UK Policy Framework for Health & Social Care Research
Summary of Responses

Introduction

The *UK policy framework for health and social care research* is intended to set out clearly the high-level principles and responsibilities, applicable in all health and social care research, that underpin high-quality ethical research in the UK. In doing so, it aims to provide the basis for operational provisions and sets the tone of what they should be like and met through operational arrangements and guidance.

This single UK policy framework will replace the existing *Scottish Executive Health Department Research Governance Framework for Health and Community Care* and similar documents currently in use in the other devolved administrations and England.

The Chief Scientist Office (CSO) has worked with the Health Research Authority in England and the devolved administrations in Northern Ireland and Wales to develop a draft version of the new UK-wide policy framework. This was published for a comment period that ran between 18th December 2015 and 24th March 2016.

This document provides a summary of the responses that CSO received as a result of the above exercise.

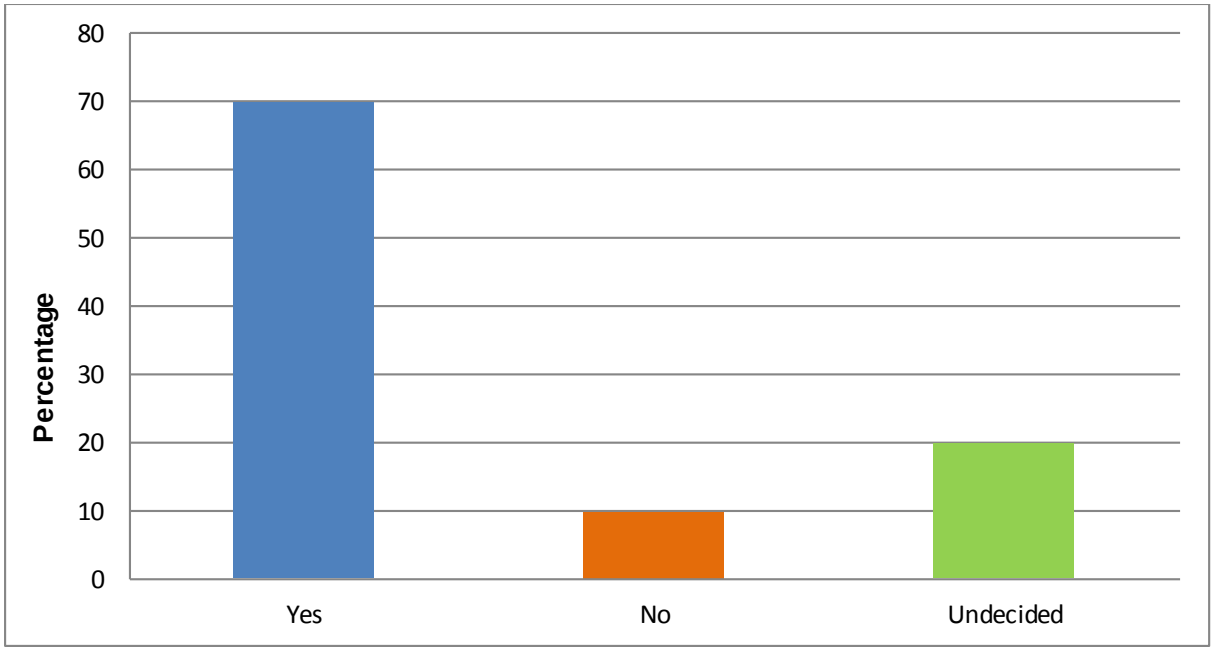
Summary of responses

In total, eleven responses were received (nine of which were organisational responses and two from individuals) that came from a mixture of health boards, university, third and public sector organisations as well as one Royal College.

Overall, responses were positive, in terms of agreement with the principles and responsibilities set out in the various aspects of the draft UK policy framework. This trend is summarised in the graphs below under the relevant question headings that were used during the comment period.

In addition, respondents also had the opportunity to provide additional comments under each question heading; this enabled respondents to provide additional context or to highlight areas of the draft UK policy framework that they felt required to be addressed. A summary of some of the main themes arising from this is also provided below.

1. The policy framework will be implemented by operational arrangements that reflect and embed the principles it sets out. Is the level of detail in the policy framework sufficient for it to be implemented? If not, how could this be improved?



The vast majority of the responses answered 'yes' with only one 'no' and two 'undecided'.

Of the two respondents providing and answer of 'undecided' one noted that: *"There is potential for the content to be open to different interpretation and hence differing approaches to implementation."*

Similarly the other 'undecided' response suggested that: *"organisations could probably implement the policy based on the document, but this would result in wide variations in interpretation. Further guidance, SOPs etc would help ensure consistency across the UK".*

The respondent answering 'no' felt that overall the Policy Framework would a good job of setting out principles of good practice welcoming this change to the previous editions of the Research Governance Frameworks. However, the respondent was unclear about the use of the term 'Principles' in section 9 – highlighting that: *"they don't appear to be principles but rather the description of the roles of 'various actors' and the best practices that each of these should ascribe".*

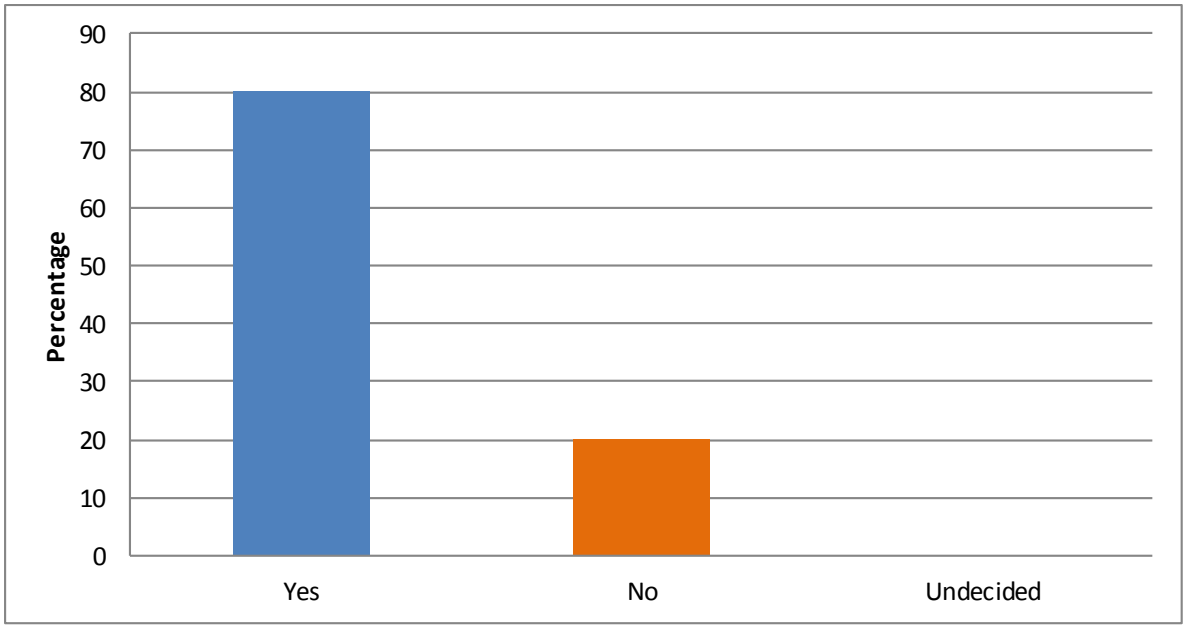
This respondent suggested retaining the section heading 'Principles' for section 8, but reframing section 9 as 'Core elements' or 'Best practices' that apply to 'individuals and organisations'. This respondent also suggested that section 8 should have an opening paragraph to described how the term 'Principles' is to be understood; indicating that the content of the document did not suggest there to be

any latitude in the context of the term 'principle' being a statement of value and a starting point for deliberating and acting. Instead the respondent indicated that the principles in the document are statements of requirements that must be complied with. This respondent also felt that it was important to mention the intended audience for this document much earlier (than para 6.2 and 7) and that this should frame the entire document.

Another respondent focussed on the need for research to take the priorities of patients into account and for researchers to collaborate with patient groups and clinicians throughout research and development. Whilst welcoming the emphasis of involving patients, service users and the public the respondent felt that: *"the principle should be **absolute**, as is the case with the discussion of funding decisions (para 9.9a) rather than simply something to be followed 'where appropriate' (para 8.4)."* This respondent considered it necessary, whether in the Policy Framework or in implementation guidance to expand more on what this should involve, including: *"the different ways patients, service users and the public can be involved in research, and what the benefits are, as well as who determines what is an appropriate level of involvement and according to what criteria."*

The above respondent went on to comment that: *"The draft framework refers to implementation resources for researchers and funder to be found at www.hra.nhs.uk/resources, however a perusal of the resources available demonstrate a distinct lack of guidance on how to involve patients and service users in research.……There is a need to make explicit both what benefits involving patients in research can bring to researchers and funders, and what their responsibilities are, otherwise it is highly likely busy researchers will seek to do the minimum required of them under the very unclear standard of "where appropriate".* Finally it suggested guidance should provide further detail on how to implement the requirement to provide information about findings [to those who took part in it] 'in suitable form' [para 8.11] as this is somewhat ambiguous in isolation.

