

Public involvement in applications to the Health Research Authority Research Ethics Service:

Comparative analysis
of data from 2010, 2012 and
2014

In memory of Jeremy Butler.
A significant contributor to and friend
of the
Health Research Authority and
Research Ethics Service

About this study

This is the third report of a joint INVOLVE and Health Research Authority (HRA) project to analyse the extent of public involvement reported in applications to the HRA Research Ethics Service (RES) and the form it takes¹. This report compares responses to the public involvement question in the ethics application form from 2010, 2012 and 2014. Non-commercial and commercially funded studies are analysed separately.

This report should be referenced as: Elliott J, Horwood A, Hunn A, Staley K and Tarpey M. (2017) Public involvement in applications to the Health Research Authority Research Ethics Service: Comparative analysis of 2010, 2012 and 2014 data, HRA London, INVOLVE Southampton.

Information about INVOLVE

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Information about the Health Research Authority (HRA)

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- make sure research is ethically reviewed and approved
- ensure transparency in research
- oversee a range of committees and services
- provide independent recommendations on the processing of identifiable patient information where it is not always practical to obtain consent, for research and non-research projects.

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¹The first study reported in 2011 and the second in 2014: see Tarpey M (2011) and Tarpey and Bite (2014)

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Executive summary

Introduction

This is the third report of a joint INVOLVE and Health Research Authority (HRA) project² to analyse the extent of public involvement³ reported in applications to the Research Ethics Service (RES) and the form it has taken. This report compares responses to the public involvement question in the ethics application form from 2010, 2012 and 2014.

The analysis focuses on responses to the two-part question in the ethics application form (QA-14). The first part has tick-boxes for each stage of the research cycle in which the public can be involved: design, management or undertaking of the research along with analysis and dissemination of the results or none of them.

The second part is a free-text box asking applicants to describe the involvement for the stages of research they indicated via the tick boxes where they had involved or planned to involve the public. The free text responses were read against an agreed definition of public involvement and coded to indicate whether or not they actually described the involvement of the public: thus involvement was 'confirmed' or 'not confirmed'.

Data for the first two reports for 2010 and 2012 were obtained from a sample of Research Ethics Committees (RECs) - the same RECs in both years. The applications to these RECs amounted to around a third of all the applications submitted in those years. For 2014, data were extracted from the applications to all the RECs, which allowed additional analyses to be undertaken, e.g. by category of funder.

The definition of involvement used for all three studies (from INVOLVE and consistent with that used by the HRA) was broadly interpreted, which led to involvement being confirmed for a wide range of activities from one-off consultations with a single individual through to extensive collaboration or co-production throughout the research cycle.

The variability in what was confirmed as involvement is explored in a qualitative analysis of data from 2014, which has been reported separately⁴. This variability was not noted in the first two reports but it is clear from the qualitative analysis that it severely limits the interpretations and conclusions that can be taken from the data.

² The first study was published in 2011 and the second in 2014: See Tarpey (2011) Tarpey and Bite (2014)

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 Staley and Elliott (2017)

Results -trends in the amount of involvement confirmed by category of funder

In all three years of the study nearly two thirds of applicants ticked at least one box in response to the question on public involvement, indicating that they were intending to involve or had involved the public in some aspects of their research (63% in 2014, 61% in 2012 and 62% in 2010). However, the overall proportion of studies where public involvement was confirmed was 36% in 2014, up from 28% in 2012 and 19% in 2010.

For non-commercially funded studies (e.g. the National Institute for Health Research {NIHR}, medical research charities and research councils) the findings show an increase in public involvement in applications for ethics approval from all categories of non-commercial funder from 2010 to 2014:

- In 2014, the level of confirmed involvement in non-commercially funded studies was 54%, up from 40% in 2012 and 29% in 2010.
- 28% of non-commercial applicants in 2014, who had ticked at least one of the involvement boxes, in fact described plans for engagement, participation or other activities but not public involvement – this number is down from 40% in 2012 and 49% in 2010.
- The remaining 18% of applicants said they had no plans for involvement – down slightly from 20% in 2012 and 23% in 2010.

For commercial studies (e.g. pharmaceutical companies) the amount of confirmed involvement reported has increased from 2010 to 2014 from a very low base but is still much lower than the level reported for non-commercial studies:

- In 2014, the level of confirmed involvement in commercial studies was 9%, up from 5% in 2012 and 2% in 2010
- 25% of commercial applicants in 2014 ticked at least one of the involvement boxes, but did not describe involvement in their free-text response - compared to 20% in 2012 and 31% in 2010.

- And 66% reported that they had no plans for involvement compared to 75% in 2012 and 67% in 2010.

The steady increase in ‘confirmed’ involvement from 2010 to 2014 overall and for all categories of funder is encouraging and reflects the increased focus from research funders, particularly non-commercial ones, on involving the public in the design and undertaking of health and social care research prior to applications for ethics approval. The most notable example of this remains the NIHR, which requires information on plans for involvement in all their research grant applications. In 2014, 89% of applicants funded by NIHR reported ‘confirmed’ involvement of the public in their studies, up from 78% in 2012 and 67% in 2010.

Applications from other categories of funder also show increases in the level of ‘confirmed’ involvement reported:

- Medical research charities – 55% in 2014, up from 47% in 2012 and 37% in 2010
- Universities – 39% in 2014; up from 31% in 2012 and 24% in 2010 and
- Research Councils – 45% in 2014 up from 28% in 2012 and 14% in 2010.

Despite the growing numbers of reports of involvement a sizeable proportion of applicants still seem to be unclear about the definition of involvement and in fact described other kinds of activities. This shows that there is still much to do to promote a common understanding of public involvement and to explain how it can help health and social care research.

The wide variation in the type of activity that was confirmed as involvement in this project was helpful in terms of allowing a broad assessment of how much involvement there is in applications to RECs. However, it limited what was possible in terms of looking for evidence of benefits from involvement such as easier and faster approvals.

Next steps

Making the requirements for information on public involvement in IRAS more useful for ethical review

Public involvement prior to ethical review could usefully inform the REC review process (Health Research Authority / INVOLVE 2016b). The findings from the qualitative analysis show that currently researchers' reports of involvement in the IRAS form rarely include information that would help REC members. The question about involvement on the IRAS form (and the accompanying guidance for applicants), does not explicitly ask for information that would be of benefit. The HRA has started to work collaboratively with RECs and the research community (researchers, funders and sponsors) to consider what information RECs need about involvement and therefore how the question and guidance might be revised to better meet these needs.

