research applications to the National Research Ethics Service:

Comparative analysis
of 2010 and 2012 data

INVOLVE

Health Research Authority

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About this study

This is the second report of a joint INVOLVE and Health Research Authority (HRA) project to provide baseline data on public involvement in applications to the National Research Ethics Service (NRES)¹. This report compares 2010 and 2012 responses to the public involvement question in the ethics application form. Non-commercial and commercially funded studies are analysed separately.

This report should be referenced as:
Tarpey M. and Bite S. (2014) **Public involvement in research applications to the National Research Ethics Service: Comparative analysis of 2010 and 2012 data**, INVOLVE Eastleigh.

Information about INVOLVE

INVOLVE is a national advisory group funded by the National Institute for Health Research (NIHR) to support public involvement in NHS, public health and social care research.

For more information about INVOLVE see:
www.involve.nihr.ac.uk

Information about the Health Research Authority (HRA) and the National Research Ethics Service (NRES)

The HRA was established in December 2011 to promote and protect the interests of patients in health research and to streamline the regulation of research. In collaboration with its partners, the HRA aims to make the UK a great place to do health research, to build confidence and participation in health research, and so to improve the nation's health.

NRES is a core function of the HRA and is committed to enabling and supporting ethical research in the NHS. It protects the rights, safety, dignity and wellbeing of research participants.

For more information about the HRA and NRES see: www.hra.nhs.uk/about-the-hra/who-we-are/ and www.hra.nhs.uk/about-the-hra/our-committees/nres/

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¹ The first study reported in 2011: Tarpey M. (2011) **Public involvement in research applications to the National Research Ethics Service**, INVOLVE Eastleigh www.involve.nihr.ac.uk/posttypepublication/public-involvement-in-research-applications-to-the-national-research-ethics-service-nres/

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Summary

This is the second report of a joint INVOLVE and Health Research Authority (HRA) project² to provide baseline data on public involvement³ in applications to the National Research Ethics Service (NRES). This report compares 2010 and 2012 responses to the public involvement question in the ethics application form reproduced in Table 1 (page 7).

Non-commercial and commercially funded studies are analysed separately to more accurately reflect the different patterns of responses to the public involvement question by type of funder.

Findings

For non-commercially funded studies applying for ethics approval (e.g. National Institute for Health Research (NIHR), medical research charities and research councils) **the findings show an increase in public involvement for 2012** (Figure 2, page 9):

- In 2012, 40% of researchers reported involving or intending to involve the public in their research – up from 29% in 2010. Applicants had ticked one or more involvement boxes on the ethics application form and their free-text responses confirmed their plans.
- 40% continued to misunderstand what the question on involvement was asking. Whilst they had ticked at least one of the

involvement boxes, their free-text responses described plans for engagement or participation⁴ and not public involvement – down from 49% in 2010.

- The remaining 20% said they had no plans for involvement – 22% in 2010.

For commercial studies (e.g. pharmaceutical companies) **the findings show little change in the responses to the question on public involvement in 2012 from those in 2010** (Figure 3, page 9).

- In 2012, 5% reported plans for involvement – up slightly from 2% in 2010.
- 20% ticked an involvement box, not confirmed by their free text response – down from 31% in 2010.
- And 75% reported that they had no plans for involvement – up from 67% in 2010.

The influence of funders (prior to application for ethics approval)

Figure 4 (page 11) suggests that whilst applications for ethics approval from studies funded by the commercial sector report almost no public involvement, there has been an increase in plans for involvement in studies funded by the non-commercial sector, even within the relatively short period between 2010 and 2012.

This is likely to reflect the growing trend amongst non-commercial funders of asking researchers to provide details of their plans

² The first study was published in 2011: Tarpey M. (2011) **Public involvement in research applications to the National Research Ethics Service**, INVOLVE Eastleigh

³ In this study, the term ‘involvement’ is used to refer to an active partnership between patients, members of the public and researchers in the research process. This can include, for example, involvement in the choice of research topics, advising on the research project design or in carrying out the research.

⁴ The term ‘engagement’ is used by NRES to describe the participation of patients, members of the public or service users or carers as subjects of the research (i.e. as participants), as well as the dissemination of research findings to research participants and to colleagues.
www.involve.nihr.ac.uk/find-out-more/what-is-public-involvement-in-research-2/

for public involvement as part of their grant application processes (prior to applications for ethics approval). The most notable example of this remains the National Institute for Health Research (NIHR), which requires information on plans for involvement in all their research grant applications. In 2012, 78% of NIHR funded applicants reported involvement of the public in their studies, up from 67% in 2010.

Other studies showing increasing levels of involvement in their ethics applications since 2010 include those funded by:

- Medical research charities
 - 47% in 2012, up from 37% in 2010
- Universities
 - 31% in 2012, up from 24% in 2010 and
- Research Councils
 - 28% in 2012, up from 14% in 2010.

Recommendations

■ Research Ethics Committees (RECs)

Research Ethics Committees (RECs) should draw on the information provided in the public involvement question for assurances on the ethical probity of the research they are assessing and do this in a consistent way across all RECs. Further, RECs should provide feedback to researchers and record the account they have taken of the information provided about plans for public involvement both during the review process and in requests for further information.

Feedback by RECs could help raise researchers' awareness of the importance of public involvement in their research as well as help to improve their understanding of public involvement and how it differs from engagement.

■ Funders

It is necessary to recognise the very different pattern of plans for public involvement reported by non-commercial and commercially funded studies. The amount of public involvement reported for commercially funded studies is very low. This may lead to such studies not addressing the needs of participants, which can hinder approvals and recruitment of participants. Companies funding research should be encouraged to involve the public in the design of their studies because of the potential benefits this can bring to gaining ethical and NHS approvals and recruitment to time and target.

Where possible, non-commercial research funders should be encouraged to emulate the question on the Integrated Research Approval System (IRAS) form about public involvement in their own research funding application forms, if they do not do so already. It would help researchers provide better quality information about their understanding of, and plans for, involvement prior to their application for ethics approval.

■ Baseline data

This joint INVOLVE and HRA project should continue to analyse the pattern of responses on public involvement in applications for ethical approval by repeating this study on a biennial basis.

The HRA should review the public involvement question on the IRAS form and the guidance for applicants with a view to improving the level of understanding of involvement over engagement and participation and so to the quality of the information provided.

Introduction

This is the second report of a joint INVOLVE and Health Research Authority (HRA) project⁵ to provide baseline data on public involvement⁶ in applications to the National Research Ethics Service (NRES).

Prior to the initial 2011 (Tarpey 2011) study a previous research project was funded by NRES, on Research Ethics Committees' (RECs) decision-making (Angell et al. 2008, 2007). This found that RECs frequently asked researchers for additional information and amendments to their research before granting ethical approval. The study showed that the most common ethical concerns raised by RECs were on: informed consent; design and conduct of studies; care, protection, confidentiality and recruitment of research participants; and the use of documentation, such as patient information materials and consent forms.

Other research that focused on reviewing the evidence of impact of public involvement on research suggested that researchers who involved the public in the design and conduct of their studies were able to address these ethical concerns (Brett et al. 2010; Staley 2009; Smith et al. 2008). Studies were showing that, by involving people, researchers were able to demonstrate that their planned research was acceptable from a patient and public perspective and helped address potential ethical concerns, prior to applying for ethical approval. This in turn could provide assurance to RECs assessing the ethical probity of these studies (Tarpey 2011; INVOLVE 2012; Ives et al 2012; Staley 2013).

