NHS
Health Research Authority

UK Policy Framework for Health and Social Care Research: Summary of Consultation Responses

v1.0 June 2016

Contents

Background

The Health Research Authority is responsible for publishing policy and guidance on principles of good practice in the management and conduct of health and social care research in England. We have been working with the three Devolved Administrations to develop a UK-wide policy framework that sets out these principles.

The UK Policy Framework for Health and Social Care Research aims to help make the UK an even better place to do research. It sets out clearly the high-level principles and responsibilities, applicable in all health and social care research, that underpin high-quality ethical research.

The policy framework provides the basis for operational provisions and sets the tone of what they should be like. These include things like guidance and systems to support researchers, standard operating procedures for research ethics committees and, in England, operational arrangements for HRA Approval. The policy framework does not go into operational details itself; it sets out high-level principles and responsibilities that will be met through operational arrangements and supported by guidance.

The policy framework addresses key known issues affecting good practice in the management and conduct of research. These have been identified from feedback since the first Research Governance Framework was published in 2001, from a group of recent projects to explore the issues in detail, and from responses to a call for comments on an initial draft of the new policy framework last year.

The new policy framework promotes appropriate safeguards while avoiding the ambiguity in the current Research Governance Frameworks and the obstacles to which that has contributed. It focuses on the real risks in research, the benefits of research, and proportionate risk assessment and management. This will ensure that people feel confident about taking part in research, that researchers find it straightforward to do high-quality ethical research, and that funding goes into carrying out research, not into navigating needless bureaucracy before it starts.

Once finalised, the policy framework will replace the four separate Research Governance Frameworks previously issued by each of the UK Health Departments.

What we did

In December 2015 the HRA published a draft version of the UK Policy Framework for Health and Social Care Research. The comment period ran from 18th December 2015 and closed on 24th March 2016.

In parallel, the HRA undertook a series of consultation workshops for researchers, the R&D community, industry and patients and the public.

A summary of all comments received and our responses can be found in this report. These comments will inform the revision of the document.

This document

This document is the post-consultation report summarising the responses to the draft Policy Framework. It also includes feedback from the public dialogue workshops.

This document covers:

- the background to the report
- a summary of responses to the report
- specific responses by question
- the next steps following this consultation

Summary of Responses

1. Responses to the online survey and by email

A total of **104 online responses** to the survey were received: 64 from organisations and 40 from individuals:

The 104 respondents were asked to state where they were based:

- England 89
- Scotland 6
- Wales 4
- Northern Ireland 4
- UK wide 1

In addition the HRA received **24 responses by email** some with attachments. There was some overlap in the respondents between these more detailed responses via email and those made via the online survey. Of the 24 email responses, 23 were organisational.

Overall Response

In general, respondents welcomed and supported the draft Policy Framework as a replacement for the Research Governance Framework and supported the approach to harmonise approval processes across the UK:

- *Cancer Research UK supports the development of a UK wide policy framework. In producing this guidance, the Heath Research Authority (HRA) will be fulfilling its responsibly to publish guidance on principles of good practice in the management and conduct of health and social care research (Care Act 2014). We believe that this document will provide a useful framework from which operational arrangements can be developed. We are particularly pleased to see the framework emphasise the importance of a proportionate approach to the management of health and social care research.*

- *The R&D Forum working groups generally found the document to be improved from the previous draft as a high-level policy for the conduct of research in health and social care in the UK. The groups accept that the policy remains high-level. At times there is more operational detail in the document but this is not enough to give clear instruction and we would therefore like to reiterate that the operationalisation of the policy remains potentially open to some interpretation and variation in practice. This variation might be reduced through issuing subsequent codes of conduct or operational guidance, and clarity on whether such guidance will follow would be welcomed.*

- *In conclusion, the ABPI is supportive of a policy framework that aims to streamline the existing research governance system for health and social care research across the UK, ensuring compliance and minimising duplication as well as protecting the interests of patients and the public*. (ABPI)

The Framework describes principles that apply to all (page 6-8) and principles that apply to individuals and organisations (page 9-20). This second group should be '*responsibilities* that apply to individuals and organisations'.

