

# INVOLVE

Supporting public involvement  
in NHS, public health and  
social care research

The NHS logo, consisting of the letters 'NHS' in white on a blue rectangular background.

National Research  
Ethics Service

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

October 2011

A decorative graphic element consisting of a thick blue curve that starts from the bottom left and sweeps upwards and to the right, ending at the bottom right corner of the page.

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# About this study

This was a joint INVOLVE/National Research Ethics Service (NRES) study conducted by Maryrose Tarpey, INVOLVE Coordinating Centre in 2010/11.

A steering group guided all stages of the study.

Members of the steering group were:

**Sarah Buckland**, Director INVOLVE Coordinating Centre

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

**Jim Elliott**, member INVOLVE's Evidence, Knowledge and Learning Working Group

**Valerie Heard**, Policy Implementation Officer NRES

**Sam Wigand**, Business Support Officer (Projects) NRES

**Janet Wisely**, Director National Research Ethics Service (NRES)

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

The study built on NRES scoping work completed by Sam Wigand and Valerie Heard in February 2010.

This report should be referenced as:

**Tarpey M., (2011) Public involvement in research applications to the National Research Ethics Service, 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 and development.

For more information on INVOLVE visit [www.invo.org.uk](http://www.invo.org.uk)

## Information about NRES

The National Research Ethics Service has a dual mission:

- to protect the rights, safety, dignity and well-being of research participants: and
- to facilitate and promote ethical research that is of potential benefit to participants, science and society.

For more information about NRES visit [www.nres.nhs.uk](http://www.nres.nhs.uk)

# Acknowledgements

I would like to thank all members of the steering group: Sarah Buckland, Jeremy Butler, Jim Elliott, Valerie Heard, Sam Wigand and Janet Wisely for their expertise, advice and guidance throughout this study.

Informed by earlier NRES in-house scoping work undertaken by Sam Wigand with work on Research Ethics Committees (REC) correspondence to researchers by Valerie Heard in February 2010, the steering group developed the brief for this work and advised on the sample frame, data extraction, analysis and interpretation.

Sarah Buckland, Jeremy Butler, Jim Elliott and Janet Wisely discussed and gave detailed comments on the findings and content of the draft and final report. Sarah Buckland, in addition to being a member of the steering group, provided guidance and support as the study developed. This included presenting the draft findings and editing the final report.

Grateful thanks to Duncan Britton, Infonetica for advising on data extraction and James Raftery, University of Southampton for advising on aspects of the data analysis. Thanks also to Helen Hayes, INVOLVE Coordinating Centre; members of INVOLVE's Evidence, Knowledge and Learning Working Group and members of the National Research Ethics Advisors' Panel for considering and commenting on the draft report and to Paula Davis for proof reading the final report.

Finally, a special thank you to Sarah Howlett, INVOLVE Coordinating Centre, for her patient work on the data presentation of the findings and commenting on the final version of the report.

**Maryrose Tarpey**

October 2011

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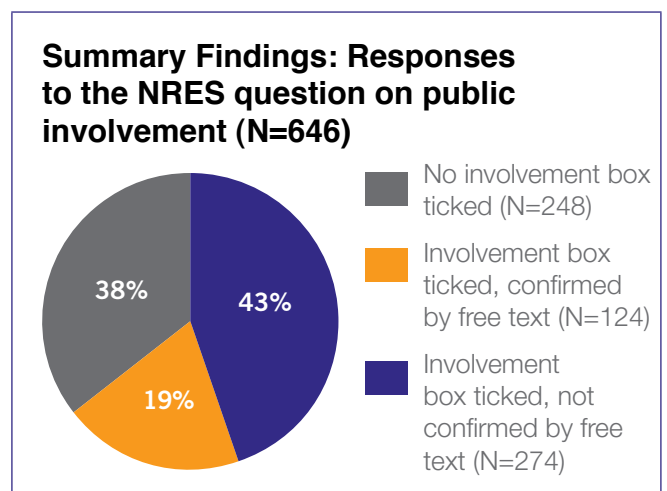
# Summary

This is a summary of a joint study by the National Research Ethics Service (NRES) and INVOLVE. The study analysed information on the extent and nature of reported public involvement in health and social care research<sup>1</sup>, routinely collected by NRES as part of the applications process for ethical approval of research projects.

The study was based on a sample of applications submitted to NRES in 2010. It focused on responses to the two-part question NRES asks about how applicants will involve the public in their research. The question has a tick-box list of public involvement activities, and then a free-text box asking researchers to describe the involvement they have ticked. The study also looked at other information on the application form, such as the source of funding and the type of study, to explore possible links to researchers' responses to the question on involvement.

## Main findings from the study:

- 19% 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;
- 43% 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<sup>2</sup>, and not public involvement. For example, they described how they were going to recruit patients to participate in their research or disseminate their study findings to research participants and to colleagues; and
- 38% said they had no plans for involvement.



<sup>1</sup> In this study, the term 'public involvement' refers to an active partnership between patients, members of the public and researchers in the research process, rather than the use of people as 'subjects' of research. This can include, for example, involvement in the choice of research topics, advising on the research project design or in carrying out the research [www.invo.org.uk](http://www.invo.org.uk);

<sup>2</sup> The term 'engagement' refers broadly to both the recruitment of patients, members of the public, service users or carers to participate in the research, as well as the dissemination of research findings to research participants and to colleagues.

## Commentary and recommendations

This study shows it is possible to produce baseline information on the extent and nature of public involvement from routine data collected by NRES. It also 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 found that researchers often appeared not to understand the involvement question, with many referring to engagement rather than involvement activities. Analysis of the free-text responses showed that while engagement and involvement are clearly linked activities and complement each other, they are also distinct, in that one does not describe the other. NRES acknowledges this difference in the form, by providing a definition of public involvement in the guidance notes, and in later sections of the form asking separate questions about recruitment, participation and dissemination.