Project aims

Informed by the studies above, this project aims to build the evidence base by:

- analysing information on public involvement in research routinely collected by NRES in QA14-1 (see Table 1) of the application form for ethical approval of research studies; and
- tracking the pattern of responses to see whether or not they change over time by repeating the same analysis on a biennial basis.

This report compares a sample of responses to the public involvement question, QA14-1, from 2010 and 2012 applications for ethical approval. Non-commercial (e.g. National Institute for Health Research, medical research charities) and commercially funded (e.g. pharmaceutical companies) studies are analysed separately in the detailed findings section (pages 10 – 17) of this report to more accurately reflect the different patterns of responses to the public involvement question by type of funder (see Figures 2 and 3).

The key analysis focuses on responses to the two-part question in the ethics application form (QA14-1) which asks applicants about the involvement of the public in their research. As Table 1 shows, this question has both a tick-box list of public involvement activities, and a free-text box asking researchers to describe the involvement they have ticked. The analysis also links the responses to this question to other information on the application form, such as the source of funding and type

⁵ The first study was published in 2011: Tarpey M. (2011) **Public involvement in research applications to the National Research Ethics Service**, INVOLVE Eastleigh

⁶ In this study, we use the term 'involvement' to refer to an active partnership between patients, members of the public and researchers in the research process. This can include, for example, involvement in the choice of research topics, advising on the research project design or in carrying out the research. For more information see: www.involve.nihr.ac.uk/find-out-more/what-is-public-involvement-in-research-2/

of involvement activities. See Appendix A for further information on this project and the study's methods of data selection and analysis.

Table 1: QA14-1: Question on Public Involvement and Guidance Note in IRAS application form for ethics approval⁷

“QA14-1: In which aspects of the research process have you actively involved, or will you involve, patients, service users and/or their carers or members of the public?

- Design of the research
- Management of the research
- Undertaking the research
- Analysis of results
- Dissemination of findings
- None of the above

Give details of involvement, or if none please justify the absence of involvement for this study (free text box)

.....

.....

.....

.....

..... ”

QA14-1 IRAS Guidance note (explanation appears on IRAS form as a hover text-box):
“Public involvement includes consultation with or working alongside members of the public, patients, service users or carers in the choice of research topic, and the design, planning, conduct and dissemination of research. The UK health departments are committed to active patient and public involvement in all stages of research.

For more information see INVOLVE (<http://www.involve.nihr.ac.uk>) or, in Wales, see Involving People (<http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=14773>)

This question does not refer to the involvement of patients, members of the public or service users or carers as participants in the research.”

⁷ QA14-1, IRAS Ethics Application Form: www.myresearchproject.org.uk/

Findings

This section summarises the study findings on the extent and nature of public involvement in applications for ethics approval comparing a sample of 2010 and 2012 responses from the same Research Ethics Committees (RECs) to the question on public involvement (see Table 1). The study analyses the tick-box and free-text responses to the involvement question and explores the links with other information provided in applications. Appendix A gives further details of the methods of data selection and analysis used in this study.

Initial analysis

As summarised in Figure 1 the initial analysis of both the 2010 and 2012 responses to the question on involvement made no distinction between whether or not applications for ethics approval came from studies funded by the non-commercial or commercial sector. It suggested that overall, in 2012, 61% of the total sample ticked at least one box in response to

the question on public involvement, indicating that they had or were intending to involve the public in some aspects of their research. This mirrored the 62% sampled in 2010. However, when the free-text responses were analysed, the overall proportion of studies with confirmed public involvement was 28% in 2012, up from 19% in 2010.

However, as Figures 2 and 3 show, Figure 1 does not adequately report the distinct patterns of responses to the public involvement question between non-commercial and commercially funded studies. When separated by funder type, the differences are significant. In summary, non-commercially funded studies have a significantly higher and increasing proportion of plans for public involvement in their research (40% in 2012, up from 29% in 2010) compared to a small proportion of commercially funded studies (5% in 2012, 2% in 2010).

The detailed findings for each funder type are presented separately in the remainder of this report. This includes a re-analysis of the 2010 data as this distinction had not been made in the previous study (Tarpey 2011).

Figure 1: All studies (non-commercial and commercially funded combined): responses to question on public involvement

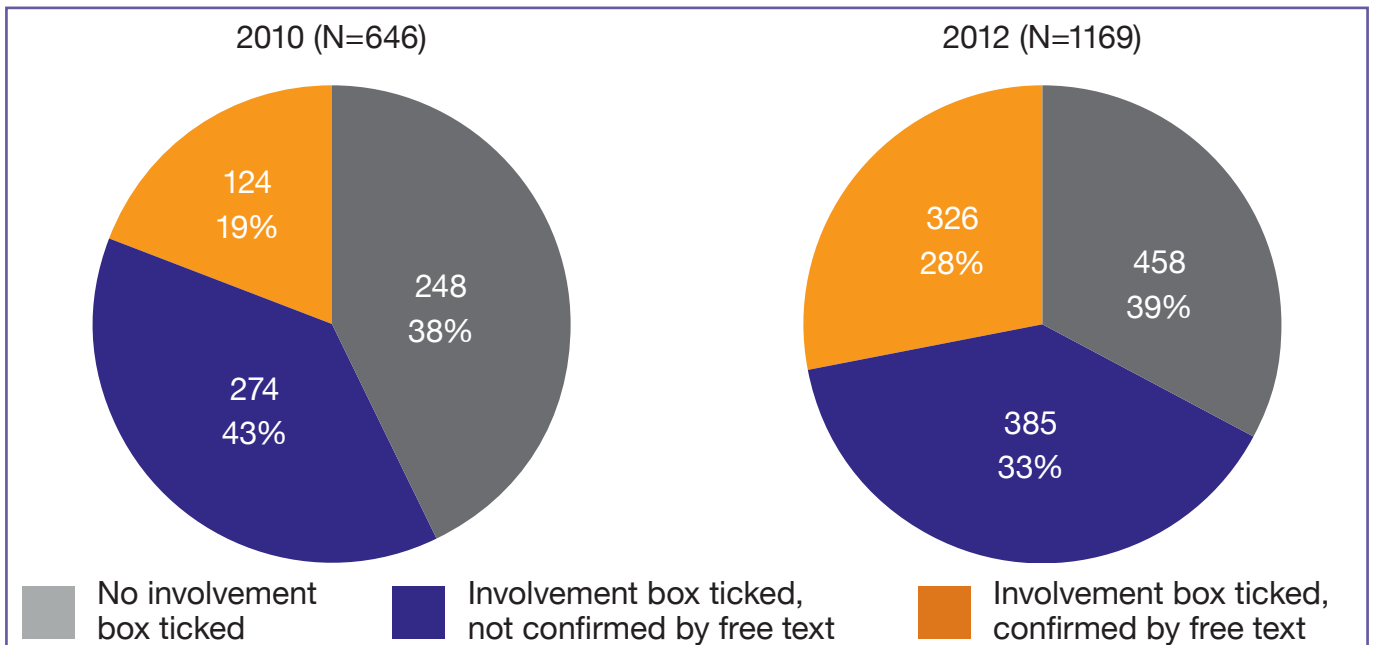


Figure 2: Non-commercially funded studies – responses to question on public involvement