Supporting Research Ethics Committees (RECs) to make more effective use of information on public involvement

Once the IRAS form and guidance has been revised, it is hoped that REC members will be able to make extensive use of researchers' reports of involvement to support their ethical review. For example, good quality involvement that has made a difference to the design of a study is likely to assure REC members of the ethical probity of a research proposal. It will be important to ensure that RECs have a shared understanding of the value of involvement in supporting ethical review and are consistent in their use of the information provided by researchers.

Supporting and encouraging more and better public involvement in health research

The HRA will continue to support and encourage researchers and organisations that fund and manage health research, both non-commercial and commercial, to involve the public in their work and to do so as effectively as possible. This will build on the joint guidance and evidence briefing issued by the HRA and INVOLVE in 2016 (Health Research Authority / INVOLVE 2016a, 2016b).

Introduction

This is the third report of a joint INVOLVE and Health Research Authority (HRA) project⁵ to analyse the extent of public involvement⁶ reported in applications to the Research Ethics Service (RES) and the form it has taken.

Prior to the initial study in 2011 (Tarpey 2011) a previous research project was funded by the then National Research Ethics Service (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. Their 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). By involving the public, researchers were able to demonstrate that their planned research was acceptable from a patient and public perspective and that they had addressed potential ethical concerns with the input from patients and the public, prior to applying for ethical approval. This in turn could provide assurance to RECs assessing the ethical probity of these studies (Tarpey 2011; Redwood 2012; Staley 2013, Health Research Authority / INVOLVE 2016).

Project aims

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

- analysing information on public involvement in research routinely collected by RES in QA14-1 (see Table 1) of the application form for ethical approval of research studies
- tracking the pattern of responses to see whether or not they change over time by repeating the same analysis on a biennial basis: and
- gathering evidence of how well applicants demonstrate their understanding of public involvement and how it can support ethical review

This report compares a sample of responses to the public involvement question, QA14-1, from applications in 2010 and 2012 for ethical approval with those for all applications made in 2014. Non-commercial (e.g. NIHR, medical research charities) and commercial (e.g. pharmaceutical companies) studies are analysed separately to more accurately reflect the different patterns of responses to the public involvement question by type of funder.

The key analysis focuses on responses to the two-part question in the ethics application form (QA-14) 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 stages of the research cycle where the public may be involved, and a free-text box asking researchers to describe this involvement. The analysis also links the responses to this question to other information on the application form, such as the source of funding.

⁵ The first study was published in 2011 and the second in 2014: See Tarpey (2011) and Tarpey and Bite. (2014)

⁶ 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.

The free text responses were compared with an agreed definition of public involvement and coded to indicate whether or not they actually described the involvement of the public: thus involvement was 'confirmed' or 'not confirmed'.

The definition of involvement used (from INVOLVE and consistent with that used by the HRA) was broadly interpreted for all three studies. This led to involvement being confirmed for a wide range of activities from one-off consultations with a single individual through to extensive collaboration or co-production throughout the research cycle. The variability of what was confirmed as involvement is explored in a detailed qualitative analysis of data from 2014, published separately in BMC's open access journal *Research Involvement and Engagement* (Staley and Elliott 2017).

Table 1: QuA-14: The question on public involvement and guidance note on 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 (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.”

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

⁷ QuA14, IRAS Ethics Application Form: www.myresearchproject.org.uk/

Findings

This section presents the study findings. They show comparative analyses of data from 2010, 2012 and 2014 and resultant trends. Results are shown for all types of studies together, by the broad categories of commercial or non-commercial funders and for non-commercial studies they are further broken down into seven categories of organisation. Finally, there are the results of analyses according to which stages of the research cycle applicants indicated that they had involved the public or where they planned to involve the public.

Results for all studies together

In all three years of the study nearly two thirds of applicants ticked at least one box in response to the question on public involvement, indicating that they were intending to involve or had involved the public in some aspects of their research (63% in 2014, 61% in 2012 and 62% in 2010, Tarpey and Bite, 2014).

However, as shown in Figure 1, the overall proportion of studies where public involvement was confirmed was 36% in 2014, up from 28% in 2012 and 19% in 2010.

The increase in the proportion of applicants whose plans for involvement were confirmed from 2010 to 2014 corresponds to the decrease in the proportion of applications where involvement was not confirmed, as shown in Figure 2, 27% in 2014, down from 33% in 2012 and 42% in 2010. The proportion of applicants reporting no plans for involvement was very similar in each year, as shown in Figure 3.

Figure 1: The change in percentage of applications where involvement was confirmed by free text from 2010 to 2014

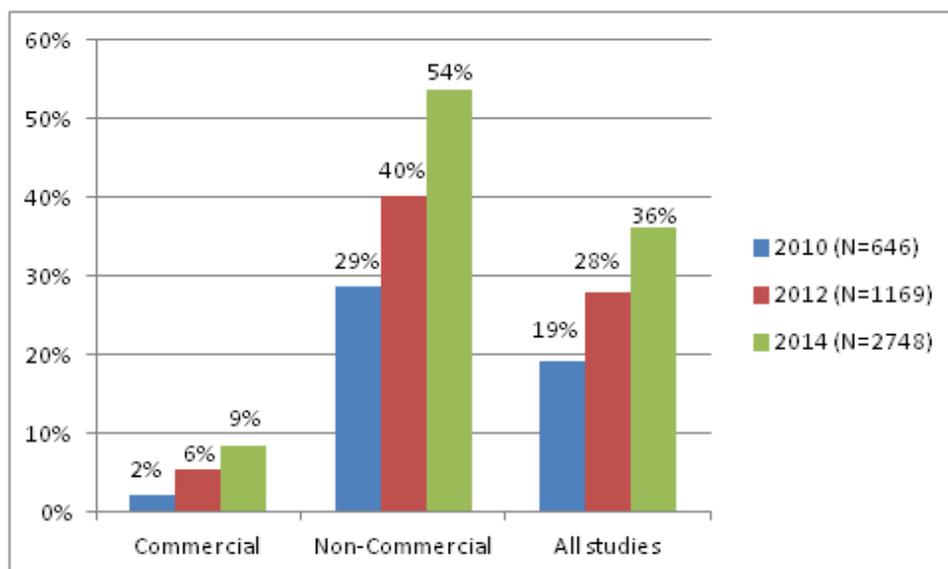


Figure 2: The change in percentage of applications where involvement was not confirmed by free text from 2010 to 2014