Given the evidence that public involvement can help contribute to the quality and ethical integrity of research, the study makes a number of recommendations:

- **funders:** funders and sponsors across all sectors should be encouraged to emulate the NRES question about involvement in their own research funding application form, if they do not do so already.
- **NRES data quality:** to help researchers provide better quality information in their applications for ethical approval, NRES should consider revising the tick-box list of public involvement activities in the IRAS form to make a clearer distinction between involvement and engagement. For example, by inserting links to the questions on recruitment and dissemination, asked in later sections of the form.
- **Research Ethics Committees:** RECs could draw more on the public involvement question for assurances on the ethical probity of studies they are assessing. They should consider providing feedback to researchers on the quality of their public involvement responses, during the review process, and in their requests for further information from researchers.
- **baseline data:** in two years, NRES and INVOLVE should repeat this study to see whether or not the pattern of responses in applications for ethical approval changes over time.

# Introduction

INVOLVE and the National Research Ethics Service (NRES) including the National Research Ethics Advisors' Panel, set up a joint study in 2010/11. The purpose of the study was to establish the extent and nature of public involvement<sup>3</sup> in research ethics applications by analysing information submitted on public involvement routinely collected by NRES as part of the application process for ethical approval of research projects.

The study follows a previous research project, funded by NRES, on Research Ethics Committees' (RECs) decision-making (Angell et al. 2008, 2007). This study 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.

The involvement of the public (such as patients, carers, service users) can help to improve research by ensuring that the research planned addresses these issues from a public perspective. Recent studies reviewing the evidence on the impact of public involvement in research, including one funded by INVOLVE, highlighted how researchers who involved the public in their studies addressed these ethical

concerns (Brett et al. 2010; Staley 2009; Smith et al. 2008). By involving people, they were able to demonstrate that their planned research was acceptable from a patient and public perspective, as well as helping to address potential ethical concerns, prior to applying for ethical approval.

This study aimed to inform this work by:

- creating baseline information on the extent and nature of public involvement in research;
- exploring the value and feasibility of future monitoring of information in research applications and making recommendations for feedback to researchers, funders and RECs about the quality of the information submitted to NRES and NHS Research and Development (R&D);
- raising awareness amongst researchers that public involvement in research applications is considered as part of the governance and ethical approval process;
- raising awareness amongst other relevant groups, for example research funders and sponsors, of the role public involvement can play in addressing ethical research issues; and
- encouraging REC committees to give attention to, and consider the information provided by researchers about public involvement in their applications for ethical approval.

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<sup>3</sup> See footnote 1 for an explanation of the term 'public involvement'

# Methods

## Background – NRES information

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](http://www.myresearchproject.org.uk)) which is used by NRES (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 the following 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 intend to involve patients, service users, carers or members of the public; and second, to use the free-text box to describe their planned involvement.

### IRAS application form:

‘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.

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

The application form guidance also refers applicants for further information on public involvement to INVOLVE ([www.invo.org.uk](http://www.invo.org.uk)) and in Wales, Involving People (<http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=14773>).

In later sections of the IRAS form, there are separate questions about participant recruitment (QA27-29) and dissemination (QA51).

## NRES scoping work

In preparation for this study, a selection of completed IRAS application forms submitted to NRES were analysed<sup>3</sup>, 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' studies<sup>4</sup>. 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 to the public involvement question were found.

## Main study

Based on this scoping work, the steering group agreed that the main study should survey a sample of non-educational studies submitted on IRAS application forms to NRES for ethical approval during 2010<sup>5</sup>. The intention was to aim for a sample size of around 10% of the total number of non-educational studies submitted to NRES during 2010.

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 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. 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 pilot for the free-text responses on the public involvement question were used as the basis for the content analysis of the free-text responses. The data is presented in the findings section of this report and in the supporting appendices.

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<sup>3</sup> NRES in-house scoping work undertaken by Sam Wigand with work on REC correspondence to researchers by Valerie Heard in February 2010.

<sup>4</sup> '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.

<sup>5</sup> NRES received around 6,300 applications in 2010 (from 1 January to 31 December 2010). Three-quarters of the total (4,725) were non-educational studies and one-quarter (1,575) educational studies. Given the focus of the study, the project advisory group made a decision to exclude educational studies in the analysis for this report.

# Findings

This section gives background information on REC decisions for applications before summarising the study findings on the extent and nature of public involvement in applications to NRES. It analyses the tick box and free-text responses to the question on public involvement and explores the possible links with other information. It also gives examples of researchers' responses to the free-text question about their involvement plans.

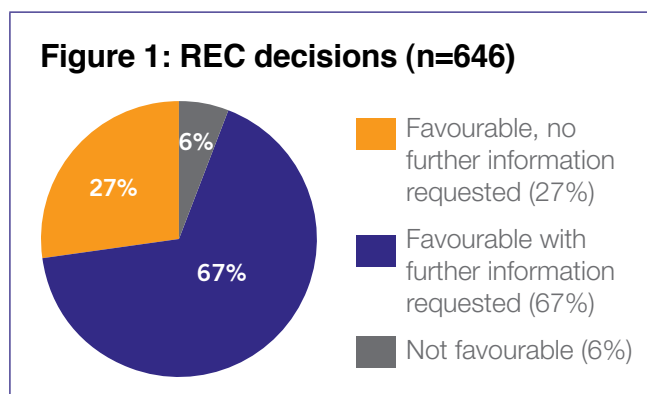
The findings are based on analysis of 646 non-educational studies submitted to NRES in 2010<sup>6</sup>.

## REC decision-making

### REC decisions: Figure 1

Figure 1 supports the previous study on decision-making, referred to in the introduction, which found that RECs commonly ask researchers for additional information and amendments to their research before granting ethical approval (Angell et al. 2008).