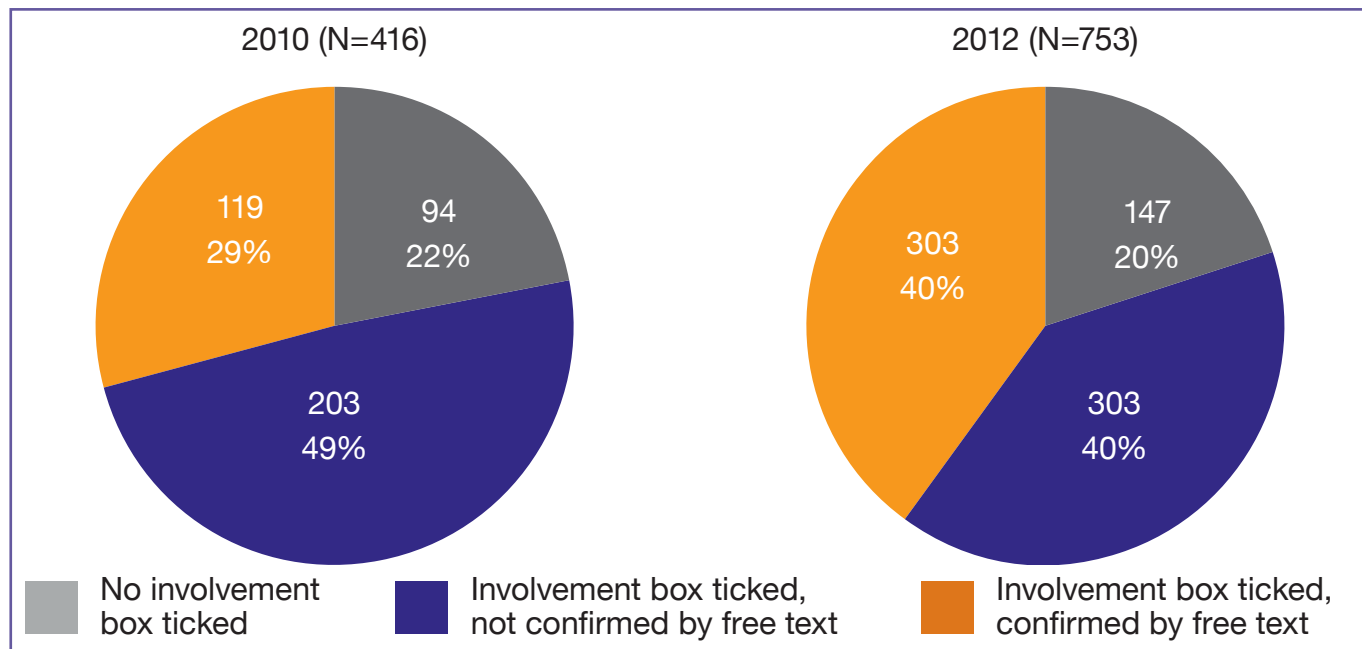
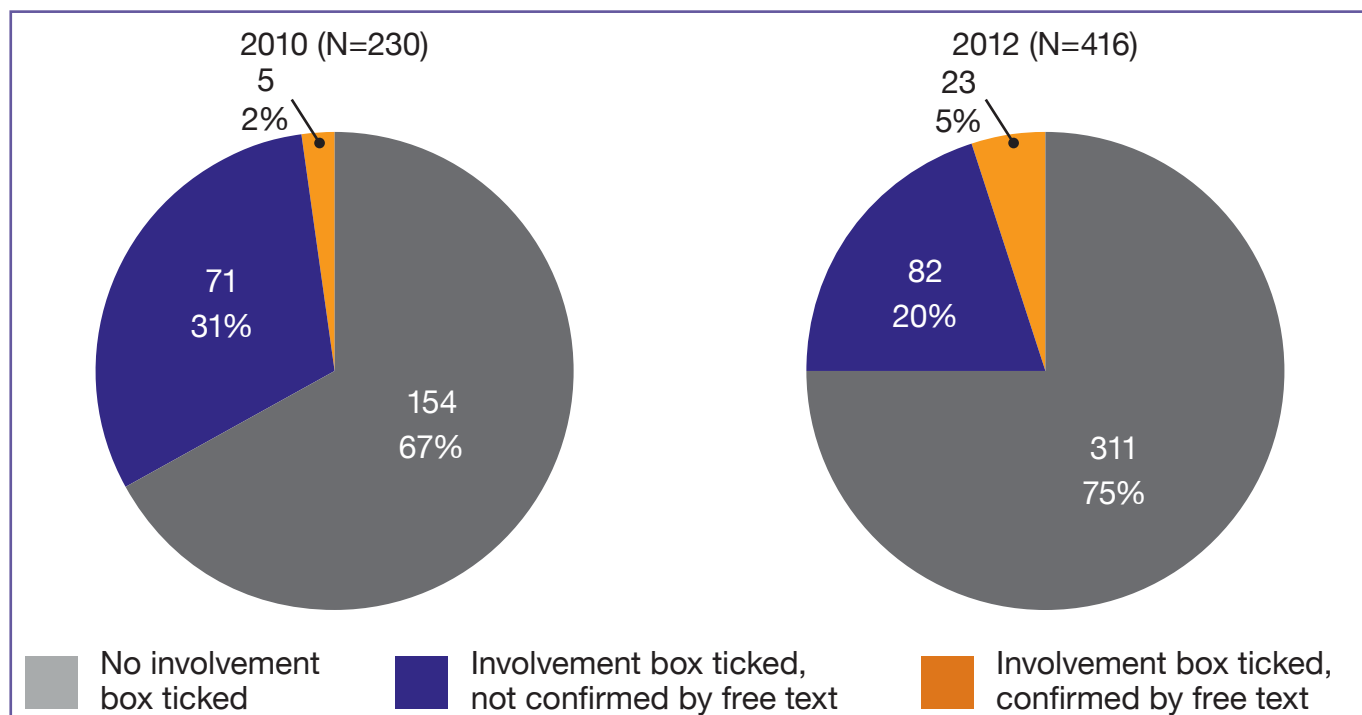


Figure 3: Commercially funded studies – responses to question on public involvement



Detailed findings

Non-commercially funded studies – responses to question on public involvement (Figure 2)

Figure 2 shows that there has been an increase in the proportion of non-commercially funded researchers reporting plans for active public involvement in their studies:

- In 2012, 40% of researchers reported involving, or intending to involve, the public in their research. They ticked one or more of the involvement boxes and their free-text responses confirmed their plans; in 2010 this proportion was 29%.
- In 2012, 40% seemed to misunderstand what the question on involvement was asking. Whilst they also ticked at least one of the involvement boxes, their free-text responses described plans for engagement and not public involvement. They explained, for example, how they were going to recruit patients to participate in their research or how they would disseminate their study findings to research participants and to colleagues; in 2010 this was 49%.
- In 2012, 20% said they had no plans for involvement; in 2010 it was 22%, which shows little change.

Commercially funded studies – responses to question on public involvement (Figure 3)

Figure 3 shows that there is little change in the responses to the question on public involvement amongst commercial studies between 2010 and 2012:

- Few commercial studies ticked a box to indicate they were involving the public which was confirmed by their free-text descriptions – 5% in 2012 and 2% in 2010.
- There was a slight increase in the number of studies which indicated that they were not intending to involve the public – 75% in 2012, which was up from 67% in 2010.