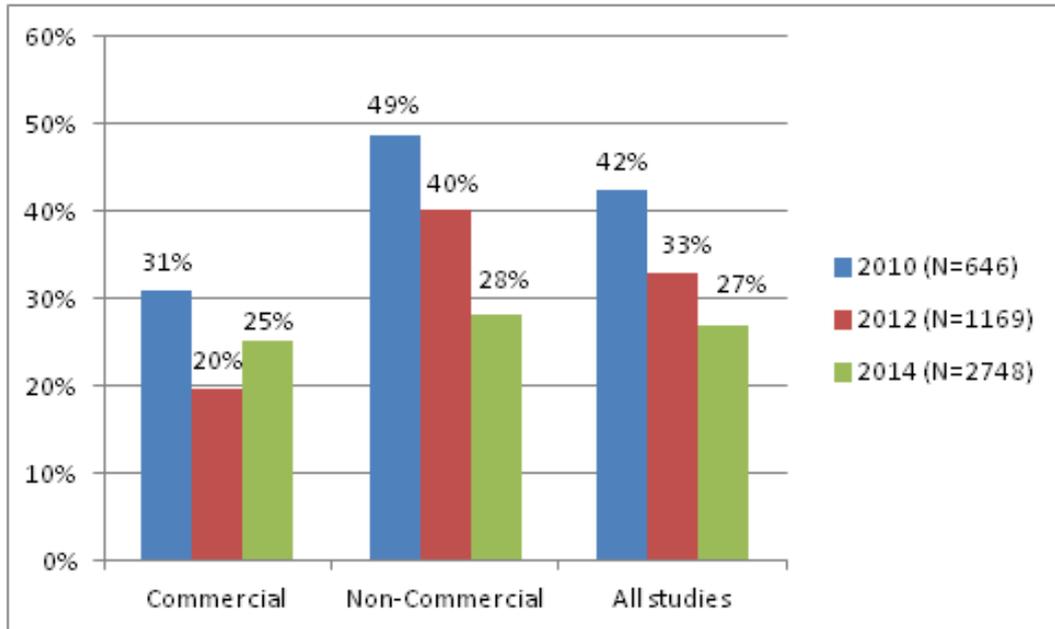
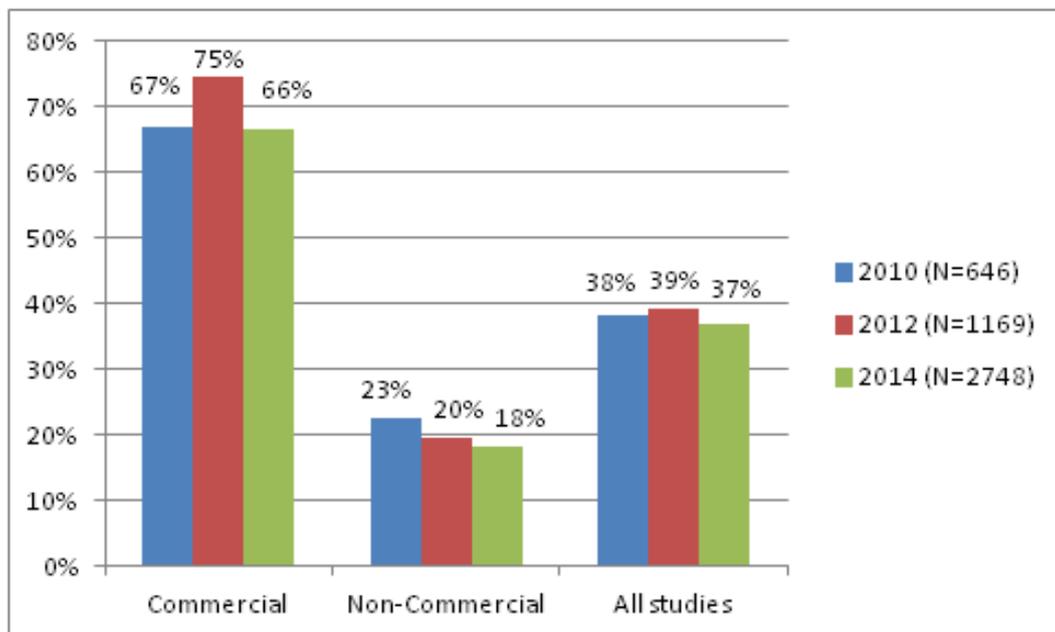


Figure 3: The change in percentage of applications where there were no plans for involvement reported from 2010 to 2014



Results according to the commercial status of the funder

In the IRAS form the funding and sponsor organisations are categorised as either commercial or non-commercial. When the results are separated out by the commercial status of the funder, the differences are very marked. As shown in Figure 1, non-commercial funded studies have a very much higher and increasing proportion of plans for public involvement in their research compared to commercially funded studies:

- In 2014, 54% of researchers of non-commercial studies 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 2012 this proportion was 40% and in 2010 it was 29%.
- In 2014 9% of researchers of commercial studies 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 just 2%, rising to 6% in 2012.

The pattern of increases in involvement confirmed with concomitant decreases in involvement not confirmed shown for all studies are similar for applications from both non-commercial and commercial funders, as shown in Figure 2:

- In 2014 28% of applicants of non-commercial studies, who had ticked at least one of the involvement boxes, in fact described plans for engagement, participation or other activities but not public involvement. This number is down from 40% in 2012 and 49% in 2010. 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 2014 25% of applicants of commercial studies, who had ticked at least one of the involvement boxes, in fact described plans for engagement, participation or other activities but not public involvement. This compared to 20% in 2012 and 31% in 2010.