It shows that 94% [605 of 646] of all applications in the sample received ethical approval, although 67% [433 of 646] did so only after researchers were asked by RECs for further information<sup>7</sup>. Only 6% [41 of 646] were not granted ethical approval.



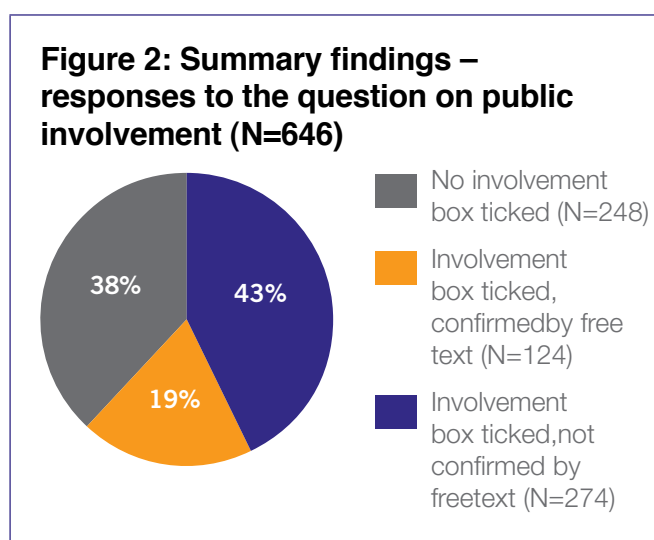
<sup>6</sup> For more information on the sample see the methods section of this report.

<sup>7</sup> Figure 1 does not include a breakdown of REC decisions by the public involvement question.

## Extent and nature of public involvement in applications

### Responses to the question on public involvement: Figure 2

Figure 2 shows that 62% [398 of 646] of the sample ticked at least one box in response to the IRAS question on public involvement, indicating that they had or were intending to involve the public in some aspects of their research. However, when the free-text entries were analysed, the figure confirming public involvement dramatically reduced to 19% [124 of 646].



In the responses of the other 43% [274 of 646], they seemed to have not understood, or misinterpreted the question. They made no mention of plans for involvement, mainly describing engagement activities instead, such as how they were going to recruit patients or disseminate their findings to participants in the study as well as to colleagues. Separate questions about these types of activities are asked elsewhere on the form<sup>8</sup>.

The remaining 38% of the sample said they had no plans to involve the public in their research.

### Funder / sponsor: Figure 3

Figure 3 shows that based on the information provided by applicants, the largest group of applicants were funded by industry (36%), followed by NHS Trusts (28%). 7% of the total sample were funded by the NIHR. This analysis was based on information provided by applicants about their funding. Where applicants provided no information on funding it was possible in most cases to impute the funding source from other information provided about the sponsor<sup>9</sup>.

Figure 3 also details the possible influence that the sources of research funding had on applicants' responses to the question on public involvement. For each funder, Figure 3 distinguishes between those who did or did not tick one or more public involvement boxes, and of those, whether or not their free-text responses confirmed involvement activities.

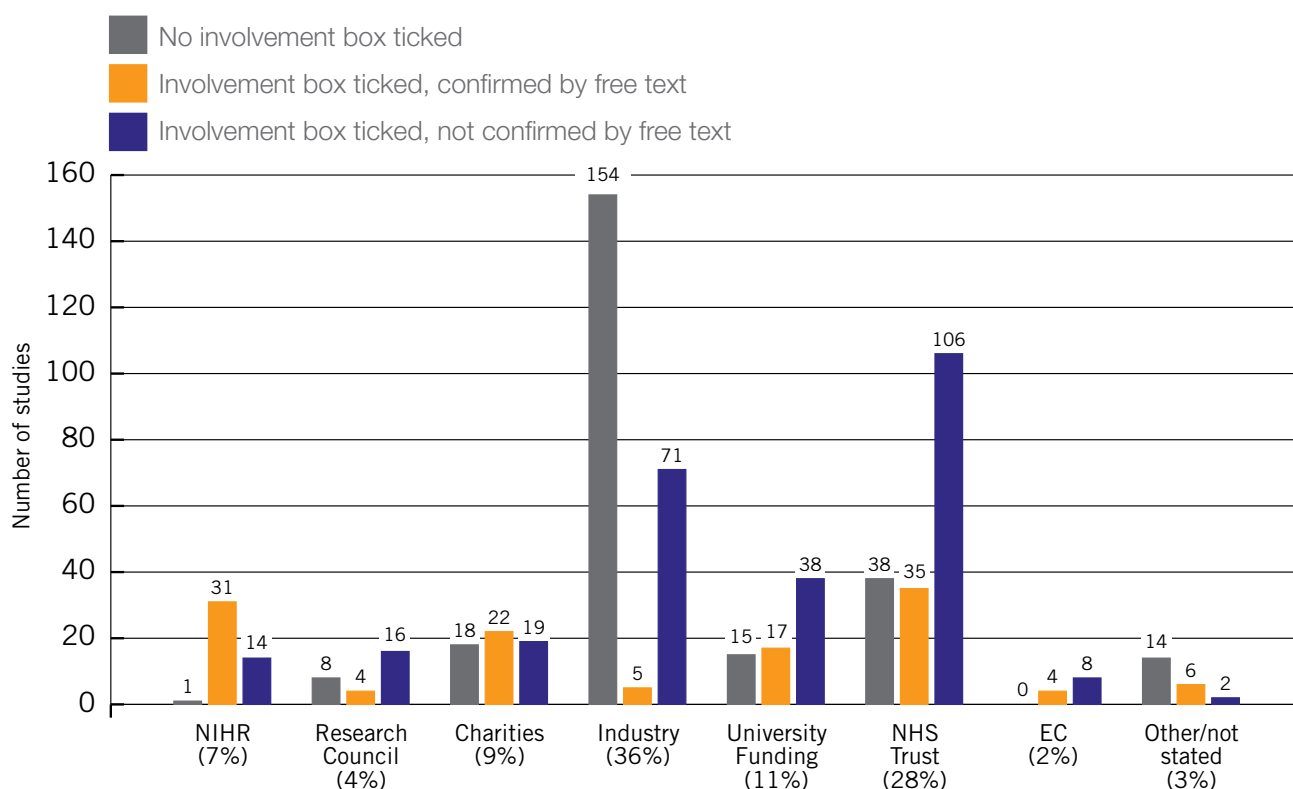
<sup>8</sup> On the IRAS form, Questions A27-29 ask applicants to describe the recruitment procedures for the study. Question A51 asks how applicants intend to report and disseminate the results of the study.