2. Does the policy framework place sufficient emphasis on a proportionate approach to the conduct and management of research?



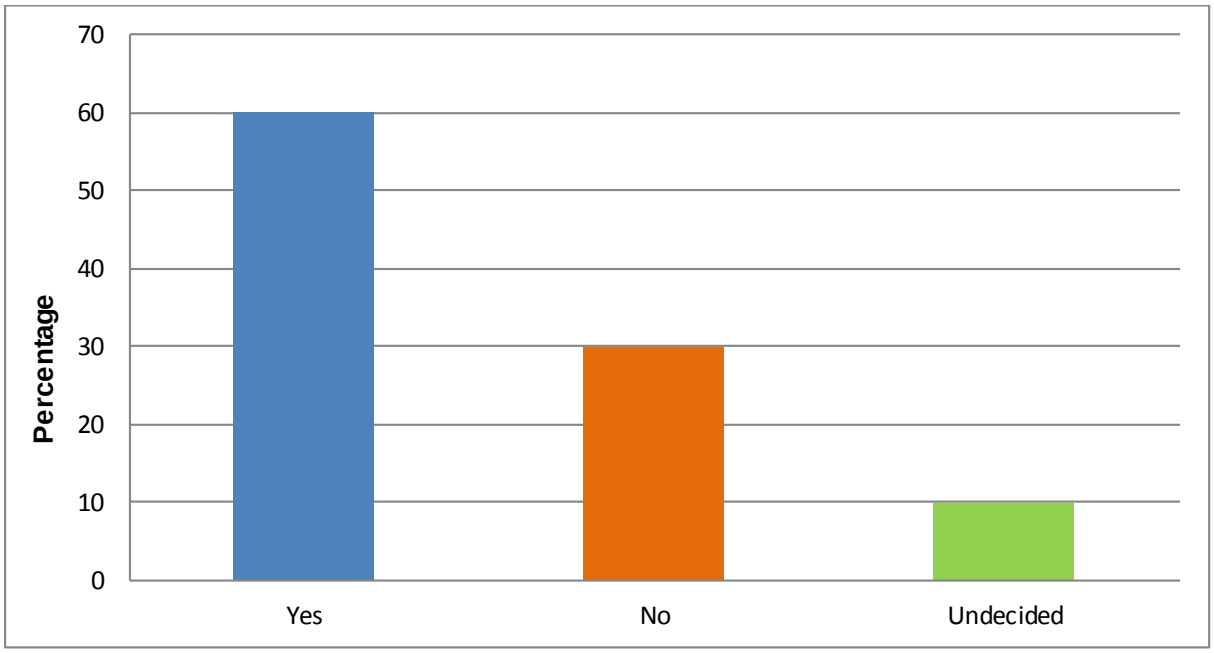
The majority of responses answered 'yes' with a minority answering 'no'. There were no 'undecided' responses.

One of the 'no' respondents indicated that: *"although it is often mentioned that certain activities should be 'proportionate', there is little guidance on what this means or how it should be achieved".* The other respondent answering 'no' indicated that it would be helpful if the [Policy Framework] specified a risk-based approach and if key approval systems were aligned.

The point about a risk-based approach was also identified by another respondent who highlighted its absence from the 'Purpose' section (2.1) suggesting the need for this to be more explicit. This respondent also highlighted that: *"whilst the Policy Framework uses the word 'proportional' in several sections, it is unclear whether there is a connection between a risk-based approach and proportionality".* The respondent felt that: *"if a risk-based approach is explicitly endorsed in the Policy Framework there is a need for clarity on who is making the risk assessment, by what standards and at what stage in the research lifecycle*". The respondent went on to indicate that questions about future, unknown risks should also be addressed, and *"whether we can know in advance what a 'high-risk' study is?".*

The above respondent also highlighted that, in contrast, proportionality is raised in the section on Regulators and this is an important point about reducing undue regulatory burden and improving efficiency. Finally the respondent noted that although the main statutory regulators are mentioned, there are other officers or bodies that operate in a quasi-regulatory fashion (e.g. Caldicott Guardians and the Confidentiality Advisory Committee) and it supported the extension of the principle of proportionate regulatory oversight to such bodies, especially in health data research.

3. Does the policy framework address all the key issues (e.g. obstacles to good practice in the conduct and management of research)? If not, what are they and how could they be addressed?



The majority of responses answered 'yes' although there were a number of 'no' responses and one 'undecided'.

One respondent felt that:

"Further definition and guidance is required on the differentiation of research from Audit/service evaluation. There need[s] to be very clear acknowledgement across the community that the word 'research' has a narrower meaning within NHS governance than it does generally".

"Although there is a large section that aims to address the perceived failings of research sites in the review and approval of research, there is nothing equivalent for funders or other bodies, such as: Sponsors have a responsibility to make full, clear and consistent information available to sites to allow them to make a clear decision on whether they can take part. They should also be aware of and abide by national central review processes and not, for example, ask a site to use a different agreement template from that which has already been centrally agreed".

Other respondents commented that:

"*No mention is made of unified monitoring requirements, independent peer reviews, authorship of publications or data quality control, nor ethical approach to research through lifespan of project."*

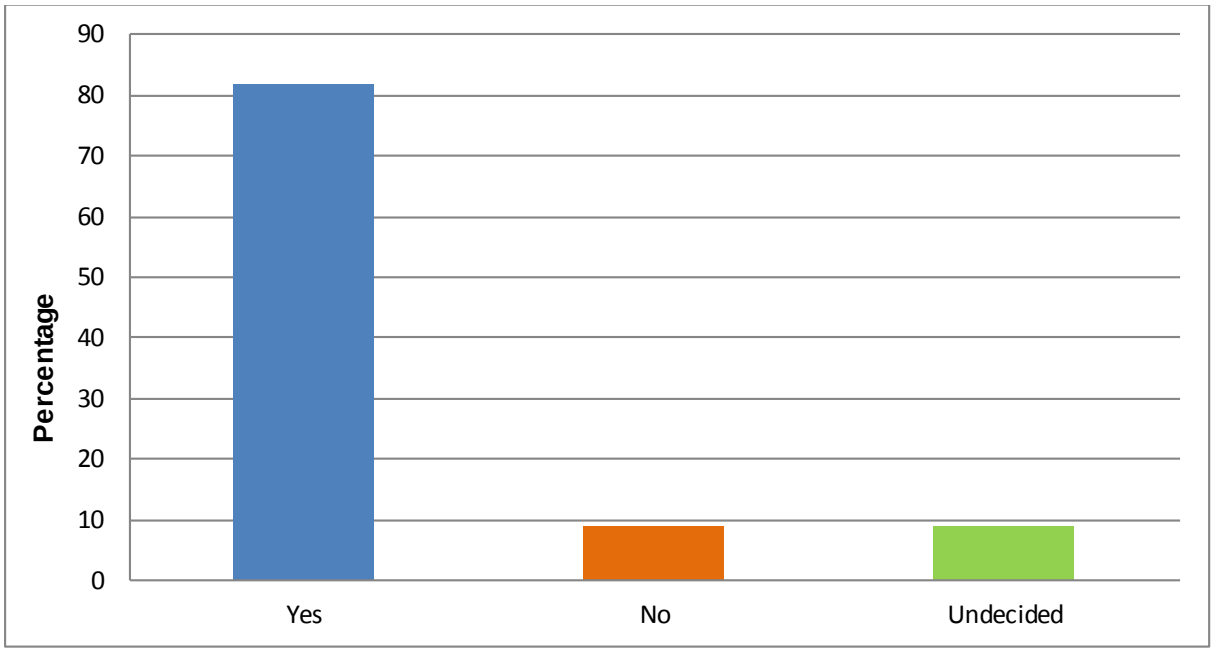
"Too many and too varied to be addressed in this document."

"…….a companion policy framework on knowledge transfer would be welcomed, so that stakeholders (including patients commissioners and providers of health and social care) can fully appreciate how health and social care benefits patients, service users, staff and the public."