The proportions of applications where no involvement was reported are again similar when broken down by the commercial status as for all funders, as shown on Figure 3:

- In 2014, 18% of applicants of non-commercial studies said they had no plans for involvement; in 2012 it was 20% and in 2010 it was 23%.
- The proportion applicants of commercial studies who indicated that they were **not** intending to involve the public in their study has been broadly similar from 2010 to 2014: in 2010 it was 67%, in 2012 it was 75% and in 2014 it was 66%

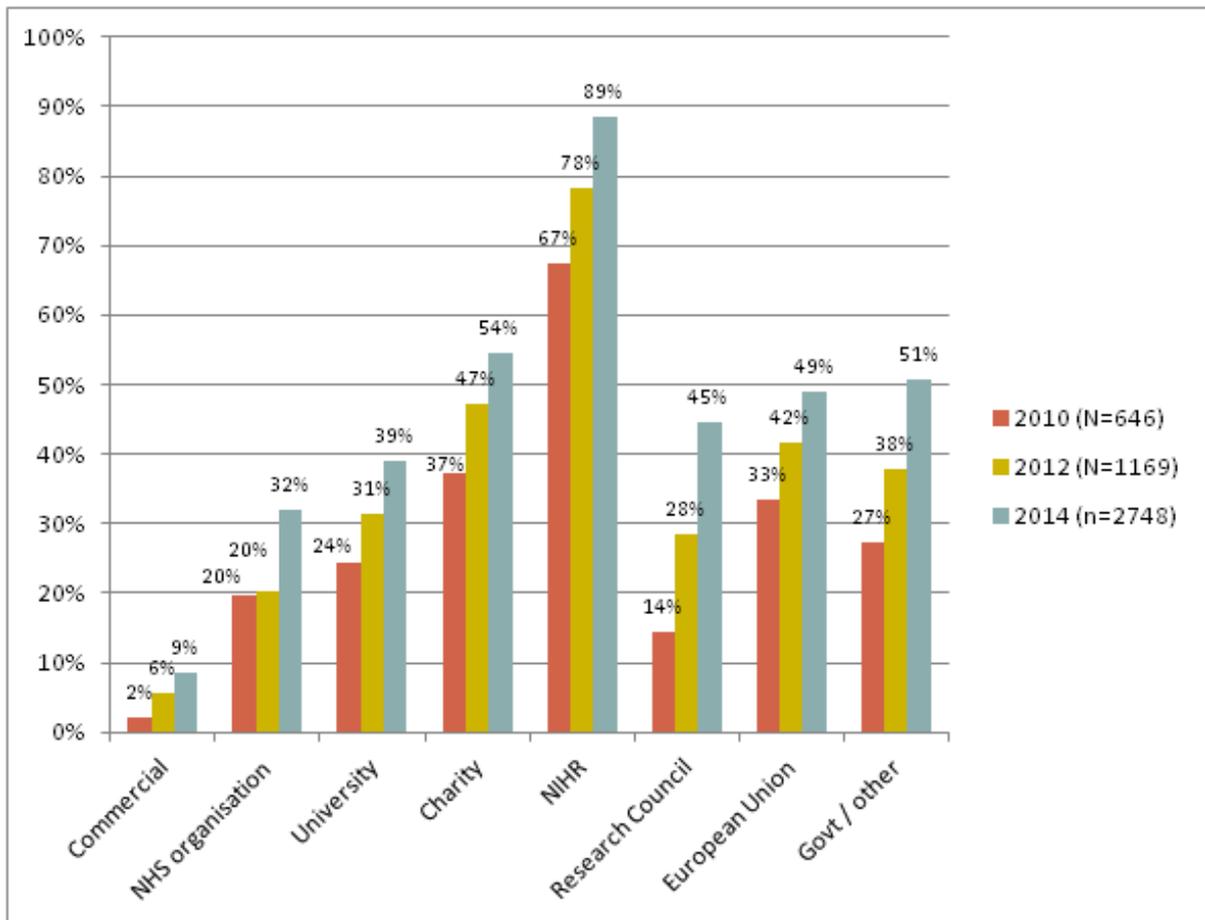
Results for different categories of non-commercial funding organisations

Around a third of all studies in all three years are commercially funded (39% in 2014 and 36% in each of 2012 and 2010) and, as shown above, they report the lowest levels of confirmed involvement. The non-commercial funders were grouped into seven categories, which were determined for the first study (for more information see Appendix A).

Figure 4 shows for each category of non-commercial research funder the percentage of studies where the involvement reported has been confirmed by the free text response, with commercial funders included for comparison. There is a steady increase for all funders from 2010 to 2014 consistent with the continued and growing trend amongst non-commercial funders asking researchers to provide details of their plans for public involvement as part of their grant application processes (prior to applications for ethics approval).

The proportion for the NIHR is the highest in each year and charities the second highest. The largest relative increase between each year is for Research Councils (14% in 2010, 28% in 2012 and 45% in 2014).

Figure 4: The percentage of studies with confirmed involvement by category of funder from 2010 to 2014



As reflected in the previous report the high and increasing level of confirmed involvement for the NIHR is the result of its requirements for information on plans for involvement in all their research grant applications. This 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. In 2014 89% of the public involvement reported in NIHR funded applications was confirmed, up from 78% in 2012 and 67% in 2010).

The high and rising level for research charities may reflect the influence of the Association of Medical Research Charities (AMRC), which has been encouraging and supporting member charities to involve the public over recent years. In 2014 54% of public involvement reported in charity funded applications was confirmed, up from 47% in 2012 and 37% in 2010.

The lowest level of confirmed involvement reported for non-commercial funders is for NHS organisations (32% in 2014, up from 20% in both 2012 and 2010).

Figure 5 shows for each category of research funder the percentage of studies where the involvement reported was not confirmed by the free text. The proportion has fallen overall from 2010 to 2014 for all the main categories of non-commercial funder but not for the “Government / other” category or for commercial funders, where there is no clear trend. This overall fall roughly mirrors the rise in the level of confirmed involvement while the level of no reported plans has stayed more or less constant (see below). This may mean that the level of awareness and understanding of involvement and the benefits it can bring has increased over time, which is to be hoped but cannot be demonstrated with this data.