<sup>9</sup> When the sponsor was either registered as a commercial company or a charity, it was assumed that this was the main funder. When the sponsor was either a university or an NHS Trust, it was more complicated to categorise the source of funding and consequently funding by NIHR and charities may have been undercounted. However, on the basis of using the information provided by applicants, a number of studies attributed to NHS Trust funding appeared to be receiving 'own account' funding, grants from various small-scale endowments or similar sources to conduct pilot/ feasibility studies.

It highlights some noticeable variations on responses about involvement, by the sources of funding. For example, whilst NIHR funding was only 7% of the sample [46 of 646], all but one of the NIHR applicants ticked one or more involvement activities, and their free-text responses were more likely to confirm plans for involvement [31 of 46], than any other source of funding.

The NIHR responses may reflect the fact that by 2010, most NIHR funding programmes included a question about patient and public involvement in their application forms. By the time NIHR funded researchers apply for ethical approval, they could be expected to have considered what a question on involvement is asking<sup>10</sup>. Other applicants, may not have had this opportunity.

**Figure 3: Funder/sponsor by responses to the question on public involvement (N=646)**



<sup>10</sup> In September 2011, the NIHR introduced a standard application form for research applicants which includes questions on plans for involvement.

### Categories of studies: Figure 4

As Figure 4 shows, there are also variations on responses to the involvement question by the different categories of studies, as well as by funders.

The IRAS form used by NRES gives applicants a choice of ten categories to describe the type of study they are planning to do. These categories cover the full range of studies that apply for ethical approval, for example from early development of medicinal products through to small qualitative studies and collection of tissue samples. Figure 4 shows that most fell within three of the ten categories. Appendix 1 lists all ten categories.

Nearly half of the applicants [311 of 646], selected the 'other clinical trial or investigation' – category 'd'. This is a category intended to describe clinical studies on patients that

are not device or medicinal trials but NRES is aware it is used more broadly and has issued further guidance.<sup>11</sup> Whilst 77% of applicants in this category, ticked one or more public involvement boxes, the free-text responses confirming involvement, reduced the figure to 31% [96 of 311].

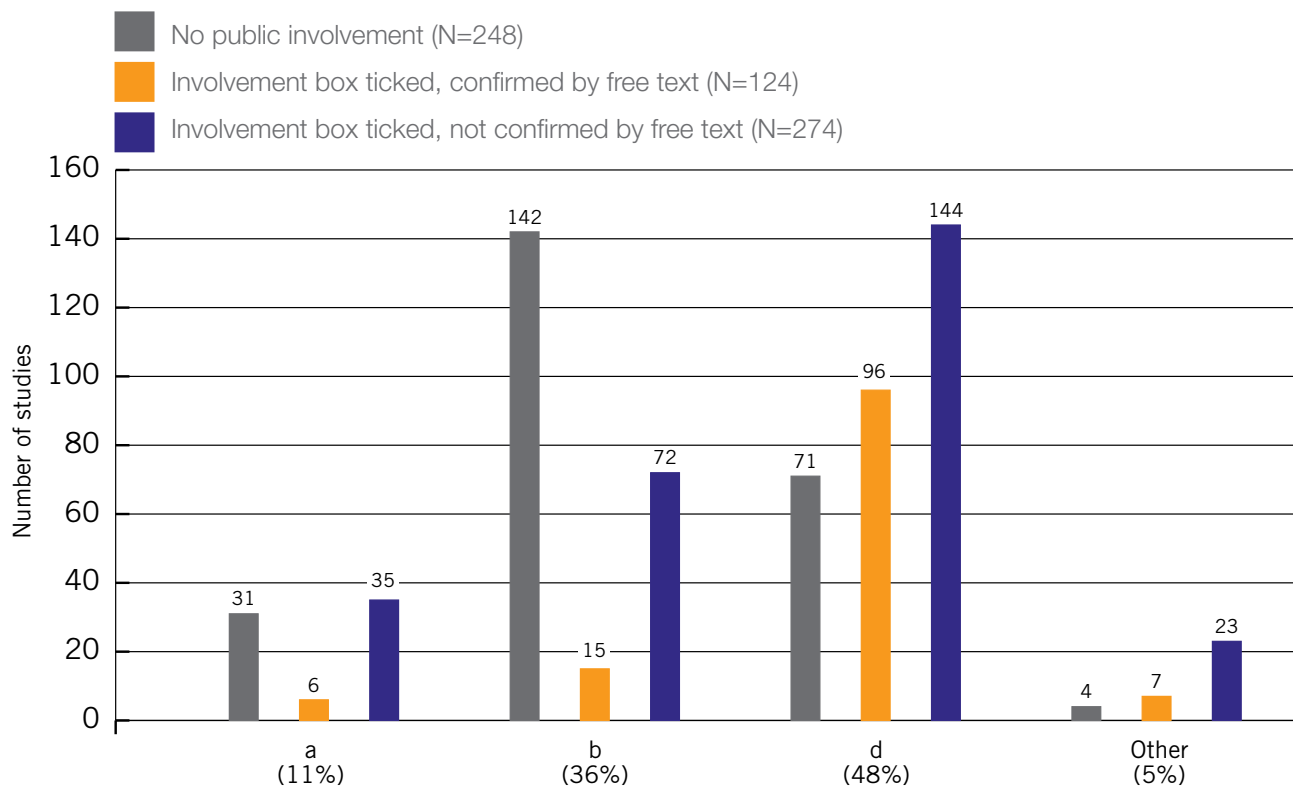
Most of the others [301 of 646] selected either clinical investigation of a 'medical device' or 'medicinal product' – categories 'a' or 'b'. Figure 4 shows that applicants in these two categories were more likely than any other category to say they had no plans for involvement.