Another respondent (who answered 'yes') provided specific comments in relation to section 8 of the Policy Framework [i.e. *'Principles that apply to all health and social care research*']. These comments included:

- 8.4 "We would amend this to read *'be given the opportunity, where appropriate, to be involved'."*
- 8.7 *"The statement that actors should consider relevant legislation has little practical meaning. We suggest they must be able to demonstrate that they have done so."*
- *8.8 "We would rephrase this to focus first on benefits then risks, not risks then benefits. It currently reads oddly."*
- 8.9 *"This para refers to expected or required, but expected by whom? And how different is this to required? Some non-exhaustive examples might help."*
- 8.10 "*This para uses the term 'normally'. What are examples of where an actor could legitimately depart? We suggest it be made clear that in such cases the onus in on such an actor to demonstrate good cause."*
- 8.13 "*Why does this para reference only a specific set of rights and not others? The document has already made it clear that it must be read in the entire legal context of compliance and respect. Accordingly, what does this specific reference add? Is it necessary to include at all?"*
- 8.16 "*This para is about emphasising the rules, but what are the sanctions for non-compliance?"*
- 8.17d "*This para makes the important (but self-evident) point that the duty of care continues. We suggest that the more important message is that if any question of likely conflict arises between research and patient interests, the duty to the participant as a patient prevails."*

4. Do you think the principles that apply to all health and social care research are right?



The vast majority of responses answered 'yes' with a minority answering 'no' or 'undecided'.

Although answering yes one respondent felt that: *"There is insufficient emphasis on the role of patients, service users and the public in relation to participation in all aspects of research design. Rather than creating a broad exemption via using the term 'where appropriate' specific exceptions could be detailed. (e.g involving patients/service users in the design of research projects that are part of a course of study may be impractical due to the time to recruit etc)".*

The comments were mirrored by another respondent who also suggested removing "*where appropriate*" from paragraph 8.4 (i.e. in relation to: *"Patients, service users and the public are involved, where appropriate, in the design, management and conduct of research")* and also the need for clarification on the wording *"In suitable form"* in paragraph 8.11 (i.e. in relation to: *"information about findings of the research is normally available, in suitable form, to those who took part in it*").

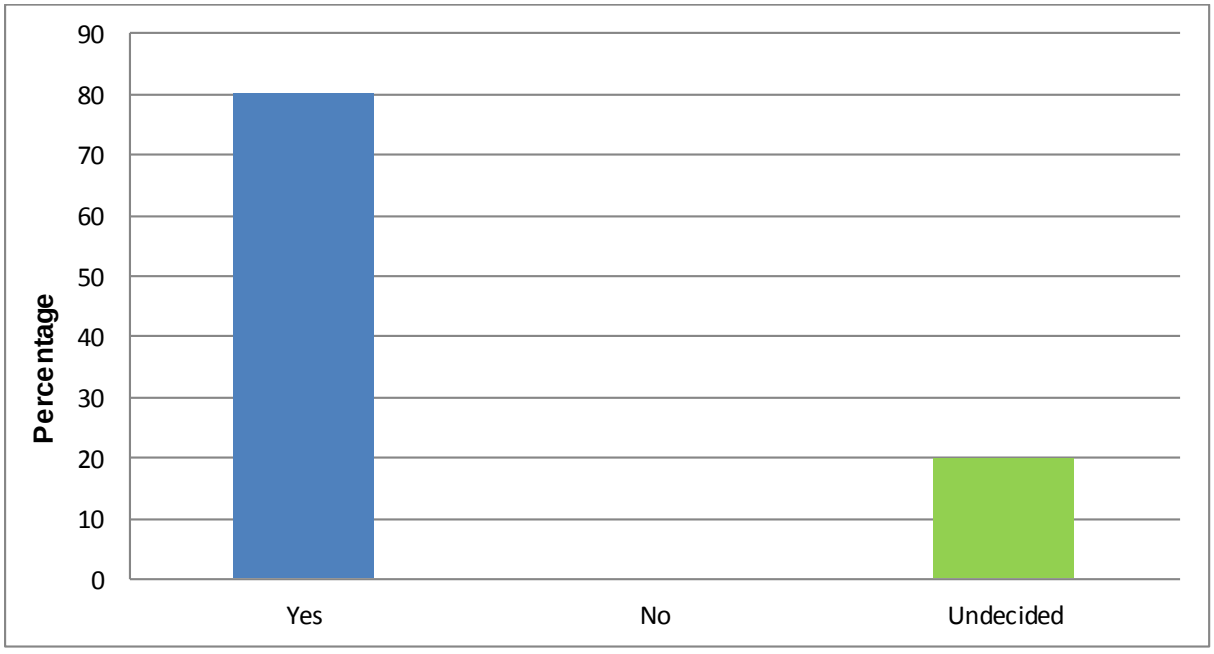
Other responses included:

"Ethical research should be more prominent. A move away from the culture of 'getting your ethics', to one where ethical considerations are taken into account in all phases of the project. Publications of results should be prominent for all research to enable others to see the workings."

"Sponsors and R&D Leads should also be able to apply administrative measures for non-compliance".

"We appreciate the principle of transparency (e.g. Principles 8.5, 8.15, 8.16), but regarding its operationalisation in Principle 8.10, it is unclear what is meant by 'information', how such information is made publicly available, what is meant by 'before they start' (before 'researchers' start?), and what is meant by 'after they have finished'. The principle should clarify that the information publicly disclosed should be enough to give the public awareness as to who is involved in a research project (both researchers and type of participants), geographic area(s), the sponsor and funder, projected start and finish date, and what the project will involve. It is unclear what Principle 8.11 adds that cannot already be captured by Principle 8.10. Principle 8.10 could be modified to state: 'In compliance with any applicable regulatory standards, sufficient information about research projects is normally made publicly available (e.g. via online registers or databases) before researchers begin their project (e.g. before intervention), and the research findings positive or negative are normally made accessible after the project is finished, in suitable form, including to those who took part in it.'"

5. Do you think the principles that apply to interventional health and social care research are right? ('Interventional research' here means research where a change in treatment, care or other services is made for the purpose of the research; it does not refer to research involving other methodological 'interventions' such as issuing a postal survey.)



The vast majority of responses answered 'yes' with a small minority answering 'undecided'.

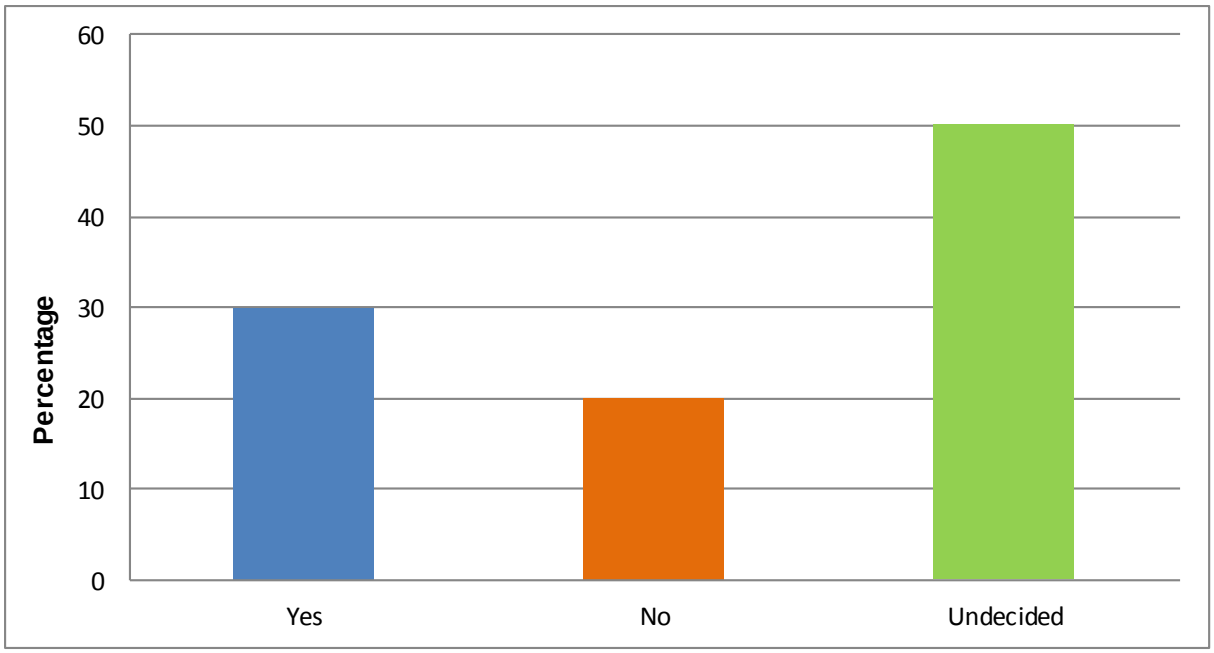
Responses included:

"Mention should be made about not disenfranchising people from taking part in research by virtue of where they live; i.e. remote parts of the country."

"Largely, at 9.5 should specify submitted for review to the Sponsor a) legal requirement for CTIMP and b) REC requirement for all. At 9.7 Investigators should provide summaries of systematic reviews to potential participants. This could be onerous. Suggest should consider. 9.8 The specific inclusion of reference to proportionality re. information PIS is welcome. I would hope this is supported by RECs in practice. Note permanent and portable copy of PIS some studies use online registration".

"We suggest that more should be said about capturing and sharing register data to help build databases internationally about findings arising from interventional research. This can often be very fragmented and dispersed".