Figure 5: The percentage of studies where involvement was not confirmed by category of funder from 2010 to 2014

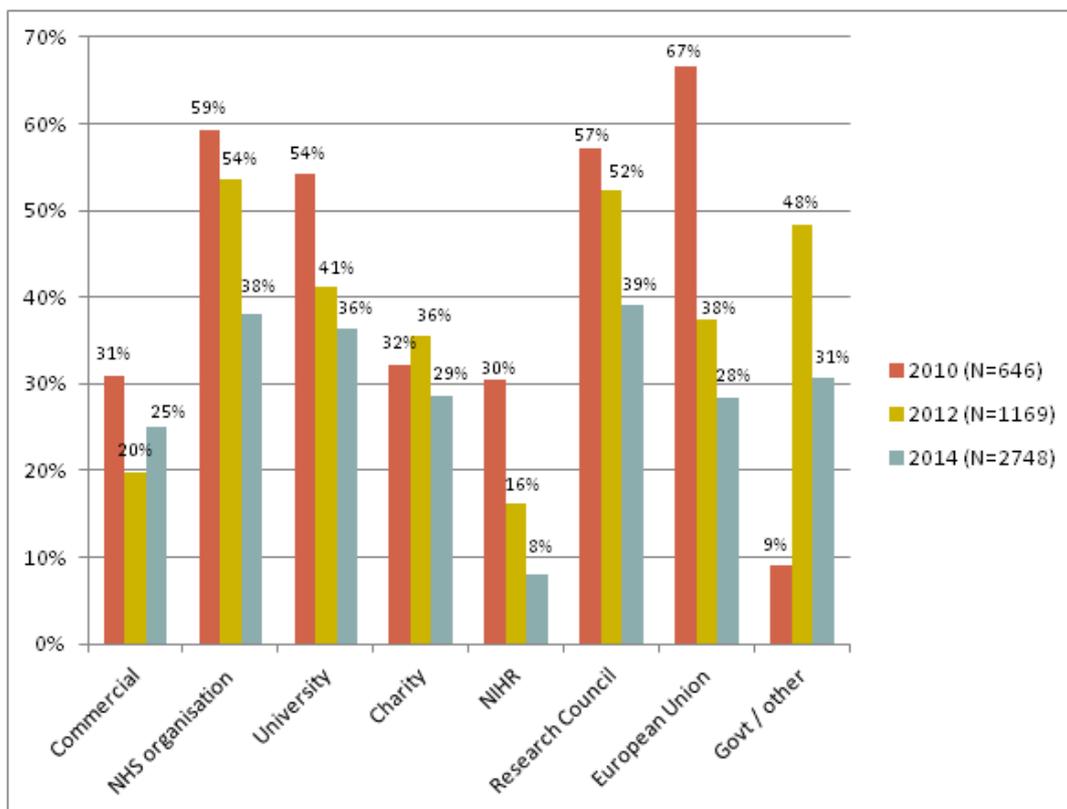
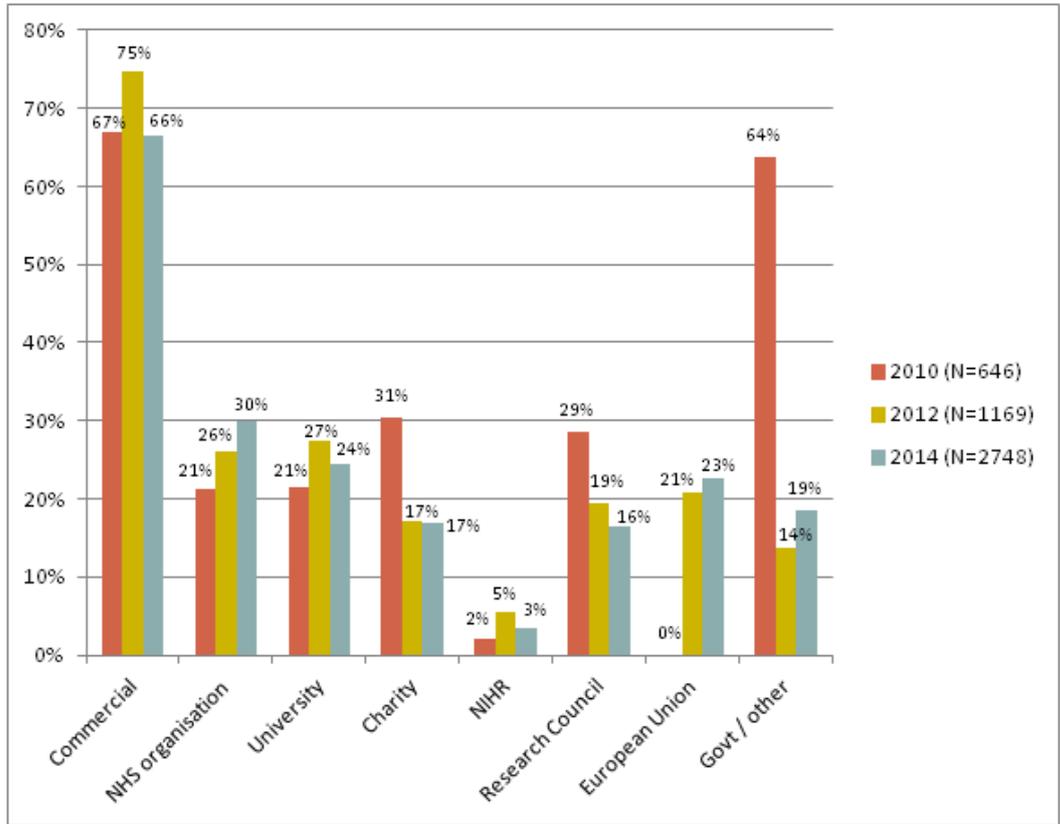


Figure 6 shows for each category of research funder the percentage of studies that reported there were no plans for involvement. There is no clear trend across all the categories of funder and little change for any category between 2012 and 2014. The biggest changes are from 2010 to 2012 for charities, research councils and the ‘Government / other’ category and may simply reflect that the data from 2010 was poorer quality than for 2012 especially in terms of the information provided on funders and sponsors.