Breakdown of responses by all funders to question on public involvement (Figure 4)

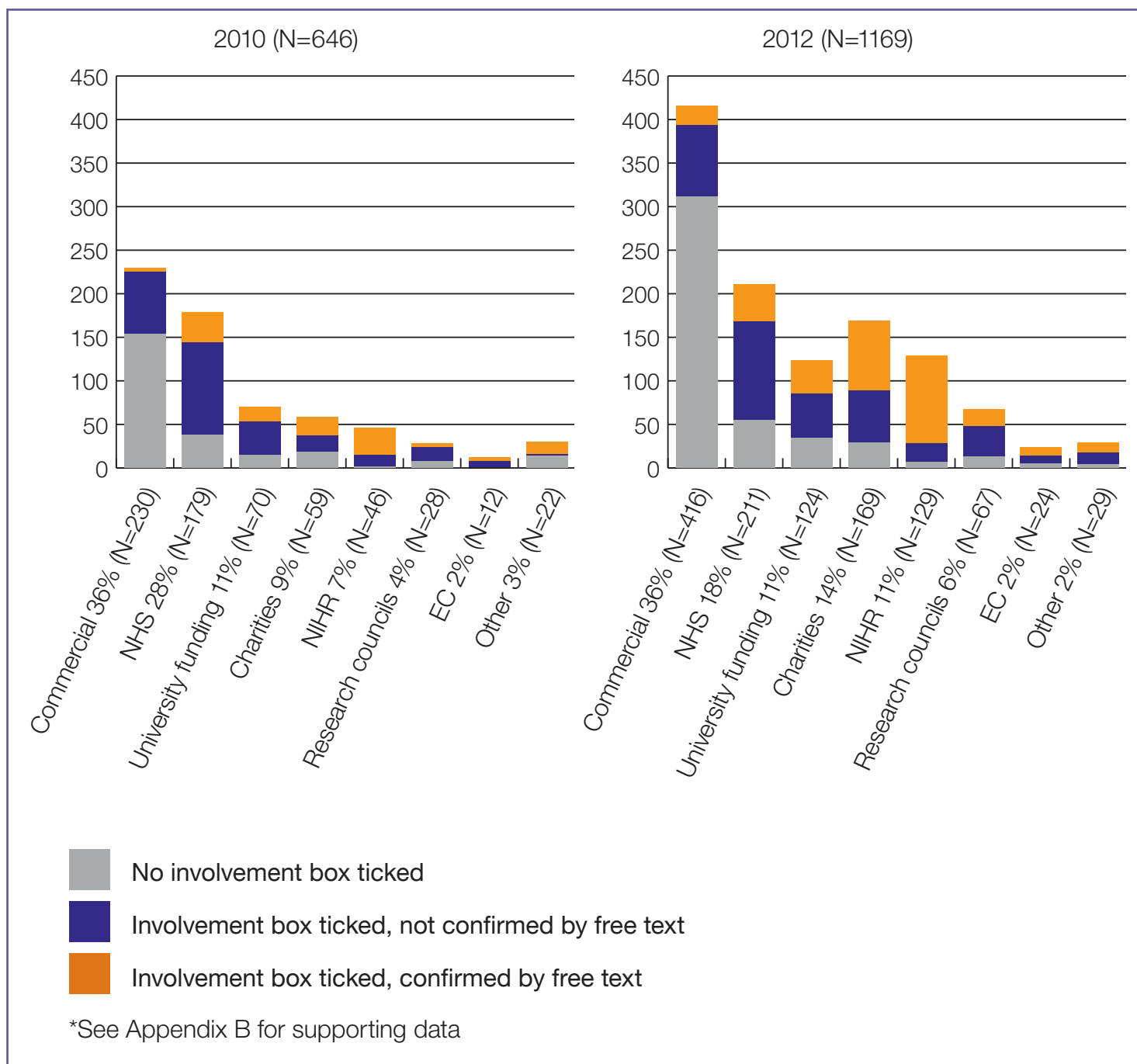
Figure 4 shows that in 2012, similar to the pattern of funding in 2010, the largest proportion of studies are commercially funded (36%), followed by NHS organisations and trusts (18%). One of the main differences is an increase in the proportion of studies funded by the National Institute for Health Research (NIHR) – 11% in 2012, up from 7% in 2010; and by medical research charities – 14% in 2012, up from 9% in 2010.

Figure 4 also provides a detailed breakdown of applicants' responses to the question on public involvement by funder. It distinguishes between those who did or did not tick one or more public involvement box, and of those, whether or not their free-text responses confirmed involvement activities. It highlights that whilst overall between 2010 and 2012, the data shows an increase in involvement by non-commercial funders – for example an increase from 37% in 2010 to 47% in 2012 by medical research charity funders – there also remain noticeable variations in responses between funders in this sector.

For example, the 2012 data shows that 78% of researchers funded by NIHR ticked one or more involvement activities, confirmed by free text responses, up from 67% in 2010. This remains a higher proportion than any other non-commercial funder and is likely to be linked to the introduction of a standard application form in all the NIHR funding programmes in September 2011. The form includes questions about patient and public involvement in the proposed research. As stated in the 2011 report: “By the time NIHR funded researchers apply for ethical approval, they could be expected to have considered what a question on involvement is asking. Other applicants may not have had this opportunity.”⁸

⁸Tarpey (2011) page 10.

Figure 4*: Breakdown of responses by all funders⁹ to question on public involvement



⁹ Analysis of the 2010 data on non-commercial funding sources was difficult to categorise accurately due to the information provided by applicants about their funding. This was acknowledged in the first study (Tarpey M (2011) **Public involvement in research applications to the National Research Ethics Service**, INVOLVE, Eastleigh page 9) which suggested that NHS funding was likely to have been overcounted and NIHR and medical research charity funding undercounted. By 2012 the IRAS form had been revised so that applicants are required to make a clear distinction between funder and sponsor, enabling us to categorise the 2012 data more accurately.

Extent and type of involvement activities (Figures 5 – 8)

Applicants for ethics approval are asked to indicate which stages of research that they had involved, or planned to involve members of the public. Figures 5 and 6 detail the number of involvement boxes ticked by applicants to non-commercial and commercial funders and Figures 7 and 8 show the types of activities recorded. They show the scale of the match / mismatch between the tick-box responses and free-text entries describing what the applicants mean by involvement.

Amongst the non-commercially funded applicants (Figure 5) it appears that the more involvement activities ticked, the more likely it is that involvement is accurately described in their free-text answers. This pattern is similar for both the 2012 and 2010 data.

Figure 5*: Non-commercially funded studies – Number of involvement boxes ticked and whether confirmed by free text responses