6. Do you think the policy framework adequately addresses the needs of social care research? If not, what needs to be covered? In particular, are the responsibilities of local authorities clear and is the terminology in relation to social care research correct?



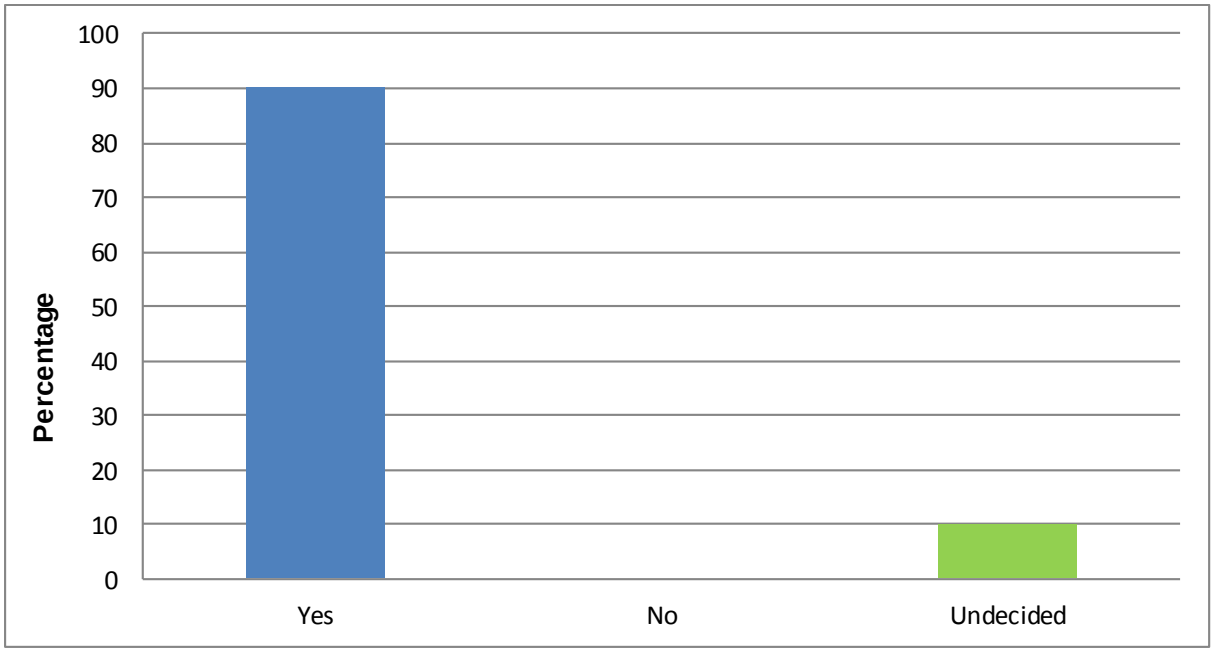
Half the responses were 'undecided' with the remainder either 'yes' or 'no'. One indicated that as its experience lay mainly within the healthcare sector it wasn't best positioned to comment on this section.

Responses included:

"The description of what is understood by 'social care research' could be expanded. While the various social sciences methodologies might be covered by 'transferrable' research, this term is not as commonly known across the spectrum of social sciences, which is why it would be good to see these included more explicitly in the scope of the policy. This is relevant not least for increasing importance of interdisciplinary research endeavours into health and social care."

"There is no mention of research with children, prisoners etc."

7. Do you agree with the responsibilities stated for chief investigators?



The vast majority of responses answered 'yes' with only one answering 'undecided'.

The undecided response highlighted: *"There is no mention of a CI being qualified to take on the role by their experience in the field and /or scientific background where relevant, previous research experience etc. Student supervisors are not necessarily conversant with regulatory approval processes. Emphasis should be made on an individual's suitability for the role."*

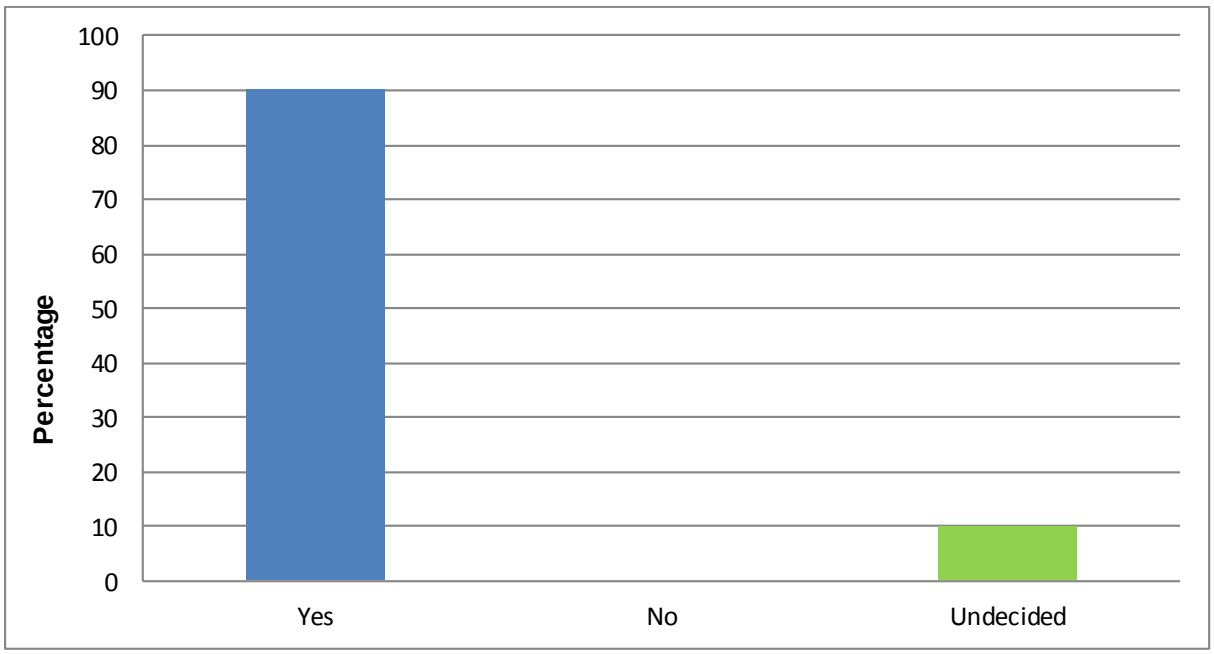
Whilst agreeing with the chief investigator responsibilities, another respondent considered that much of the section about student research is not relevant to the responsibilities of the chief investigator, suggesting a separate section for student or university responsibilities.

Other responses included:

"….we would recommend that 9.5 acknowledges that the PI must ensure that research proposals and protocols are accessible to all member of the research team. Consequently there may be a need for the reasonable adjustment of versions of these documents where members of the research team have specific needs."

"Paras 9.4 and 9.5 'protocol' suggest that this is of crucial importance and gets lost here. We suggesting moving this up to immediately after para 9.1 emphasising people and roles, and then the protocol as the plan of action or roadmap that is a pivotal feature of the research and communication landscape".

8. Do you agree with the responsibilities stated for research teams?



The vast majority of responses answered 'yes' with only one answering 'undecided'.

The 'undecided' response highlighted that: *"Sufficient resources must be available to ensure that all activities, such as case report form completion, data queries, management of the site file etc. are undertaken effectively, as well as clinical care and medical cover where required".*

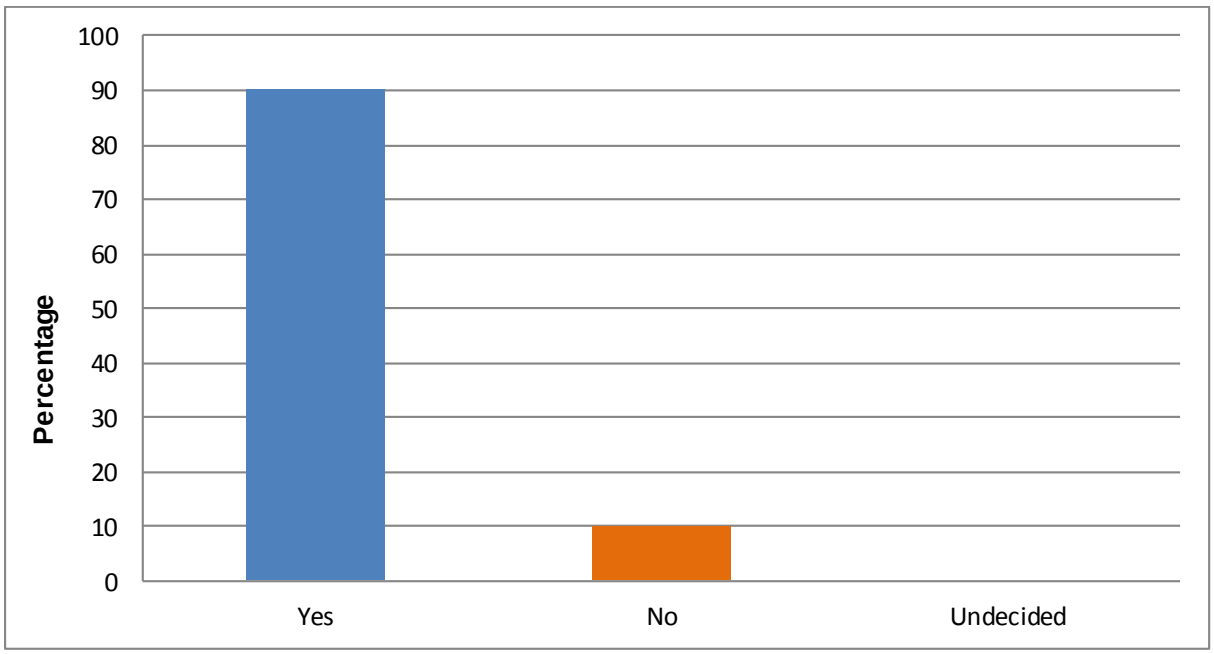
Another respondent felt it appropriate to add a statement to the effect of research teams having the *"Responsibility to participate in/contribute to data analysis and writing up of findings*" as well as having the *"right to be named as an author or contributor in publications proportionate to the individual contribution to the research project".*