Figure 6: The percentage of studies with no plans for involvement by category of funder from 2010 to 2014



Results for different stages of the research cycle

The reports for the first two studies included analyses of which stages of the research cycle involvement were reported and the number of stages (Tarpey 2011, Tarpey and Bite 2014). These showed that for non-commercial studies involvement was:

- Reported most often for design and dissemination
- Confirmed most often for management and analysis
- Confirmed least often for undertaking and dissemination
- Reported most often for just one stage, then two, then three and so on, with all five stages reported least often
- Confirmed more often the more stages of the research cycle were reported

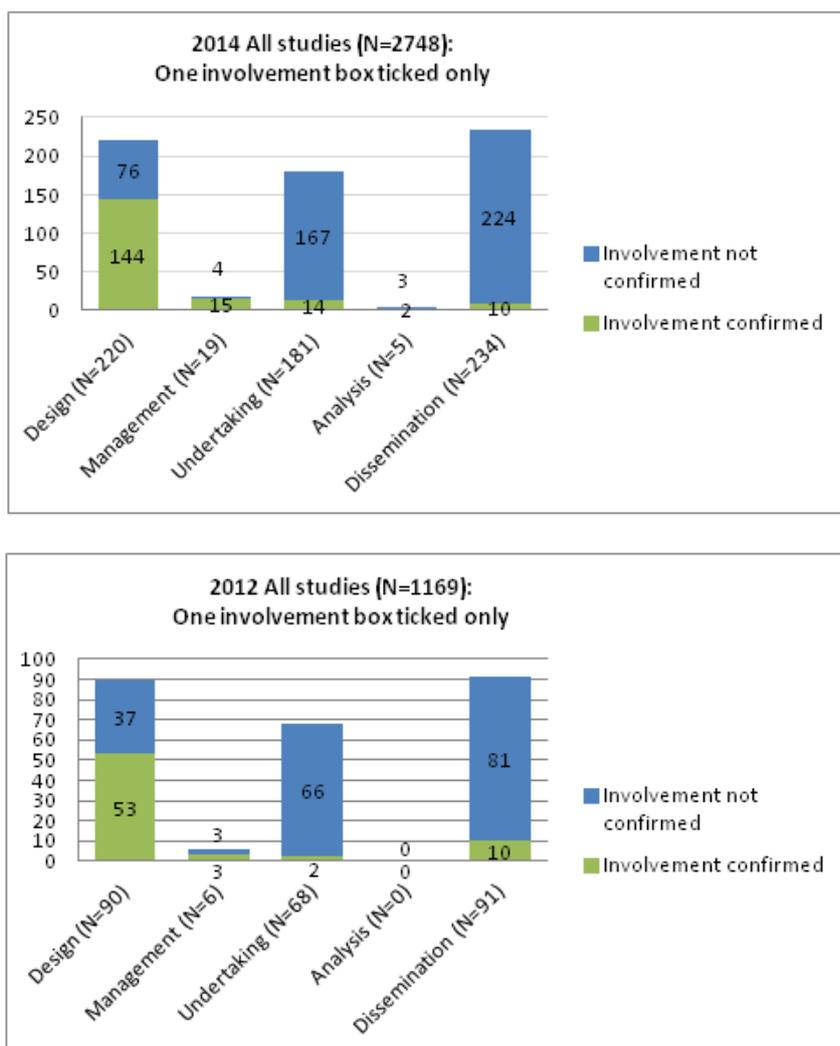
For commercial studies involvement was:

- Reported most often for undertaking and dissemination
- Confirmed most often for design and management
- Confirmed least often for undertaking and dissemination
- Reported most often for just one stage, then two, then three and so on, with all five stages reported least often (and very rarely)
- Rarely reported in more than one more stage but more often confirmed when it was

A similar pattern was present in the data from 2014. These analyses clearly illustrate the effect of the variation in the type of activity that was confirmed as involvement and the lack of clarity around the definition of involvement. This is most clearly demonstrated in the descriptions given for involvement in the undertaking or dissemination of research where the vast majority of the activities were not involvement.

This was explored further for the data from 2012 and 2014 where involvement was reported for only one stage of the research cycle⁸. In 2012 22% of applicants (255 out of 1169) reported involvement for just one stage of the research cycle and in 2014 this was 24% (659 out of 2748). Figure 7 shows the level of involvement confirmed when it was reported for just one stage of the research cycle for all studies together.

Figure 7: All studies - One involvement box ticked only: type of involvement activity ticked and whether confirmed by free text responses for 2012 and 2014



⁸The data for 2010 was not available to undertake the same analysis

Detailed qualitative analysis of the descriptions of involvement in the free text responses to the public involvement question (2014 entries)

The analysis of what applicants said in their free-text responses about their plans, or otherwise, for public involvement in their studies has been published separately in the open access BMC journal Research Involvement and Engagement (Staley and Elliott 2017). The free text responses from applications in 2014 were analysed using Nvivo qualitative analysis software to look for common themes in what applicants wrote about the involvement they indicated in the tick boxes. This allowed a more in depth understanding to be reached than in the previous analyses for 2012 and 2010 where the free text responses were simply read in Microsoft Excel and themes looked for manually (Tarpey and Bite 2014 and Tarpey 2011). However, the broad themes found in the 2014 entries are similar to those for 2010 and 2012⁹.

Although a number of clear themes emerged from this analysis one of the most marked finding was that in many cases not enough detail was provided to make a judgement about what had actually been done or was planned to be done or about the quality of involvement that was described.

The analysis does indicate that there is a lot of confusion about what involvement in the different stages means. It also seems unclear as to whether the questions are asking about the impact of any involvement prior to REC review, or the potential for involvement in different stages of the planned project.

The paper describes the themes found in the free text according to the different stages of research where involvement was reported.

⁹The data for 2010 was not available to undertake the same analysis

Concluding comments

This study and the qualitative analysis of 2014 data (Staley and Elliott 2017) confirm and build on the previous studies in showing that it is possible to obtain a measure of the extent of public involvement from routine data collected by RES and the form it takes even though there is considerable variation in what was described as involvement. However, the qualitative analysis of the 2014 data revealed the extent of the variability of what applicants write about involvement and that for most applications the information is of limited value to RECs in assuring them about the ethical aspects of studies. The analysis of records where involvement was only reported for one stage of the research cycle, which is included for the first time in this report, further illustrates the limitations of the data for use by RECs.

The main finding from this report is that the rise in the amount of confirmed involvement described in applications for ethical approval that was seen from 2010 to 2012, as shown in the second report (Tarpey and Bite, 2014), continued from 2012 to 2014. This is encouraging and hopefully shows the increasing awareness of the importance of public involvement in helping to ensure that health and social care research studies are ethical and acceptable to participants.