Of those who ticked one or more involvement boxes, only 8% [6 of 72] and 7% [15 of 229] respectively, confirmed their plans in the free-text responses.

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<sup>11</sup> In April 2011 NRES revised the category 'other clinical trial or investigation' on the IRAS form to encourage a more accurate description of whether the research is intended to be an interventional or non-interventional study.

**Figure 4: Categories of studies\* by responses to question on public involvement (N=646)**



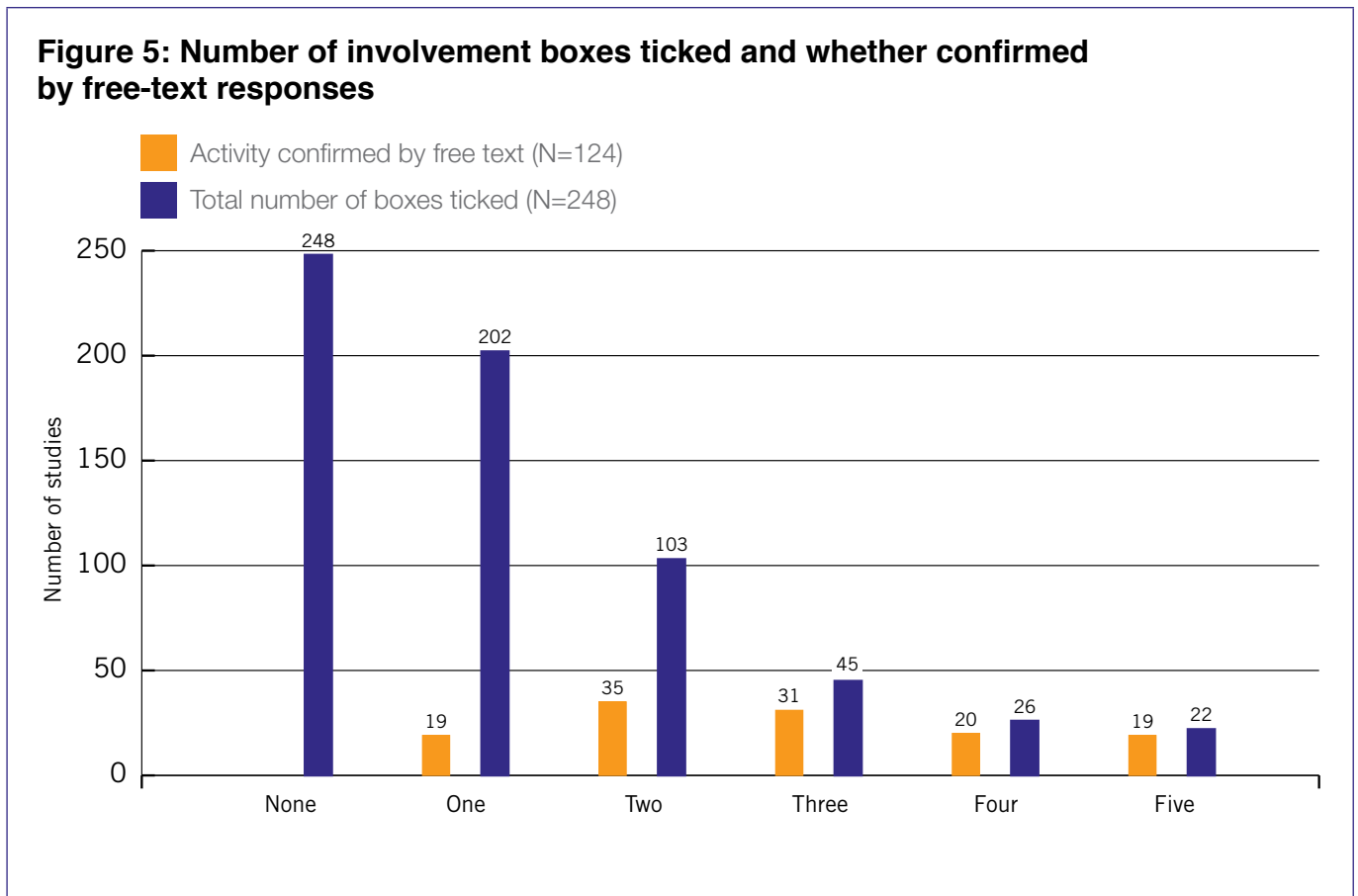
| *Code        | Categories of studies                                       |
|--------------|---|
| <b>a</b>     | Clinical investigation or other study of a medical device   |
| <b>b</b>     | Clinical trial of an investigational medicinal product      |
| <b>d</b>     | Other clinical trial or clinical investigation              |
| <b>other</b> | Other seven categories - c,e,f,g,h,i,j listed in Appendix 1 |

### Extent and nature of involvement activities: Figures 5 and 6

Figure 5 details the number of involvement boxes ticked, and Figure 6 shows the types of activities ticked. They also highlight the scale of the match/mismatch between the tick box responses and free-text entries about plans for involvement. The supporting data for Figures 5 and 6 is in Appendix 2.

However, in their free-text descriptions about dissemination, researchers referred to their plans to report the findings of their research to participants in their research and to their peers, even though there are questions later on the IRAS form that ask about this as a separate activity to involvement<sup>12</sup>.

Figures 5 and 6 show that just over half [202 of 398] of those who ticked at least one involvement activity, ticked one box only and that the most common single involvement activity was ‘dissemination’, followed by ‘undertaking of research’.