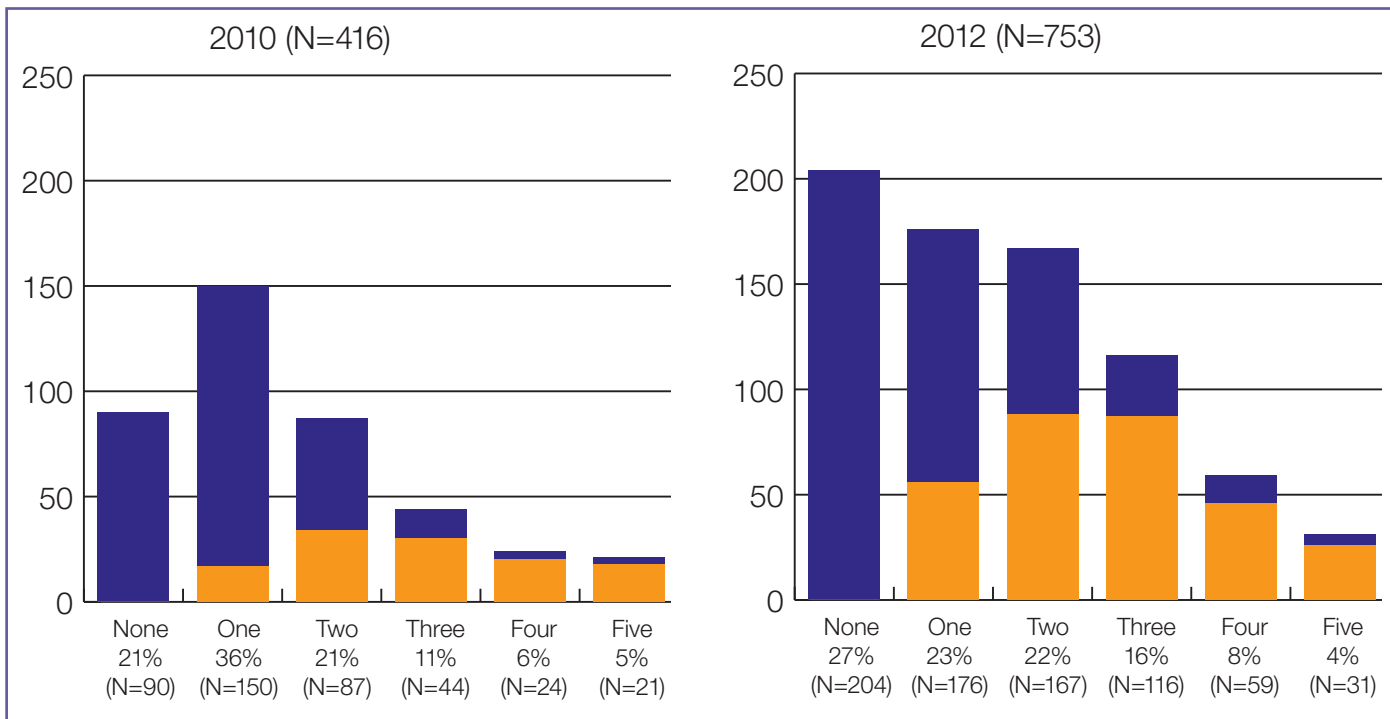
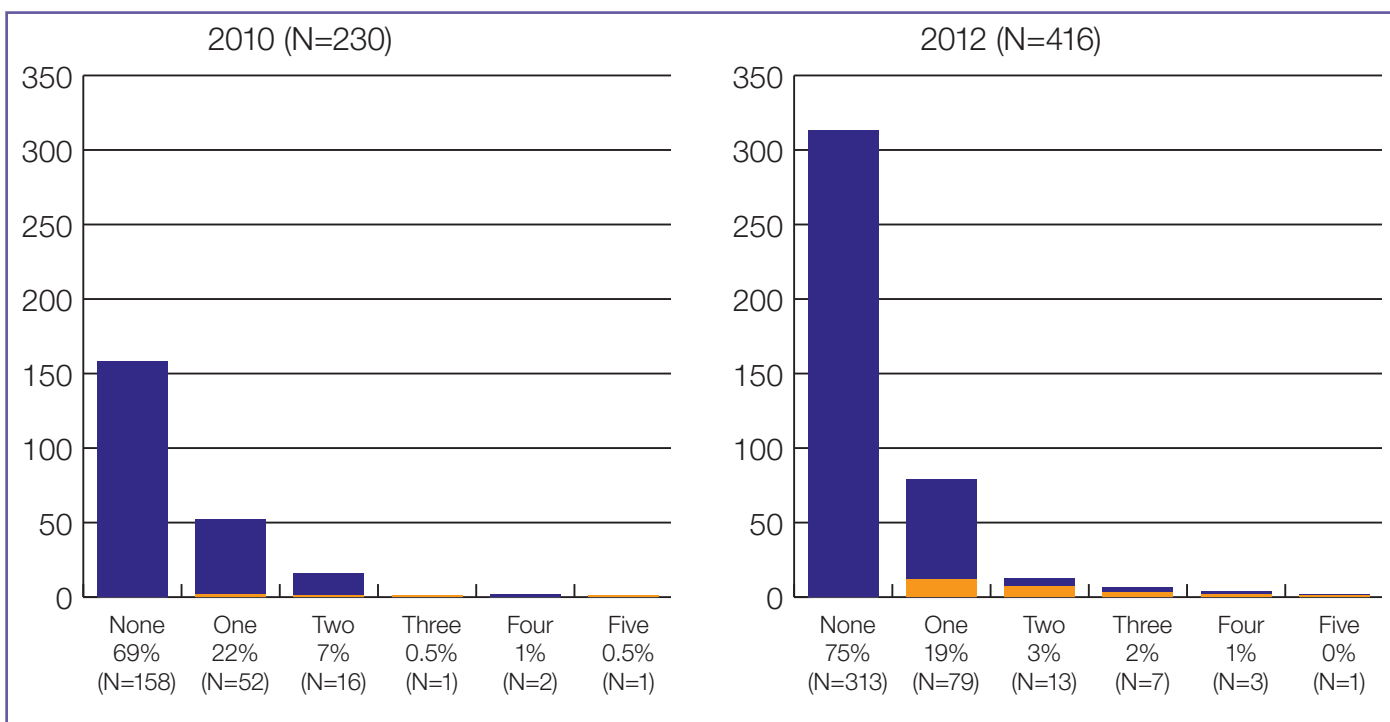


Figure 6*: Commercially funded studies – Number of involvement boxes ticked and whether confirmed by free-text responses



■ Public involvement not confirmed by free text ■ Public involvement confirmed by free text

* See Appendix B for supporting data

Figure 7*: Non-commercially funded studies – type of involvement activities ticked and whether confirmed by free text