Although this study and, particularly, the qualitative analysis of 2014 data, show that the information applicants for ethical review provide is not as helpful as it could be, members of RECs are able to and do ask applicants who attend meetings for more details about their involvement of patients and the public. Often this additional information is helpful to the ethical review of applications and would be more so were it included in the applications in the first place.

Therefore, the HRA has decided to use the evidence in this report as the basis for reviewing the information about the involvement of patients and the public in applications for ethical review with a view to making it more useful in assessing whether studies are ethical and acceptable to participants.

The intention is to think about what RECs do with researchers' reports of involvement in a different way. The important thing will be for RECs to assess whether researchers have made good use of the outputs of the involvement of patients and the public rather than trying to judge the quality of the process of involvement for itself. While it will be important to know that what has been done has been done well what will be more important is to look at what has changed as a result.

While the work for this report was being undertaken the HRA and INVOLVE published revised and updated guidance about public involvement and ethical review (Health Research Authority / INVOLVE 2016a) and an associated evidence briefing on the impact of public involvement on ethical review (Health Research Authority / INVOLVE 2016b). These documents build on earlier versions referenced in the first two studies and provide a point of reference for the work the HRA has started to improve the usefulness of the information on involvement in applications for ethical review.

Next steps

Making the requirements for information on public involvement in IRAS more useful for ethical review

Public involvement prior to ethical review could usefully inform the REC review process (Health Research Authority / INVOLVE 2016b). The findings from the qualitative analysis show that currently researchers' reports of involvement in the IRAS form rarely include information that would help REC members. The question about involvement on the IRAS form (and the accompanying guidance for applicants), does not explicitly ask for information that would be of benefit. The HRA has started to work collaboratively with RECs and the research community (researchers, funders and sponsors) to consider what information RECs need about involvement and therefore how the question and guidance might be revised to better meet these needs.

Supporting Research Ethics Committees (RECs) to make more effective use of information on public involvement

Once the IRAS form and guidance has been revised, it is hoped that REC members will be able to make extensive use of researchers' reports of involvement to support their ethical review. For example, good quality involvement that has made a difference to the design of a study is likely to assure REC members of the ethical probity of a research proposal. It will be important to ensure that RECs have a shared understanding of the value of involvement in supporting ethical review and are consistent in their use of the information provided by researchers.

Supporting and encouraging more and better public involvement in health research

The HRA will continue to support and encourage researchers and organisations that fund and manage health research, both non-commercial and commercial, to involve the public in their work and to do so as effectively as possible. This will build on the joint guidance and evidence briefing issued by the HRA and INVOLVE in 2016 (Health Research Authority / INVOLVE 2016a, 2016b).

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Appendix A

Project background and study methods

Background

Management of the project

This project was guided by a steering group between 2010 and 2011 made up of the following members:

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.

The second study was also guided by Sarah Buckland (INVOLVE Coordinating Centre), Janet Wisely (Chief Executive of the Health Research Authority, HRA) Jim Elliott (Public Involvement Lead, HRA) and Jonathan Bell (technical adviser).

The first two studies were carried out by Sarah Bite and Maryrose Tarpey at the INVOLVE Coordinating Centre.

This third study was carried out by Jim Elliott, Andrea Horwood and Amanda Hunn from the HRA, Kristina Staley from TwoCan Associates and Maryrose Tarpey (independent consultant and formerly with the INVOLVE Coordinating Centre).

The 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 HRA's Research Ethics Service (RES, formerly 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 RES' Research Ethics Committees (RECs) as well as other organisations 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 which stages of the research process they have involved or intend to involve patients, service users, carers or members of the public; and second, to use the free-text box to describe what they have done or plan to do. See table 1 in the main report. In later sections of the IRAS form, there are separate questions about participant recruitment (QA27-A34) and dissemination (QA51 and QA53).

Methods

National Research Ethics Service (NRES) scoping work (2010)

In preparation for the first study in 2011, a selection of completed IRAS application forms submitted to NRES was analysed¹⁰, 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' studies¹¹. 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.

2011 first joint study (analysing 2010 data)

Based on the 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).

RES (and NRES before it) does not hold a research database but has an administrative database through which all applications submitted to it 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 adviser 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% (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. The free text responses from the question on public involvement were read against an agreed definition of public involvement and coded to indicate whether or not they actually described the involvement of the public: thus involvement was either confirmed or not confirmed. 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 findings section of this report.

¹⁰ NRES in-house scoping work undertaken by Sam Wigand with work on REC correspondence to researchers carried out by Valerie Heard in February 2010.

¹¹ '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.

2014 second joint study (analysing 2012 data)

The exact same specifications and search criteria were used to extract the 2012 data as for the 2010 data.

Despite this, there are two differences to the previous study: a) the second study had 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 exact same RECs 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 presumed to reflect the reorganisation of NRES and increased workload of the RECs specified in the search criteria since being relocated within the Health Research Authority established in December 2011¹²

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 the 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, duplicates and educational studies 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 where the absolute number is most relevant.

2016 third joint study (analysing 2014 data)

The exact same specifications and search criteria were used to extract the 2014 data as for the 2012 and 2010 data. The detailed specifications developed for the data extraction and search criteria are available on request from: hrapublicinvolvement@nhs.net

When the first two studies were conducted the data from IRAS were handled by a third party organisation for the RES. This had moved in house by the third study and the cost of extracting data for all applications from 2014 was insignificant compared to the previous situation. Therefore, data for all applications were extracted for 2014 to allow additional analyses to be conducted and to validate the sample used in the first two studies.

The free text responses were read against an agreed definition of public involvement and coded to indicate whether or not they actually described the involvement of the public: thus involvement was either confirmed or not confirmed. For the initial coding of data from the same sample of RECs as for 2010 and 2012 all records were coded by JE and KS. In order to ensure that the coding was consistent with that for the previous studies a third of the sample was also coded by MRT, who coded the data for the first two studies and a third coded by AHo with a small overlap such that around 10% of records were coded by all four raters. Differences in the coding results were discussed and a mutually agreed result reached for all of them.

The remaining records (around two thirds of the total sample) were coded by JE and KS only. A sample of these responses were analysed by both JE and KS to compare for inter-rater reliability following the previous moderation with four raters. The results were analysed to determine the Cohen's kappa co-efficient of agreement¹³ for two raters with the results equal to 0.87, where a value greater than 0.80 indicates very good agreement.