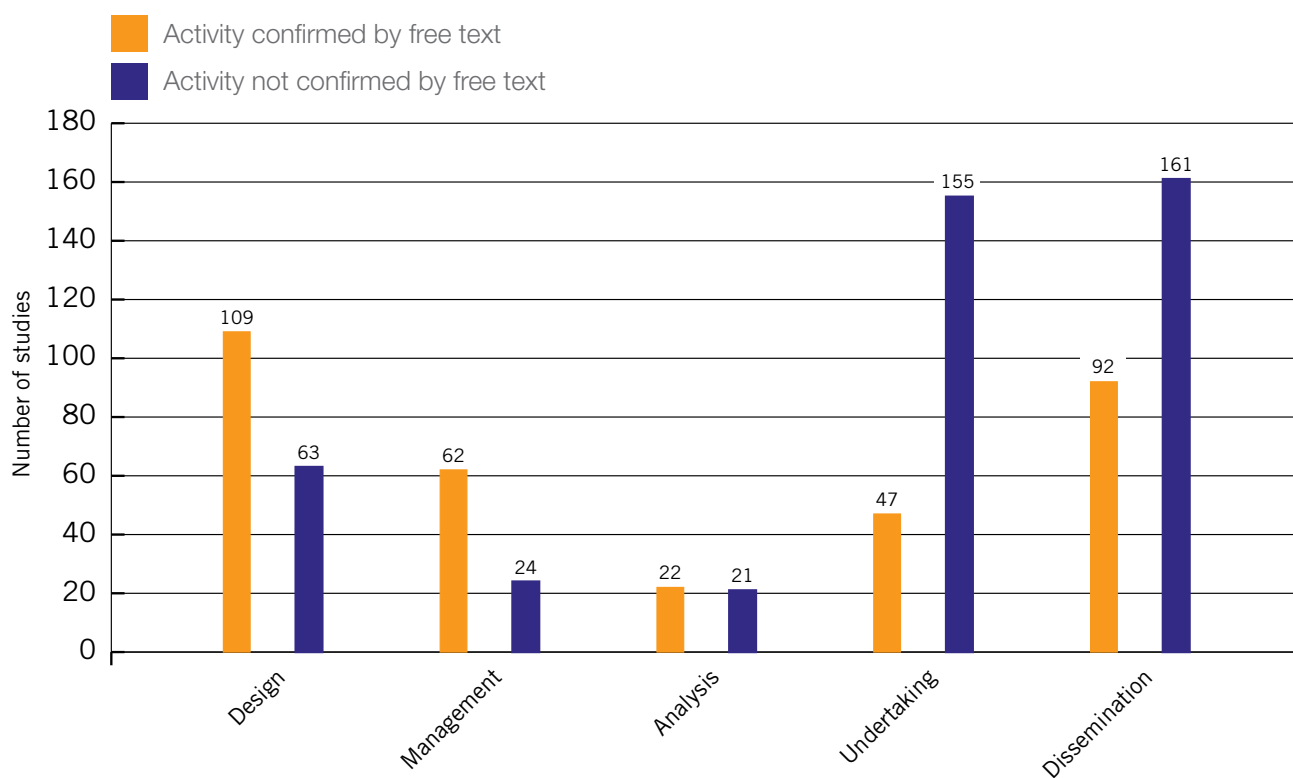
<sup>12</sup> On the IRAS form, Question A51 asks how the results of the study will be reported and disseminated and A53 asks for details of how participants will be informed of the results.

In discussing plans for undertaking of research, researchers talked about the recruitment and participation of patients as ‘subjects’ in their research, not active involvement. ‘Analysis’ was the least common involvement activity.

Researchers who ticked three or more involvement activities were more likely to be part of the 19% in Figure 2, whose free-text entries confirmed their involvement plans. They tended to describe involvement early in the research process, for example in the design, planning and management of research.

They also planned to follow through their involvement for other stages of the research such as in ‘undertaking of the research’ and ‘dissemination’<sup>13</sup>.

**Figure 6: Type of involvement activities ticked and whether confirmed by free-text responses**



<sup>13</sup> This supports the scoping work conducted by Sam Wigand NRES, February 2010.

## Free-text responses to the public involvement question

This section gives more information on the content of what applicants said in their free-text responses about their plans, or otherwise, for public involvement.

### Already involving or inviting involvement (19% of sample)

Of those who said they were already involving people in their research, some gave comprehensive descriptions of what they were planning to do and appeared to be accustomed to involving people, for example by:

- including a service user researcher as a grant holder on the study and as part of the research team, or stating that other service users will be joining the research advisory group;
- describing how user and carer groups provided consultancy for the development of the proposal, including detailed feedback regarding the study aims and methods; and
- already asking people to sit on trial steering groups and be involved throughout the studies.

However for most of those already involving, the plans were much more limited. The following descriptions were common examples:

- providing the name of one person, usually cited as an 'expert patient' who input into the research design and had been invited to continue to be involved in the research;
- involving a service user group to comment on, or produce patient information materials for the research study;
- drawing on the views of service users on the research topic and on what research questions should be asked.<sup>14</sup>

Researchers who said they were inviting people to get involved in some aspect of their research, but had not already involved them in the design stage tended to say they were:

- planning to involve one or two patients on a trial steering, or research advisory group;
- intending to ask patients or user groups to comment on research materials such as questionnaires.

<sup>14</sup> This type of response was difficult to interpret. The entries provided by researchers were analysed as active public involvement. However it was not always clear whether or not this type of consultation had indeed been involvement or not.

### **Not involving people – engaging with research participants and peers (43% of sample)**

Researchers in this grouping ticked one or more involvement boxes but showed by their free-text responses that they had misunderstood the question on involvement. For example, by describing their plans for recruitment of people taking part in their research as participants or ‘subjects’ of the research and how they plan to disseminate the results of the research to them. They also outlined dissemination activities aimed at their peers.