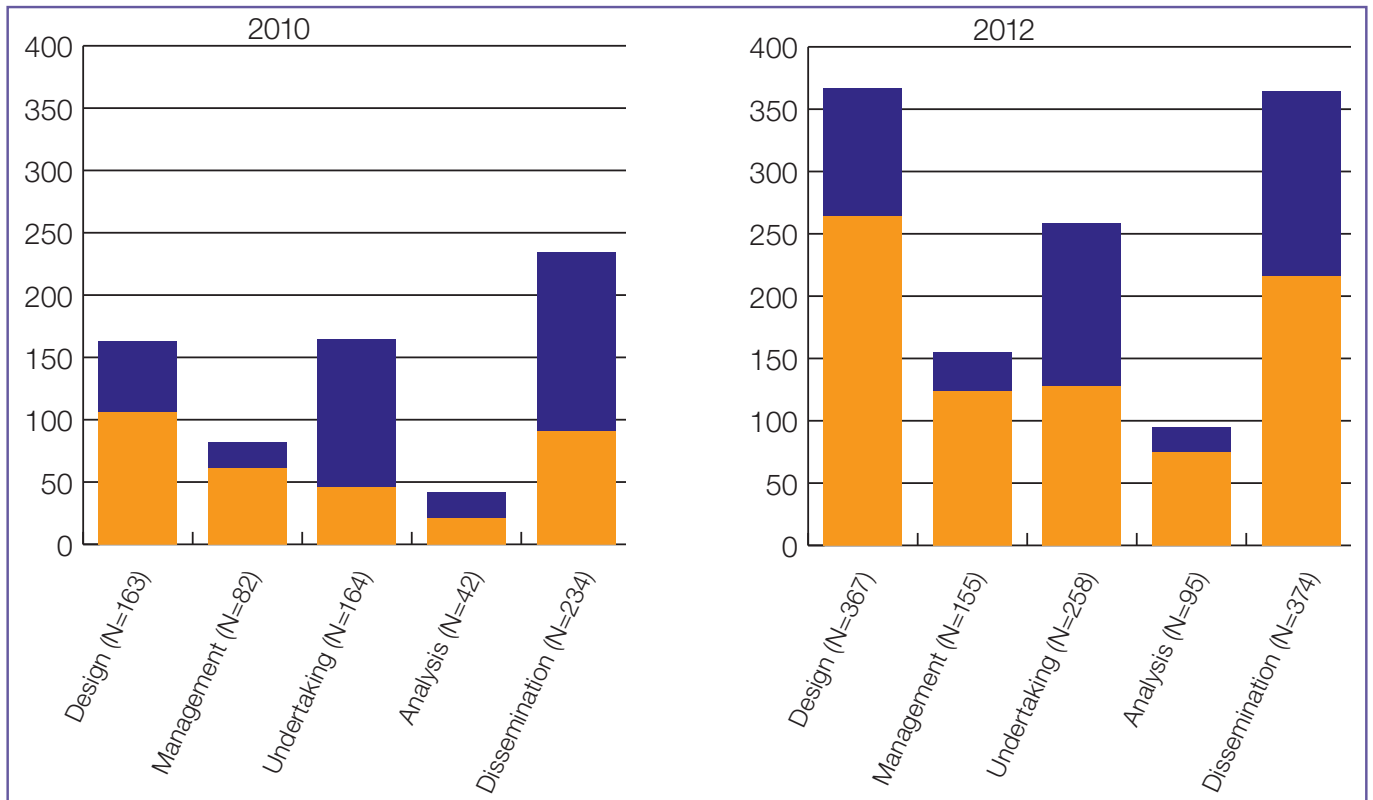
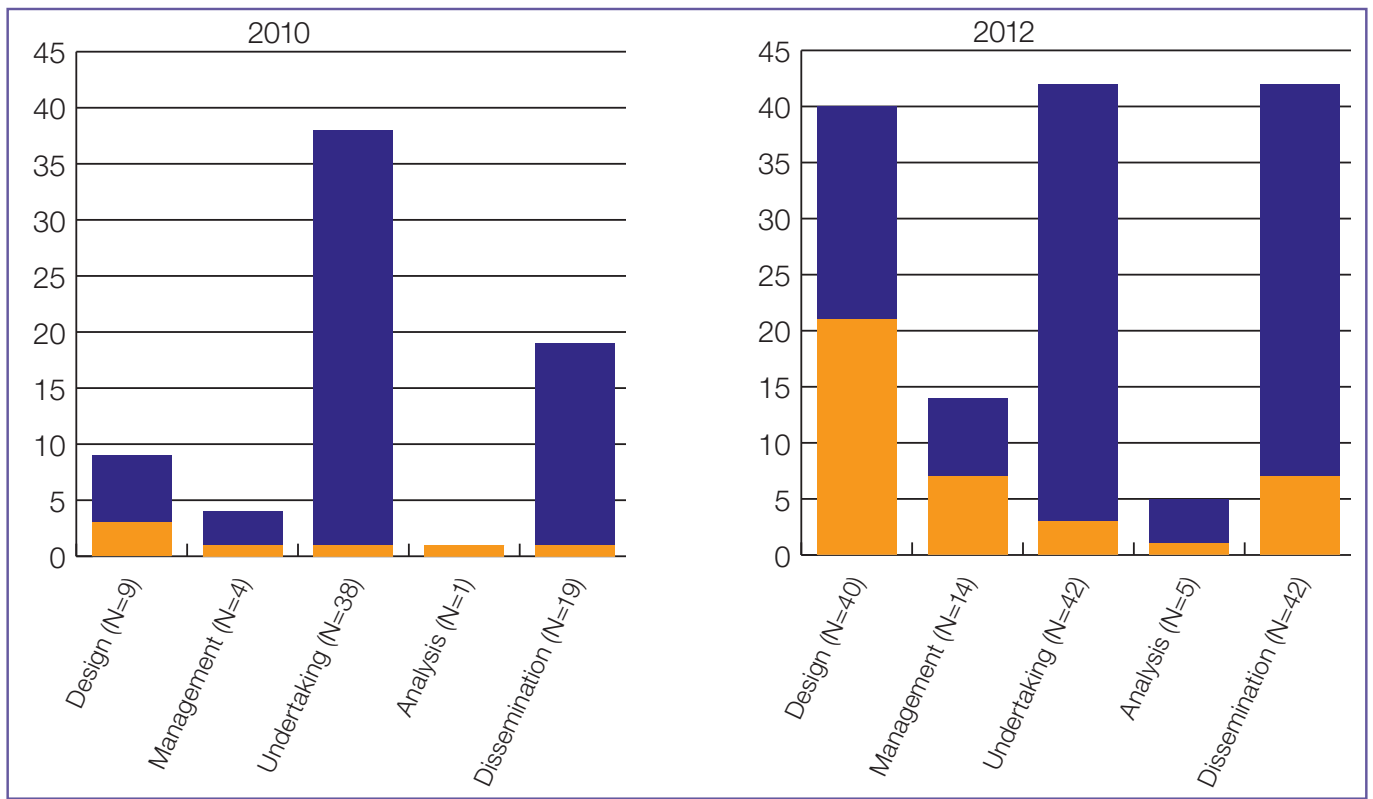


Figure 8*: Commercially funded studies – type of involvement activities ticked and whether confirmed by free text



■ Public involvement not confirmed by free text ■ Public involvement confirmed by free text

* See Appendix B for supporting data

Figure 7 shows the number of involvement activities ticked by non-commercially funded applicants and whether public involvement was confirmed by their free-text responses. The applicants could tick as many stages of research as applicable, therefore this data is presented as absolute numbers rather than percentages.

Figure 8 shows the number of activities for commercially funded applicants and whether public involvement in the research was confirmed by the free-text answers.

Figure 7 shows that, in discussing plans for the research, non-commercially funded studies most commonly referred to plans to involve people in the 'design' and 'dissemination' stages of the research, confirmed by their free-text responses. This remained the same in 2012 and 2010. Both showed that 'analysis' was the least common involvement activity.

Figure 7 also shows that in 2012, amongst non-commercially funded studies, applicants who ticked 'management' were more likely to have the involvement confirmed by free text, followed by 'analysis' and 'design'. In 2010 the applicants who ticked 'design' were most likely to have the involvement confirmed by free text, followed by 'management' and 'analysis'.

For commercially funded studies, Figure 8 shows that in the 2012 responses half of those that indicated involvement in the 'design' and 'management' stages of research (separately or combined) were confirmed by their free-text responses.

Free-text responses to the public involvement question (2012 entries)

This section gives more information on the content of applicants' free-text responses about their plans, or otherwise, for public involvement in their studies. The responses report 2012 entries, although there are notable similarities to 2010 free-text entries included in our previous report (Tarpey 2011).¹⁰

Already involving or planning to involve (40% of non-commercial and 5% of commercially funded studies, 2012 responses)

Of those who indicated they were already involving people in their research, some provided information on the type of involvement that was being undertaken or planned. The descriptions ranged from limited to much more comprehensive descriptions of what the involvement would be.

The descriptions covering **limited public involvement** in the research often described just one area of the research where members of the public were involved. For example:

- the patient information sheets were written by a patient advisory group
- the proposed study was discussed with patients
- patients were invited on the trial steering group.