¹² <https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/>

¹³ McHugh M L. Interrater reliability: the kappa statistic. *Biochemia Medica* 2012;22(3):276-82

201 records were analysed by both raters with agreement for 188 records (83 agreed yes and 105 agreed no) and disagreement for 13, equivalent to an observed proportionate agreement of $(83+105) / 201 = 0.935$ (P_o).

Rater 1 said yes to 94 and no to 107 = 46.8% yes, 53.2% no

Rater 2 said yes to 85 and no to 116 = 42.3% yes, 58.7% no

Probability of both saying yes randomly = $0.468 \times 0.423 = 0.198$

Probability of both saying no randomly = $0.532 \times 0.577 = 0.307$

Therefore overall probability of random agreement = $P_e = 0.198 + 0.307 = 0.505$

Cohen's kappa, $k = (P_o - P_e) / (1 - P_e) = (0.935 - 0.505) / (1 - 0.505) = 0.87$

The seven categories of non-commercial funders as used for the two previous studies were used for this third study except the final category of 'other'. This was re-labelled 'government / other' to indicate that, following analysis of the data for 2014, it was clear that most of the organisations in this category were government organisations other than NIHR, Research Councils and the European Union. The order of funder categories in figures 4 to 6 from left to right is based on the numbers of studies in each category from the first study in 2010, where the highest number were commercial studies.

The proportions of studies in the seven different categories of non-commercial funder vary somewhat across the three years. However, the proportion of charity and National Institute for Health Research (NIHR) studies have both risen from 2010 to 2014 (charities from 7% in 2010 to 14% in 2012 to 18% in 2014 and NIHR from 7% in 2010 to 11% in 2012 to 12% in 2014) and they are the two categories of funder reporting the highest levels of confirmed involvement.

The proportion of studies in the NHS organisations category has fallen steadily from 2010 to 2014 (28% in 2010 to 18% in 2012 to 12% in 2014). This may be due to whether NHS organisations were reported as either the sponsor or research funder and possible differences in the interpretation of this in each year of analysis.

The data extracted included, as for the two previous studies, the names of both the funders and sponsors of the research and a field for commercial status. Where no data were present for one or more of these fields, the commercial status and funder category had to be interpreted from the information available. In cases where the funder was not named but the sponsor was the funder was assumed to be the same organisation and its commercial status similarly.

Appendix B

Supporting data for the figures

Figures 1 to 3: The change in percentage of applications where involvement was confirmed by free text, not confirmed by free text and where there were no plans for involvement reported from 2010 to 2014

Commercial status of funder	No Involvement	Involvement not confirmed	Involvement confirmed	N
2014:				
Commercial	711 (66%)	268 (25%)	91 (9%)	1070
Non-Commercial	304 (18%)	473 (28%)	901 (54%)	1678
All studies	1015 (37%)	741 (27%)	992 (36%)	2748
2012:				
Commercial	311 (75%)	82 (20%)	23 (6%)	416
Non-Commercial	147 (20%)	303 (40%)	303 (40%)	753
All studies	458 (39%)	385 (33%)	326 (28%)	1169
2010:				
Commercial	154 (67%)	71 (31%)	5 (2%)	230
Non-Commercial	94 (23%)	203 (49%)	119 (29%)	416
All studies	248 (38%)	274 (42%)	124 (19%)	646

Figures 4 to 6: The percentage of studies with confirmed involvement, involvement not confirmed and no plans for involvement by category of funder from 2010 to 2014

Funder category	No Involvement	Involvement not confirmed	Involvement confirmed	N	% studies in category
2010					
Commercial	154 (67%)	71 (31%)	5 (2%)	230	36%
NHS organisation	38 (21%)	106 (59%)	35 (20%)	179	28%
University	15 (21%)	38 (54%)	17 (24%)	70	11%
Charity	18 (18%)	19 (32%)	22 (37%)	59	9%
NIHR	1 (2%)	14 (30%)	31 (67%)	46	7%
Research Council	8 (29%)	16 (57%)	4 (14%)	28	4%
European Union	0 (0%)	8 (67%)	4 (33%)	12	2%
Govt / other	14 (64%)	2 (9%)	6 (27%)	22	3%
Total	248	274	124	646	
2012					
Commercial	311 (75%)	82 (20%)	23 (6%)	416	36%
NHS organisation	55 (26%)	113 (54%)	43 (20%)	211	18%
University	34 (27%)	51 (41%)	39 (31%)	124	11%
Charity	29 (17%)	60 (36%)	80 (47%)	169	14%
NIHR	7 (5%)	21 (16%)	101 (78%)	129	11%
Research Council	13 (19%)	35 (52%)	19 (28%)	67	6%
European Union	5 (21%)	9 (38%)	10 (42%)	24	2%
Govt / other	4 (1%)	14 (48%)	11 (38%)	29	2%
Total	458	385	326	1169	
2014					
Commercial	711 (66%)	268 (25%)	91 (9%)	1070	39%
NHS organisation	99 (30%)	126 (38%)	106 (32%)	331	12%
University	45 (24%)	67 (36%)	72 (39%)	184	7%
Charity	85 (17%)	143 (29%)	272 (54%)	500	18%
NIHR	11 (3%)	26 (8%)	288 (89%)	325	12%
Research Council	18 (16%)	43 (39%)	49 (45%)	110	4%
European Union	20 (23%)	25 (28%)	43 (49%)	88	3%
Govt / other	26 (19%)	43 (31%)	71 (51%)	140	5%
	1015	741	992	2748	

Figure 7: All studies - One involvement box ticked only: type of involvement activity ticked and whether confirmed by free text responses for 2012 and 2014

Boxes ticked	Involvement not confirmed	Involvement confirmed	N
2014			
Design	76 (35%)	144 (65%)	220
Management	4 (21%)	15 (79%)	19
Undertaking	167 (92%)	14 (8%)	181
Analysis	3 (60%)	2 (40%)	5
Dissemination	224 (96%)	10 (4%)	234
	474	185	659
2012			
Design	37 (41%)	53 (59%)	90
Management	3 (50%)	3 (50%)	6
Undertaking	66 (97%)	2 (3%)	68
Analysis	0	0	0
Dissemination	81 (89%)	10 (11%)	91
	187	68	255

INVOLVE



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