Others, despite having ticked involvement activities, used the free-text entry to give reasons why they thought involvement was not necessary.

Recurring free-text descriptions about researchers’ plans relating to study participants included these type of statements:

- participants will be offered written summaries of the findings
- patients will be involved during the research as subjects
- patients will be asked to carry the sampling storage equipment (bottles and paper) and present them to staff at reception.

And about informing peers of their research, or why involvement was not deemed necessary:

- given the nature of the study the findings would only be of interest to peers, key physicians and thought leaders in the field
- the intention is to report the findings in peer-reviewed journals
- we see patients all the time, we know what their views are on this.

### **No plans for involvement (38% of sample)**

Of the 38% [248 of 646] who said they had no plans for public involvement, 24% [154 of 646] were industry-funded studies, mostly investigations/ trials of a medical device or medicinal product (see Figure 3 and Appendix 1).

The comments were similar to the 43% who seemed to have misunderstood the involvement question, with a focus on engagement activities instead. The difference being that by not ticking public involvement activities, this group of applicants appeared to understand what the question was about. Their free-text explanations showed that they were able to make a distinction between involvement and engagement:

- we discuss and seek feedback on our research from members of the public but have not sought their involvement in this study
- due to the experimental nature of this Phase 3 study, we did not formally seek the opinion of members of the public or patients. However, the participants’ experiences during this clinical trial will be explored and will form the basis for future studies.
- the results of the study will be published as original papers at international congresses and in peer-reviewed journals. They will then be available to be read by patients and members of the public.

# Commentary

This study shows it is possible to produce baseline information on the extent and nature of public involvement from routine data collected by NRES. It also 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.

The study found that researchers often do not appear to understand the involvement question, with many referring to engagement rather than involvement activities. Analysis of the free-text responses shows that while engagement and involvement are clearly linked activities and complement each other, they are also distinct, in that one does not describe the other. This is acknowledged in the IRAS form, by the inclusion of a definition of public involvement in the guidance notes attached to the involvement question, and in later sections of the form which have separate questions about recruitment, participation and dissemination.

RECs have a particular role to protect the rights, safety, dignity and wellbeing of research participants. This, and other studies show that RECs frequently raise a broad range of concerns with researchers about the design and conduct of the research they are assessing. It is important to keep RECs informed about public involvement in research as this involvement should provide the assurance required on many of the questions raised by RECs, for example whether or not a study will be a burden to participants or a particular community.

Currently, researchers do not usually receive comments from RECs on their responses to the question on public involvement and so are unaware when their responses are not about involvement. Given the evidence that public involvement can help contribute to the quality and ethical integrity of research, feedback to researchers could help to raise awareness of the importance of public involvement in improving their applications as well as help develop their understanding of public involvement.

Once researchers receive funding, they cannot start the work until they receive governance approvals, including ethical approval. If plans for involvement have not been included in the funding application then RECs are not likely to comment on the absence of involvement. However, RECs will look for assurances on issues that involvement could have addressed, such as the suitability of the consent information, acceptable burden and relevance of the research. Involvement earlier in the research process, could improve approval times, by reducing the volume of additional information and assurances requested by RECs. One way of helping would be for funders to ask researchers about public involvement in their funding applications, if they do not do so already.

# Recommendations

**Funders:** funders and sponsors across all sectors should be encouraged to emulate the NRES question about involvement in their own research funding application form.

**NRES data quality:** to help researchers provide better quality information in their applications for ethical approval, NRES should consider revising the tick-box list of involvement activities in the IRAS form to make a clearer distinction between involvement and engagement. For example, by linking to the questions on participation and dissemination, asked in later sections of the form.

**RECs:** RECs could draw more on the public involvement question for assurances on the ethical probity of studies they are assessing. They should consider providing feedback to researchers on the quality of their public involvement responses, during the review process, and in their requests for further information from researchers.

**Baseline data:** in two years, NRES and INVOLVE should repeat this study to see whether or not the pattern of responses in applications for ethical approval changes over time.

# References

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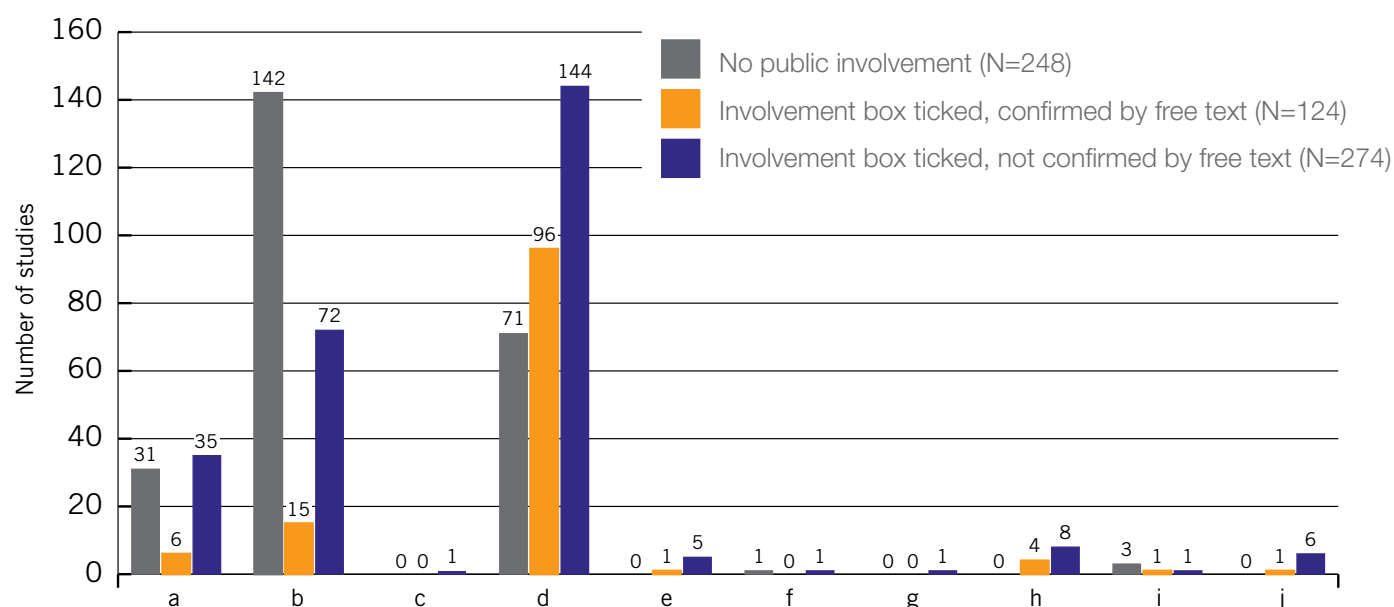
Smith E., Ross F., Donovan S., Manthorpe J., Brearley S., Sitzia J. & Beresford P., (2008) Service user involvement in nursing, midwifery and health visiting research: a review of evidence and practice, *International Journal of Nursing Studies*, Vol 45, No 2, p298-315.