Of those that gave more **comprehensive descriptions of involvement** they tended to include multiple areas of the research process where public involvement would take place.

Examples included:

- service users helped develop the research topic and what research questions should be asked and will continue to be involved
- researchers have worked with a service user group and have service users as co-applicants who have influenced the design
- the study was conceived, designed and led by a patient group who led the application for funding and will be involved in all aspects including undertaking the research and dissemination.

Not involving people although claiming to do so – engaging with research participants and peers

(40% non-commercial and 20% commercially funded studies, 2012 responses)

Researchers who ticked a box to indicate public involvement in their research but where this was not confirmed in their free-text responses most commonly described intended participation or engagement¹¹ activities or discussed pilot studies that had taken place.

Typical responses provided were:

- at the end of the study all the participating families will be written to, to thank them and inform them of the main findings of the study
- the study will recruit subjects to take part in the research
- the researchers will disseminate findings that are of interest to the public
- patients will be invited to participate by completing questionnaires
- family or friends may become involved with helping patients in their decision whether to participate in the research study.

¹⁰Tarpey M (2011) pages 15-16.

¹¹For further information on definitions of involvement, engagement and participations see INVOLVE (2012) **Briefing notes for researchers, briefing note 2**

www.involve.nihr.ac.uk/posttyperesource/what-is-public-involvement-in-research/

Some respondents reported that they had taken note of feedback from previous study participants which had informed the design of the research. For example:

- the study was informed by the experience of participants in our previous studies
- similar studies had been conducted in the research department before and previous participant feedback will inform the consent process and patient information sheets.

Others described the involvement of health professionals as providing the public input into the research or advisory group. For example:

- active input was sought from research nurses
- dentists will provide feedback on the proposed interview guide
- the doctors and research team have been consulted
- clinicians were surveyed to determine the most acceptable choice of control arm for this trial.

No plans for involvement

(20% non-commercial and 75% commercially funded studies, 2012 responses)

The researchers who ticked to indicate they would not be involving people in their research also described their reasons for this. These free-text responses generally reported that there was no need, because input had been gained from other sources or because it was not appropriate due to the type of study. They were most likely, although not exclusively, to be investigations / trials of a medicinal product or device. Whilst their comments were similar to those who appeared to misunderstand the involvement question, this group of respondents did seem to understand what the question was asking. Their free-text explanations showed that they were able, for example, to make a distinction between the terms involvement, engagement and participation in research:

- it was an early phase exploratory study so involvement was not deemed appropriate
- it was a laboratory based study so there was no opportunity for public involvement
- the outcomes of the study were unlikely to have an effect on the care of individuals participating in the study.

Other reasons included having a short time frame for the project, it was not suitable due to the nature of the project, or there was not a reference group available for people with a particular illness.

Concluding comments

This study shows that it is possible to produce baseline information on the extent and nature of public involvement from routine data collected by NRES. As reported in the 2011 study (Tarpey 2011), it highlights the merits of using free-text alongside tick-box questions to be able to check the accuracy and quality of the information provided by researchers. It also highlights the relevance of separately analysing responses from non-commercial and commercially funded studies.

Based on the analysis of the free-text responses to the public involvement question (QA14-1), the findings confirm that many researchers still do not seem to understand the involvement question, continuing to describe engagement rather than involvement activities.

This and other studies (e.g. Angell et al. 2008) show that Research Ethics Committees (RECs) frequently raise a broad range of ethical concerns with researchers about the design and conduct of the research they are assessing and have a particular duty to ensure that patients take part in high quality studies and will not be harmed. In light of this, it may be helpful to keep RECs informed of the evidence that suggests that public involvement in research prior to applying for ethics approval, encourages researchers to ensure it is relevant and acceptable from a patient and public perspective. It would also be helpful to encourage REC members to draw on the information provided in the public involvement question for assurances on the ethical probity of the research they are assessing.

Once researchers receive funding, they cannot start the work until they receive ethical approval. Often a provisional opinion is granted with a request for further information prior to agreeing a favourable opinion (with or without conditions). Evidence of public involvement

in research plans could potentially help to reassure ethics committees that ethical issues from a public perspective have or will be addressed and so reduce the numbers of requests for further information and hence provisional opinions. RECs consider responses to the public involvement question but do not take a consistent and coordinated approach to this. Further, researchers do not usually receive feedback from RECs on the information they provide on public involvement and so are unaware whether their responses have provided assurance, are unsatisfactory or are not about involvement.

Feedback by RECs could help to raise awareness of the importance of public involvement in improving researchers' applications as well as help to improve their understanding of what the question on public involvement is asking and how involvement differs from engagement.

However, it is important to acknowledge that for those researchers who have not already included plans for public involvement in their funding applications it is much harder to include public involvement at this relatively late stage of the research process. Where possible non-commercial research funders could be encouraged to ask researchers about public involvement in their funding applications (i.e. prior to application for ethics approval), if they do not do so already. We also need to recognise the very different patterns of public involvement activities reported by non-commercial and commercially funded studies, with the latter reporting very low levels of involvement. Companies should be encouraged to look at the emerging evidence of the benefits that involving the public brings with respect to simplifying approvals and aiding recruitment to time and target and start to involve the public more in the design of their studies.

Recommendations

■ **Research Ethics Committees (RECs)**

Research Ethics Committees should draw on the information provided in the public involvement question for assurances on the ethical probity of the research they are assessing and do this in a consistent way across all RECs. Further, RECs should provide feedback to researchers and record the account they have taken of the information provided about plans for public involvement both during the review process and in requests for further information.

Feedback by RECs could help raise researchers' awareness of the importance of public involvement in their research as well as help to improve their understanding of public involvement and how it differs from engagement.

■ **Funders**

It is necessary to recognise the very different pattern of plans for public involvement reported by non-commercial and commercially funded studies. The amount of involvement reported for commercially funded studies is very low. This may lead to such studies not addressing the needs of participants, which can hinder approvals

and recruitment of participants. Companies funding research should be encouraged to involve the public in the design of their studies because of the potential benefits this can bring to gaining ethical and NHS approvals and recruitment to time and target.

Where possible, non-commercial funders should be encouraged to emulate the question on the IRAS form about public involvement in their own research funding application forms, if they do not do so already. It would help researchers provide better quality information about their understanding of, and plans for, involvement prior to their application for ethics approval.

■ **Baseline data**

This joint INVOLVE and HRA project should continue to track the pattern of responses on public involvement in applications for ethical approval by repeating this study on a biennial basis.

The HRA should review the question on the IRAS form and the guidance for applicants with a view to improving the level of understanding of involvement over engagement and participation and so the quality of information provided.

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Sarah Buckland, Director INVOLVE Coordinating Centre

Janet Wisely, Director National Research Ethics Service (NRES)

Jeremy Butler, member National Research Ethics Advisors' (NREA) panel

Jim Elliott, INVOLVE Group member

Valerie Heard, Policy Implementation Officer NRES

Sam Wigand, Business Support Officer (Projects) NRES

Duncan Britton, Infonetica, acted as technical advisor to the steering group.

This second study has continued to be guided by Sarah Buckland (INVOLVE Coordinating Centre), Janet Wisely (now Chief Executive of the Health Research Authority), Jim Elliott, (now Public Involvement Lead, Health Research Authority), Jonathan Bell (technical advisor) and James Raftery, University of Southampton who advised on aspects of the data analysis.