Other responses included:

"Responsibility for Adverse Event reporting lies with the Sponsor and is normally delegated to the CI."

"Para 9.6 Research teams should be reminded explicitly that they are responsible for keeping the protocol and ethical issues under review. Team members will be often be the frontline in identifying unforeseen issues as and when they arise. They need to recognise such issues and action them appropriately. This could be cross-referenced to employer responsibilities in paras 9.20 and 9.21. Due recognition of the contribution of team members should be explicitly provided. See, for example, the recent report from the Academy of Medical Sciences on Team Science (March 2016): http://www.acmedsci.ac.uk/policy/policy-projects/team-science/. After Para 9.8 what should happen when consent is not sought? What about the role of privacy notices alerting patients and citizens to the use of their data for research?"

9. Do you agree with the responsibilities stated for funders?



The vast majority of responses answered 'yes' with only one answering 'no'.

The 'no' response highlighted: *"No mention of how funders will be held accountable if projects do not complete; i.e. will this be published on their websites. I am not sure that the funder is responsible* [for] *the scientific quality of the research I am not sure the funder is responsible for ensuring a Sponsor is agreed There should be some mention of involving the public on Funder Committees where possible Mention needs to be made of any conflict of interest by the funder and publications".*

Another respondent considered it appropriate to add a responsibility of the funder to:

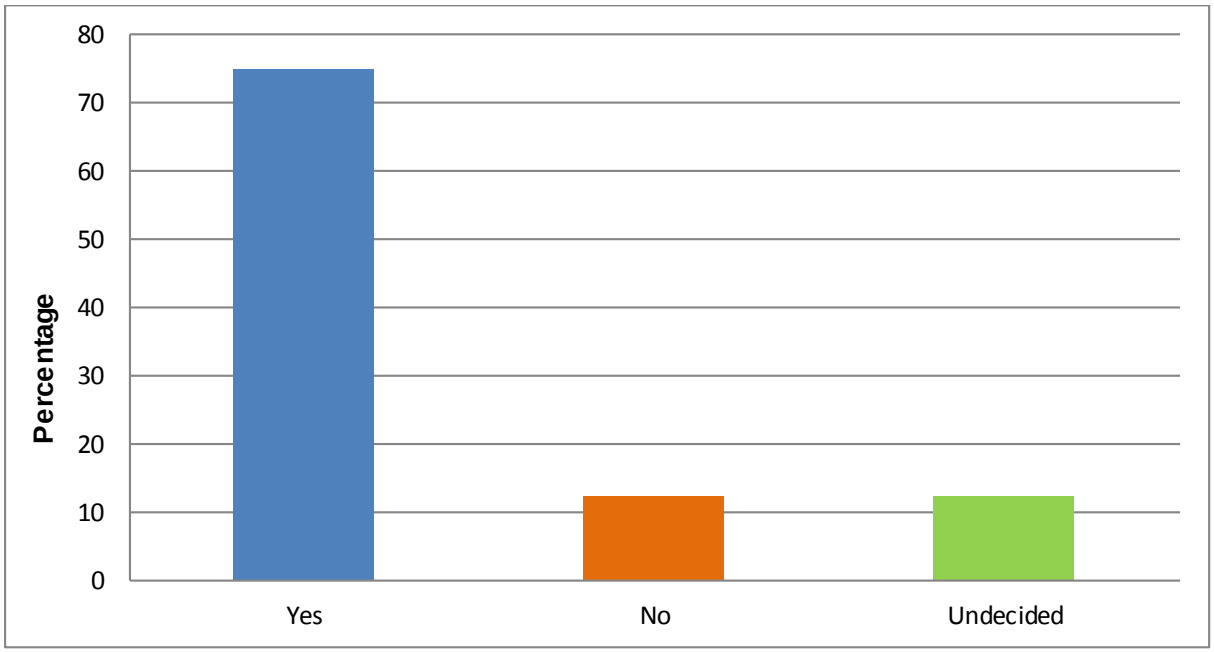
"withhold influencing the process or the outcomes of the research project to the advancement of the funder or their interests."

As well as the responsibility of the funder to:

"uphold the integrity of the research process."

Another also made a suggestion to making reference in this section to Accord guidance.

10. Do you agree with the responsibilities stated for sponsors?



The vast majority of responses were answered 'yes' with one answering 'no' and another 'undecided'. Two other responses to this question were received but neither indicated 'yes', 'no' or 'undecided'.

The 'no' response did not provide further information.

The 'undecided' response highlighted its disappointment that the information relating to roles and responsibilities of Higher Education Institutions had been removed from the earlier draft version. It had welcomed the increased clarification (in sections 8.13 to 8.16) in the first draft document. They also made an observation that there appears to be no reference to the requirement for a UK-based sponsor's representative for non-CTIMP studies out-with the UK.

Another respondent felt that some of the statements in the relevant section of the Policy Framework required clarification including:

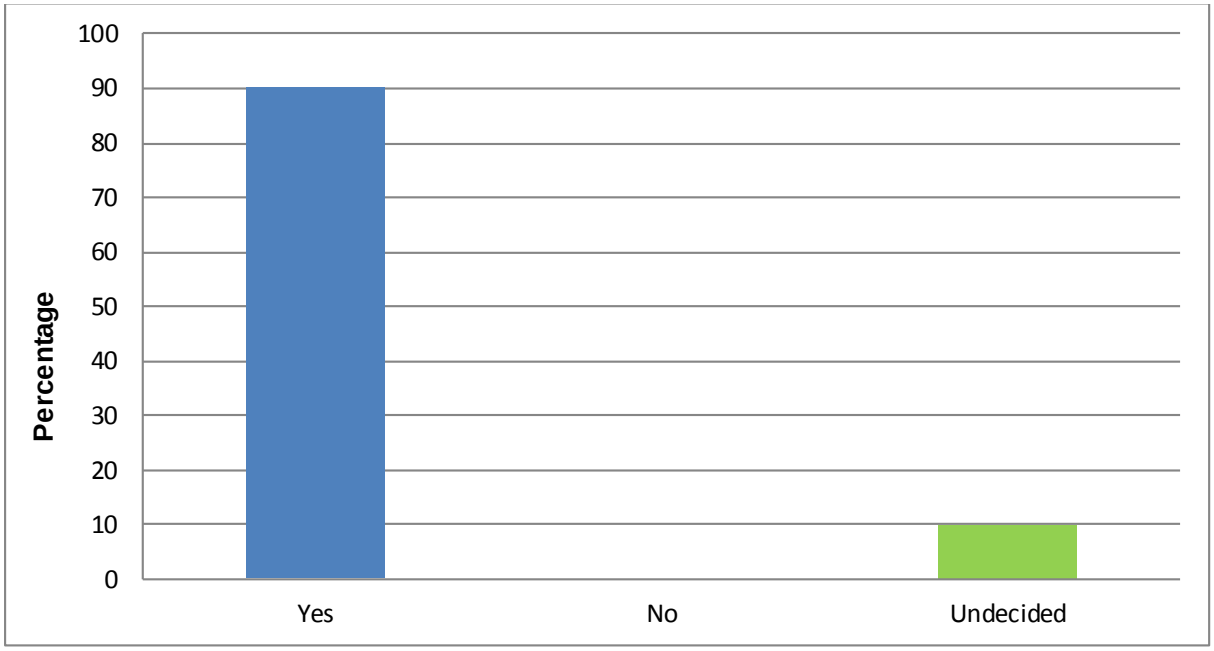
- Inclusion of a statement in paragraph 9.10 to account for situations where sponsors retain responsibility for ensuring that delegated functions are appropriately performed.
- Changing the "footnote 32" wording to: *"The employer or funder is not automatically the sponsor; they must explicitly agree to take the responsibilities of being the sponsor"*
- Changing the wording in paragraph 9.10 (i) to read: *"ensuring that appropriate, effective procedures and arrangements are kept in place and adhered to for monitoring the research and acting on the findings of the monitors, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments (see paragraph 9.2.a)."*

Other responses included:

"Should include sponsor responsibilities for appropriate peer review and oversight of publications. Should include responsibility for ongoing assessment of risk-benefit ratio via SAEs etc, and continuous review of capability of research teams. More detail required in regard to the Sponsor having responsibility for reviewing, risk assessing and approving any amendments made to the original application before they go to REC as potentially impacting on insurance."