# Appendix 1:

## list of categories of studies on IRAS form

| Codes    | IRAS Question 2: Categories of studies   |
|----------|--|
| <b>a</b> | Clinical investigation or other study of a medical device  |
| <b>b</b> | Clinical trial of an investigational medicinal product   |
| <b>c</b> | Combined trial of an investigational medicinal product and an investigational medical device                                 |
| <b>d</b> | Other clinical trial or clinical investigation <sup>15</sup>   |
| <b>e</b> | Other study  |
| <b>f</b> | Research database  |
| <b>g</b> | Research tissue bank   |
| <b>h</b> | Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology |
| <b>i</b> | Study involving qualitative methods only   |
| <b>j</b> | Study limited to working with data and/or human tissue samples or other human biological samples (specific project only)     |

### All categories of studies by responses to question on public involvement (N=646)



<sup>15</sup> In April 2011 NRES revised this category 'other clinical trial or investigation' on the IRAS form to encourage a more accurate description of whether the research is intended to be an interventional or non-interventional study.

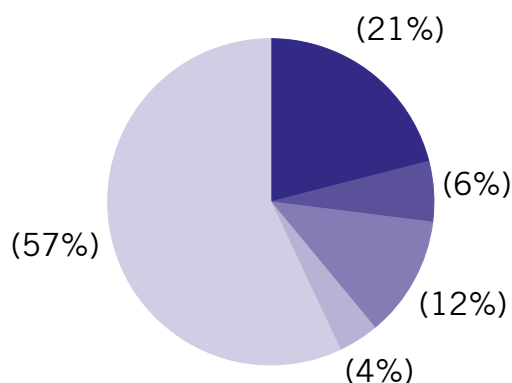
# Appendix 2:

## supporting data for Figures 5 and 6

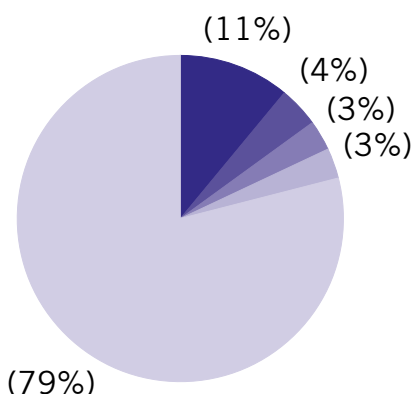
### Analysis of question on public involvement



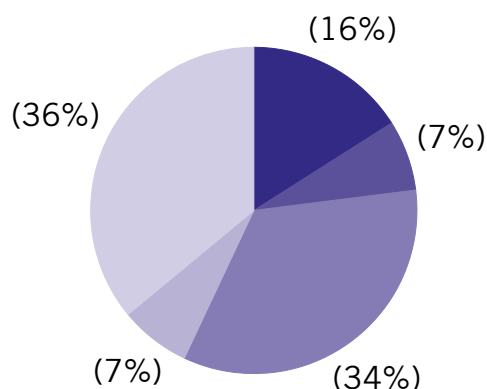
### Design of research – free text information used to check ticked box responses (N=398)



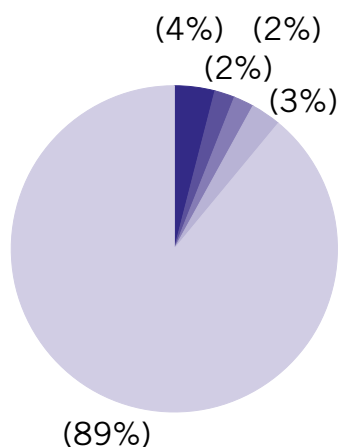
### Management of research – free text information used to check ticked box responses (N=398)



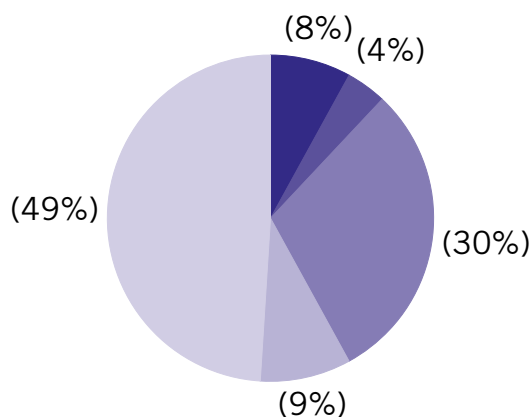
### Dessemination of research – free text information used to check ticked box responses (N=398)



### Analysis of research – free text information used to check ticked box responses (N=398)



### Undertaking of research – free text information used to check ticked box responses (N=398)



# INVOLVE

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