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Appendix A

Project background and study methods

Project background

The IRAS ethics application form

When researchers receive funding for a health or social care research study, before that study can start, they must firstly obtain ethical approval from the National Research Ethics Service (NRES). They do this by filling in the Integrated Research Application System (IRAS) application form (www.myresearchproject.org.uk) which is used by NRES' Research Ethics Committees (RECs) (as well as others required to approve research including NHS R&D) to assess applications for ethical approvals.

Since September 2009, the IRAS form has included a two-part question (QA14-1) asking researchers about their plans for active public involvement, with a guidance note explaining what public involvement does, and does not cover. They are asked: first, to tick the boxes listing at which stages of the research process they intend to involve patients, service users, carers or members of the public; and second, to use the free-text box to describe the planned involvement (see Table 1 in the main report). In later sections of the IRAS form, there are separate questions about participant recruitment (QA27-34) and dissemination (QA51 and QA53).

Study methods

i) NRES scoping work (2010)

In preparation for the first 2011 study, a selection of completed IRAS application forms submitted to NRES were analysed¹², focusing on responses to the involvement question as well as cross-referencing with background information including the type of study, funder and sponsor. It included applications from both 'educational' and 'non-educational' studies¹³. NRES analysed both quantitative and free-text responses to the questions and developed summary categories to analyse the content of the free-text responses on public involvement. The work also looked at the linked administrative records of REC committee meetings and related correspondence with researchers for a sub-sample of these forms, but no references referring to the public involvement question were found.

ii) 2011 first joint study (analysing 2010 data)

Based on this scoping work the 2011 study surveyed a sample of non-educational studies submitted on IRAS application forms to NRES for ethical approval during 2010 (from 1 January to 31 December inclusive).

¹² NRES in-house scoping work undertaken by Sam Wigand with work on REC correspondence to researchers carried out by Valerie Heard in February 2010.

¹³ 'Non-educational' studies are the main, externally funded research studies. They are categorised as such to distinguish them from 'educational studies', which cover research where the principal purpose is the training of researchers, for example by doing doctoral or masters research degrees. Given the focus of this study, educational studies were excluded from the 2011 study and again from this study.

NRES does not hold a research database but has an administrative database through which all applications submitted to NRES can be accessed. The database is designed to assist and manage the ethical review process. Therefore, access to the data for the purpose of review across applications is possible but not routinely available. The technical advisor on the steering group recommended that the most straightforward way of creating the study sample was to extract all applications submitted to Manchester and London Research Ethics Committees (RECs) and the Social Care REC during 2010 (compared to alternatives of more REC centres and a shorter time frame). All other RECs were excluded. This method produced a final sample size of 14% of the total applications (646 non-educational studies).

The data extracted from the IRAS form included the public involvement question and other information covering the purpose and design of the research, type of study, lead funder and sponsor. Whilst some of this data was available as quantitative (tick-box) responses, most were free-text, qualitative entries. Both sets of data, quantitative and qualitative, were coded and analysed after an initial sort according to the responses to the public involvement question (as the key variable). The categories developed during the 2010 scoping study for the free-text responses on the public involvement question were used as the basis for the content analysis of the free-text responses and are reported in the free-text responses findings section of this report (pages 16-17).

iii) 2014 second joint study (analysing 2012 data)

The specifications and search criteria used to extract the 2010 data were also used for the 2012 data. The detailed specifications developed for the data extraction and search criteria are available on request from admin@invo.org.uk

Despite using exactly the same specifications and search criteria, there are two differences between this study and the previous one: a) the 2014 study has a larger sample size and b) the analysis applied to both sets of data (2012 and 2010) was extended. The reasons for this are summarised below:

a) Difference in sample size:

Although the 2012 data was extracted from the same REC Centres sampled for the 2010 data, this resulted in a much larger sample size - 30% (N=1169) of the total non-educational study applications in 2012, compared to 14% (N=646) of the total applications in 2010. This was due to the reorganisation of NRES and different number of RECs for the two Centres since being relocated within the Health Research Authority which was established in December 2011¹⁴.

b) Extended analysis of the data:

The 2011 study had not made a distinction between non-commercial (e.g. NIHR, medical research charities) and commercially (e.g. pharmaceutical companies) funded studies. For this second study, the two main funding streams were separated out and the 2010 data resorted and reanalysed to better reflect the extent of the very different scale of responses to the public involvement question by type of funder.

As for the 2011 study, the 2012 data was checked, and duplicates and educational studies were removed. The only data not presented as percentages of the 2010 and 2012 data samples was where the applicants were able to tick more than one option (Figures 7 and 8) so the absolute number is most relevant.

¹⁴ www.hra.nhs.uk/about-the-hra/our-committees/nres/

Appendix B

Supporting data for Figures 4 – 8

Figure 4: Breakdown of responses by all funders to question on public involvement: supporting data

	2010			N
	no involvement	involvement not confirmed	involvement confirmed	
Commercial	154	71	5	230
NHS	38	106	35	179
University funding	15	38	17	70
Charities	18	19	22	59
NIHR	1	14	31	46
Research Councils	8	16	4	28
EC	0	8	4	12
Other	14	2	6	22
Total	248	274	124	646

	2012			N
	no involvement	involvement not confirmed	involvement confirmed	
Commercial	311	82	23	416
NHS	55	113	43	211
University funding	34	51	39	124
Charities	29	60	80	169
NIHR	7	21	101	129
Research Councils	13	35	19	67
EC	5	9	10	24
Other	4	14	11	29
Total	458	385	326	1169

Figure 5: Non-commercially funded studies – Number of involvement boxes ticked and whether confirmed by free-text responses: supporting data

	2010		N
	involvement not confirmed	involvement confirmed	
None	90	0	90
One	133	17	150
Two	53	34	87
Three	14	30	44
Four	4	20	24
Five	3	18	21
Total	297	119	416

	2012		N
	involvement not confirmed	involvement confirmed	
None	204	0	204
One	120	56	176
Two	79	88	167
Three	29	87	116
Four	13	46	59
Five	5	26	31
Total	450	303	753

Figure 6: Commercially funded studies – Number of involvement boxes ticked and whether confirmed by free-text responses: supporting data

	2010		
	involvement not confirmed	involvement confirmed	N
None	158	0	158
One	50	2	52
Two	15	1	16
Three	0	1	1
Four	2	0	2
Five	0	1	1
Total	225	5	230

	2012		
	involvement not confirmed	involvement confirmed	N
None	313	0	313
One	67	12	79
Two	6	7	13
Three	4	3	7
Four	2	1	3
Five	1	0	1
Total	393	23	416

Figure 7*: Non-commercially funded studies – type of involvement activities ticked and whether confirmed by free text

	2010		
	involvement not confirmed	involvement confirmed	N
Design	57	106	163
Management	21	61	82
Undertaking	118	46	164
Analysis	21	21	42
Dissemination	143	91	234

	2012		
	involvement not confirmed	involvement confirmed	N
Design	103	264	367
Management	31	124	155
Undertaking	130	128	258
Analysis	20	75	95
Dissemination	158	216	374

Figure 8*: Commercially funded studies – type of involvement activities ticked and whether confirmed by free text

	2010		
	involvement not confirmed	involvement confirmed	N
Design	6	3	9
Management	3	1	4
Undertaking	37	1	38
Analysis	0	1	1
Dissemination	18	1	19

	2012		
	involvement not confirmed	involvement confirmed	N
Design	19	21	40
Management	7	7	14
Undertaking	39	3	42
Analysis	4	1	5
Dissemination	35	7	42

*Note: Figures 7 and 8 had multiple responses to these questions

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Health Research Authority

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