"Reference to GCP/EU Directive not mentioned. Suggest they are added and since role of sponsor is primarily for quality and conduct of the study including ensuring appropriate training for research teams - perhaps that could be addressed in section 9.10 at the start with a note that these 'functions' may be delegated to others such as the CI, local researchers, local authorities, NHS organisations etc. etc."

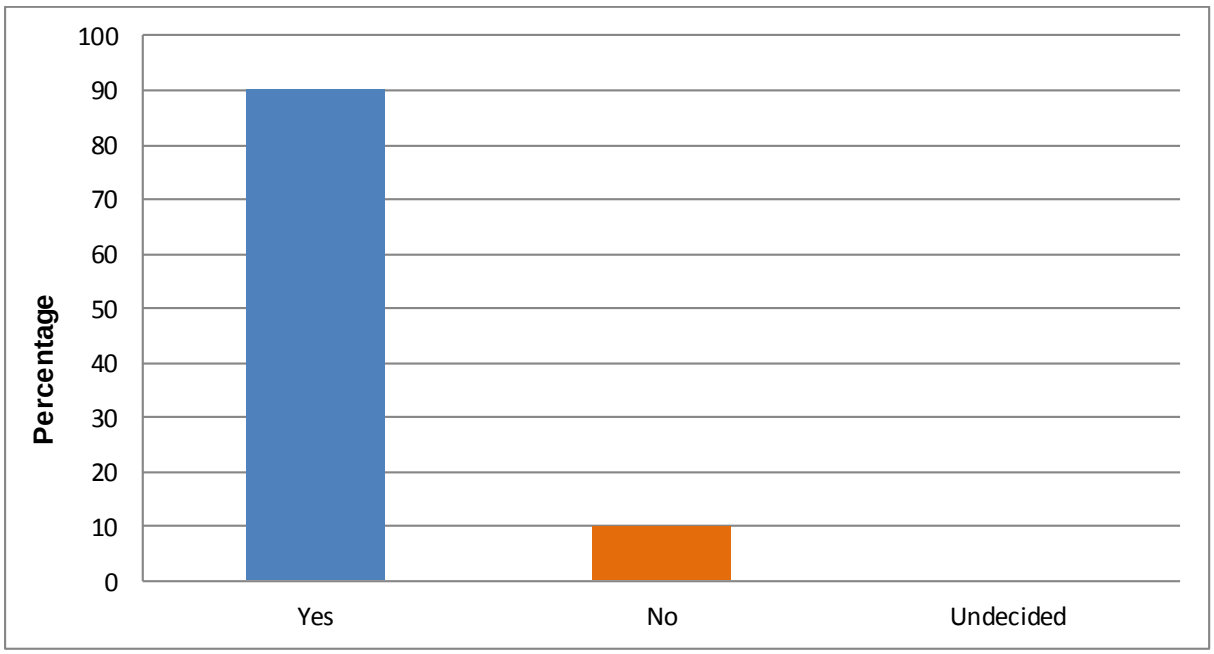
11. Do you agree with the responsibilities stated for contract research organisations?



The vast majority of responses answered 'yes' with only one answering 'undecided'.

The 'undecided' response highlighted that this section would best be commented on by contract research organisations.

12. Do you agree with the responsibilities stated for research sites?



The vast majority of responses answered 'yes' with only one answering 'no'.

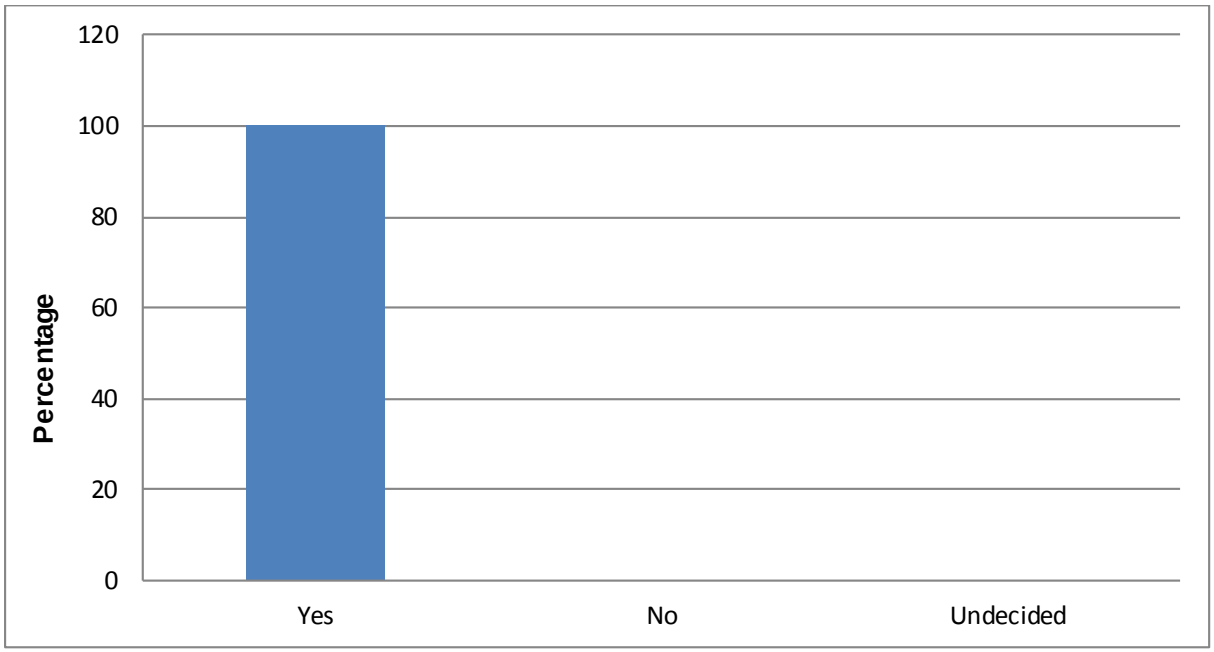
The 'no' response made specific reference to the responsibilities stated in paragraphs 9.15 and 9.16 and did not *"agree with the lack of ability to repeat checks made by ethics committees or other approval bodies"*. It highlighted it has *"experienced situations where there have been issues with decisions made by such parties"*. It did not agree that *"liability can be assumed by the HRA particularly in respect of data control. In addition this would address any reputational risk and patient safety issues associated with incorrect decisions made elsewhere"*.

Another respondent felt that as written the document gives the impression that nearly all issues to do with the review and approval of studies are the fault of the research sites. It also queried whether paragraph 9.15 should detail approval bodies with statutory authority that sites can accept without liability (possibly suggesting that it would only be checks conducted by those types of bodies that research sites could reasonably rely on?). In response to paragraph 9.16 (a), which highlighted the responsibility of research sites to make information available about their capacity and capability, this respondent also made the point that sponsors also have a responsibility to make full, clear and consistent information available to sites to allow them to make a clear decision on whether they can take part.

Other responses included:

"Welcome the reference at 9.16f to transfer of participants." This was made in the scenario where a 'transferring' research site facilitates the transfer of a study to a new site by providing all information to the 'receiving' site to support the continuation of research.

13. Do you agree with the responsibilities stated for professional bodies?

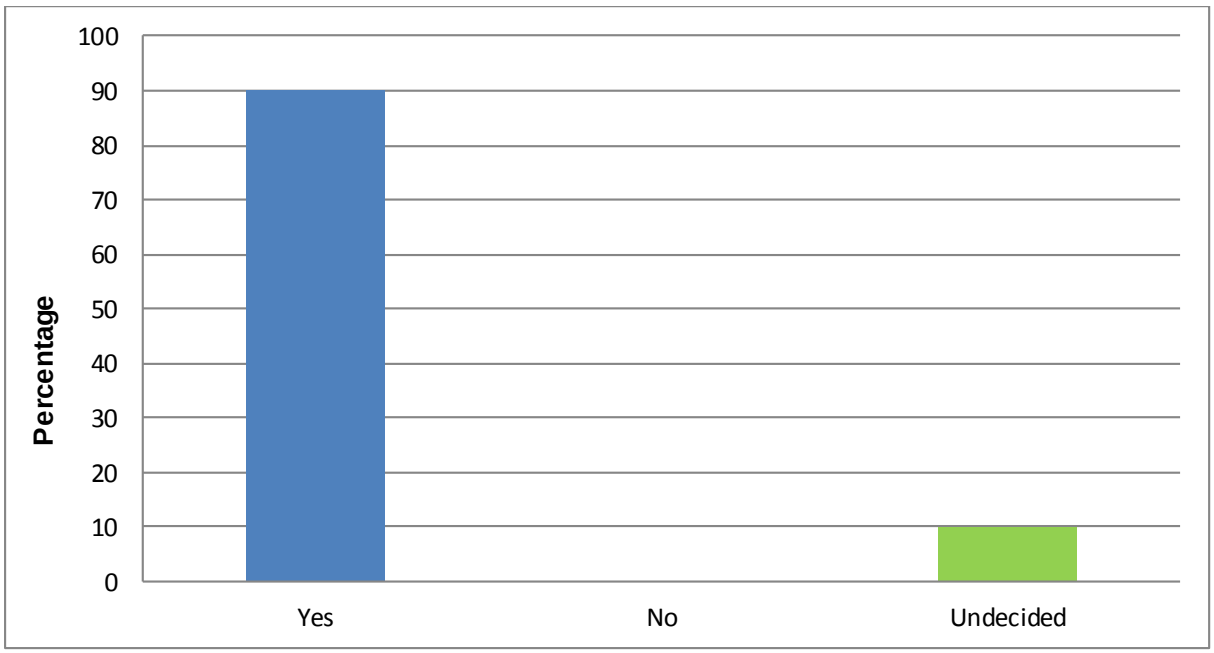


All responses to this question were answered 'yes'.

Responses included:

"…..might be clearer if the title of this section was professional regulatory bodies to distinguish it from the Royal Colleges."

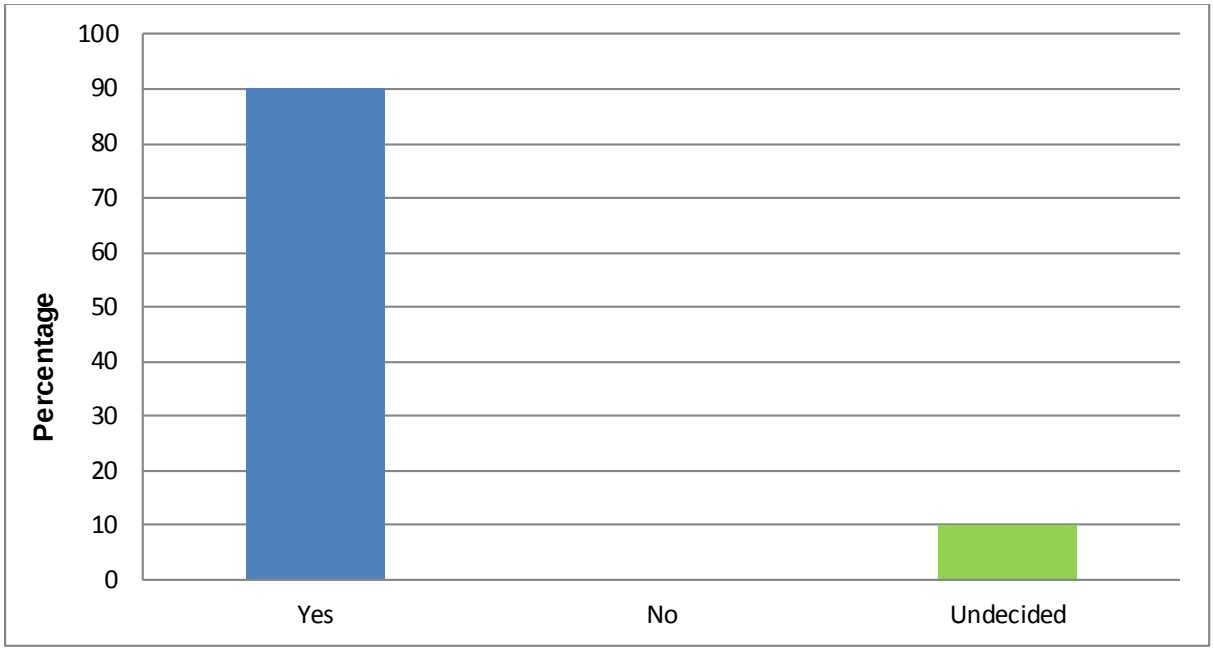
14. Do you agree with the responsibilities stated for regulators?



The vast majority of responses answered 'yes' with only one answering 'undecided'.

The 'undecided' response highlighted concerns over clarity of the role of the HRA as a regulator in the devolved administrations and how the responsibilities of the HRA align within the devolved administrations.

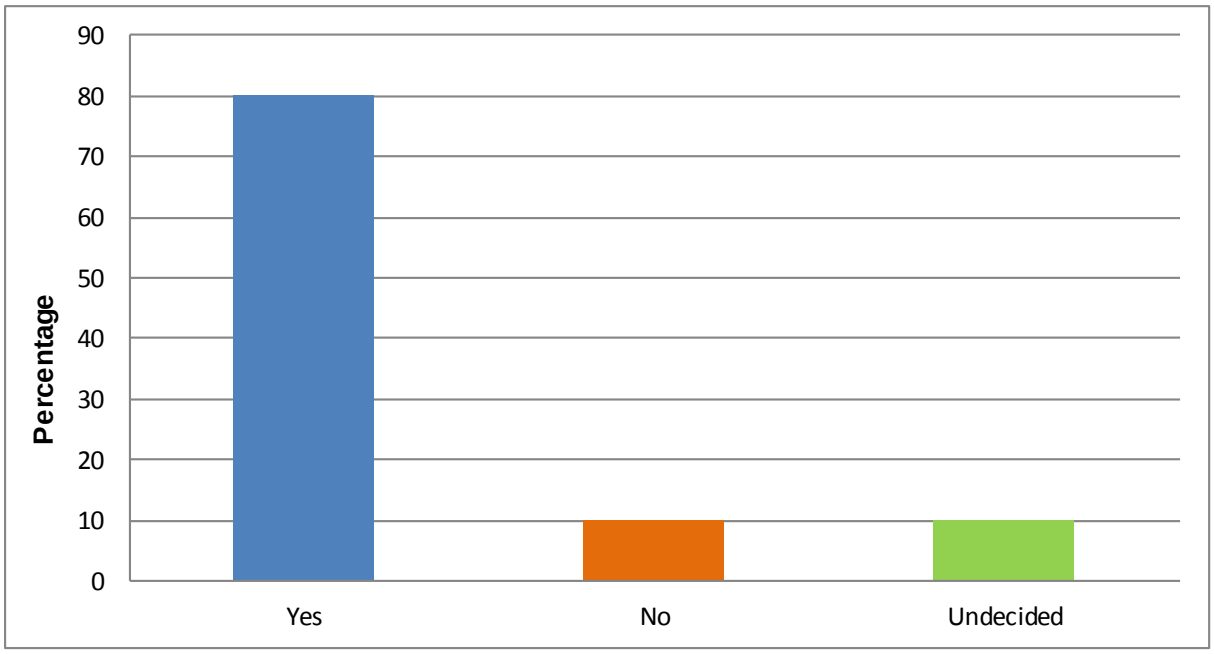
15. Do you agree with the responsibilities stated for employers?



The vast majority of responses answered 'yes' with only one answering 'undecided'.

The 'undecided' response highlighted: *"9.20 It would be helpful to include mention of training of supervisors here. Supervisors of research projects are often not up to date with approval processes and give incorrect advice to students."*

16. Do you agree with the responsibilities stated for health and social care providers?

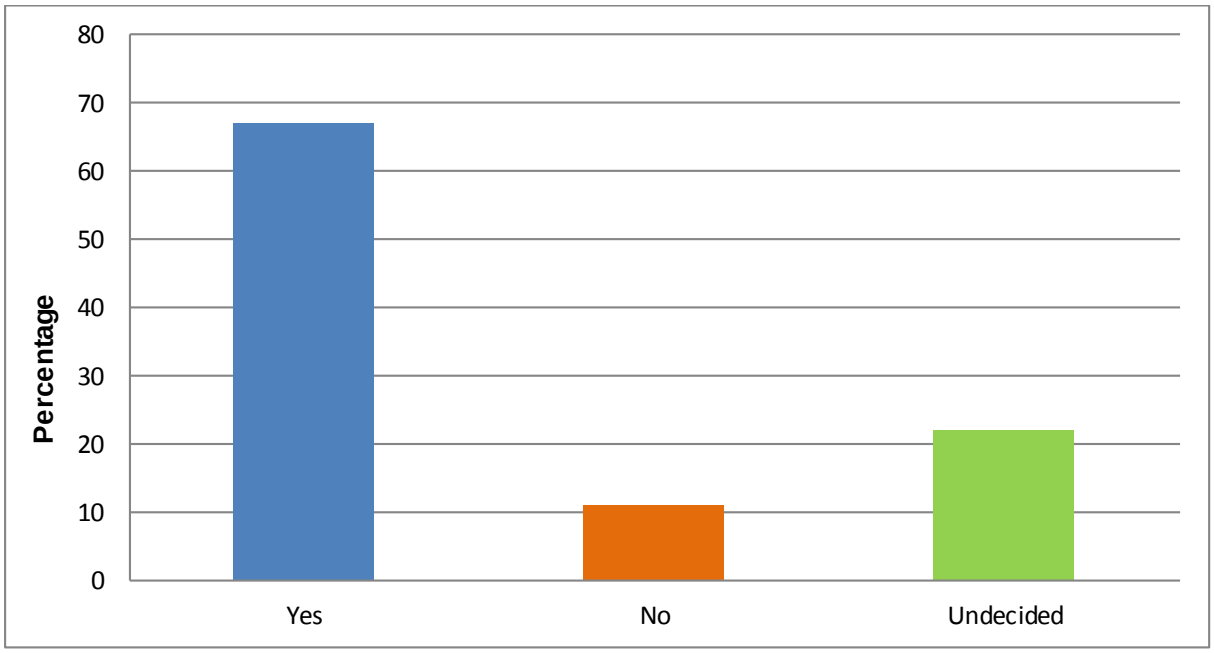


The vast majority of responses answered 'yes' with only one answering 'no' and the other 'undecided'.

The 'no' response highlighted that: *"Further clarification for the organisations in Scotland would be helpful."*

The 'undecided' respondent did not provide further information.

17. Do you think the policy framework will help make the UK a better place to do research? If not, is there anything more it could say in order to achieve this?



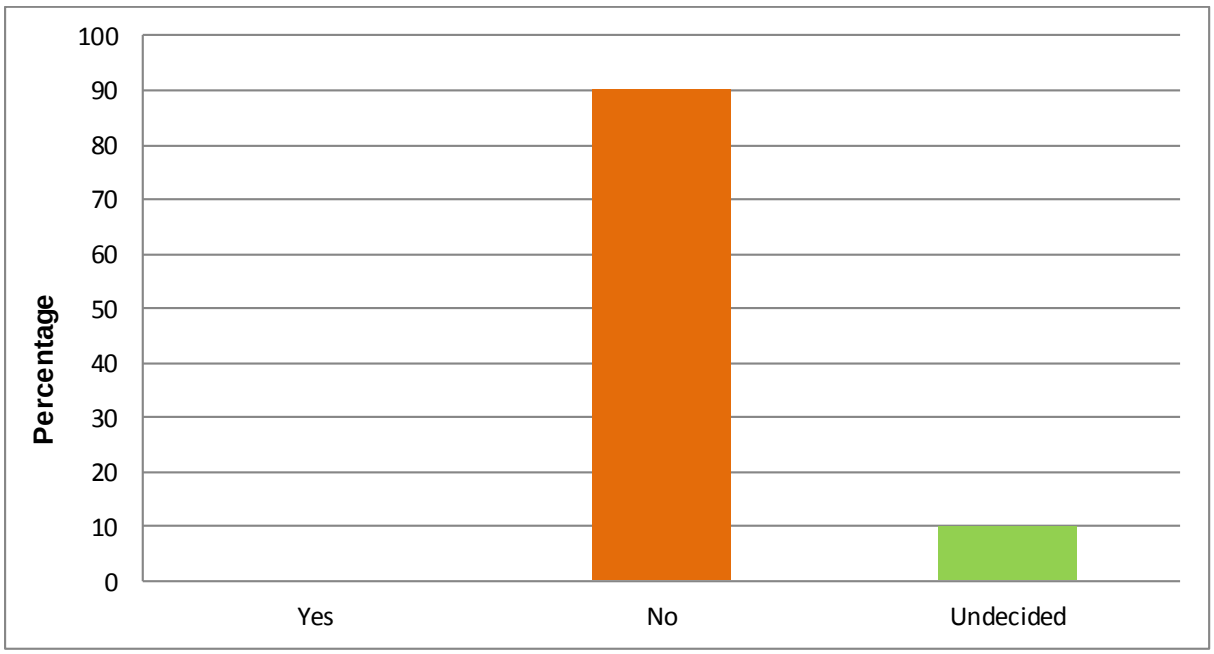
The majority of responses answered 'yes' with only one answering 'no' and two 'undecided'. Two other responses to this question were received but neither indicated 'yes', 'no' or 'undecided'.

The 'no' response did not provide further information.

One respondent highlighted that: *"recruitment is not addressed in this framework"* and that: *"failing to recruit to target is an enormous burden"*. The respondent went on to comment that the: *"framework is directed at researchers, but is not proposing any way to address the public, to make them more engaged as participants".* It mentioned that *"public involvement now takes place in the design of research, the management of research and even where grants are spent, however no-where are we addressing the fact that volunteers are needed to actually take part in the projects".* The respondent concluded by indicating that: *"a culture shift is needed whereby taking part in research is commonplace for all users of the NHS and that it is seen as a positive thing to participate in".*

Comments from an undecided respondent highlighted that: *"if enough is done to reduce ambiguity and ensure consistency among all 4 nations and all organisations involved, and to ensure that all parties are fully educated and follow the policy, this should help reduce frustration with the governance processes in the UK".* This respondent also made the comment that [the Policy Framework] *"is unlikely to have much effect on the quality of research activity here, which is generally very good".*

18. Is there anything the policy framework should leave out?



The vast majority of responses answered 'no' with only one answering 'undecided'.

There were no substantial comments provided in response to this question although there was a suggestion that there is some repetition that could be trimmed.

19. Do you have any suggestions about how to measure the policy framework's contribution to achievement of the ambitions set out in the "Purpose" section?

Responses included:

"Measure the number of approved projects that recruit to target, within timescale and without the need for extension or amendments".

"Would suggest that these metrics are more appropriately collected by Sponsors and/or R&D Leads and that HRA should actively work in collaboration re. this".

"Public perceptions of health and social care research and their willingness to participate, study recruitment data, research activity across the UK, feedback from all of the stakeholders listed, monitoring of the research register…….a companion policy framework on knowledge transfer to ensure impact 'success breeds success'!"

"Main outcome measures would be number of projects approved, number of sites involved".

One respondent indicated that: *"the language of the "Purpose" section does not really define a purpose; rather it explained the requirements set out in the document". It went on to say that it should be "relatively easy to measure the*

consistency across the 4 nations, by surveying and comparing the processes each has put in place. Otherwise the achievement of high quality research and research governance can probably be measured indirectly by collecting information on complaints and problems with the system".

Another respondent highlighted that: *"the Academy of Medical Sciences encourages effective dialogue with the research community and public involvement to ascertain opinion".* It went on to suggest that: *"Such an approach with investigators, service users and commerce could be used to help evaluate the effectiveness of the policy and whether there has been an improvement to stakeholder experience of the research process".*

20. We would appreciate your views about the scope of the policy framework set out in paragraph 3.1. In particular, what are the positive or negative consequences for health and social care research that is not currently covered (e.g. relevant sports research or nutrition research in universities, phase I clinical trials in private units)?

Respondent comments included:

"Would suggest that organisations outwith the scope are actively encouraged to use the framework as a standard. Sponsor organisations working with such organisations could require it and/or HRA could ask them to adopt it".

"+ve Great advancement with health and social care under this framework - makes collaboration much easier and provides opportunities to develop protocols across the care environments and for the benefit of patients e.g. inclusion of all care facilities whe"

One respondent felt that *"the scope should also more explicitly cover different types of social science research methodologies*". Another, suggested that: *"it might be helpful to stipulate what type of research is not in the scope of the policy framework"* It went on to suggest that: *"from the perspective of research participants, inclusion of phase I clinical trials in private units within the scope may warrant consideration".*

21. Do you have any other comments?

Respondent comments included:

In the context of defining what research is: *"The word 'generalizable' is still confusing".*

"Section 1.2 sets out the involvement of patients, service users and the public in the pursuit of knowledge that may benefit them and others however it makes no reference to PPI involvement in research priority setting. We recommended this section is expanded to acknowledge the importance of PPI engagement in the entire research processes to ensure the maximum impact of research activity".

"In Section 6.1, whilst the HRA is said to be responsible for maintaining this policy, it leaves unclear how the Policy Framework will be maintained. Is it intended to be a living document subject to regular periodic revisiting, or an as needed basis?.....In Footnote 17, it should be clarified that UKECA is responsible for establishing, recognising and monitoring only recognised RECs, ie those reviewing CTIMPs, rather than all NHS RECs".

One respondent, commented that: *"there is relatively light emphasis on dissemination of research findings".* It suggested that: *"it might be better to state that strenuous efforts should be made to ensure that the findings of research are made available to those who would benefit most from the research and, where appropriate, those who provide care for them".*

Another highlighted that: *"the policy document has no mention of research or ethics procedures regarding the research of minors or other vulnerable groups"….*indicating that this should be taken into account in the policy framework.