Context

It was noted that the context focuses on research for new treatments and does not acknowledge the need for research of existing treatments. The Academy of Medical Sciences (AMS) recommends that the second bullet point is amended to:

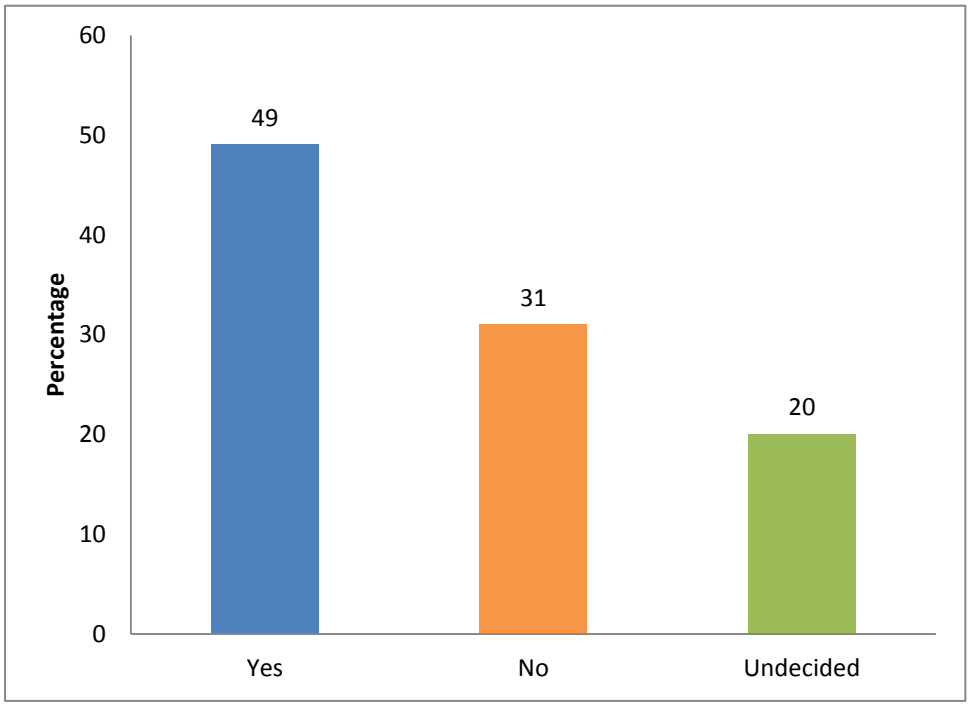
'Both for new and (where reliable evidence about their effects is absent) existing treatments, and for care and other services, there should be a rigorous process of evaluation by ethical and scientifically sound research for the benefit of patients, service users and the public'.

The framework should be amended throughout to remove any implication that research is only relevant for new treatments. A similar point was made by the MRC and ESRC, and Nuffield Department of Population Health:

'Throughout the document there is a focus on the value of research being only to evaluate <u>new treatments</u> without mention of the need for research to evaluate many existing treatments where reliable evidence on their effects does not exist.'

Response by question

Q8. **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?**



Almost half of respondents to the online survey thought that there was enough detail in the Framework but almost a third wanted to see more. In some cases respondents were asking for operational detail which would not be appropriate here but others were just seeking greater clarity.

Whilst there is widespread support for the new Policy Framework, there was clear demand for greater clarity; in particular for some of the wording to be clearer and more accessible. It was thought that sentences are overly long and consequently confusing, for example, section 9.15. It would benefit from being broken down and a greater use of bullet points. The level of detail was mostly seen to underpin the overarching principles and responsibilities but clearer wording and structure would aid understanding.

Some of the demand for clarity related to improved definitions and examples. In particular, respondents wanted greater clarity around the definition of research and the exclusions. In defining what research is, it is equally important to clearly define what is excluded. A separate sub-heading entitled the definition of research would be useful here.

Specifically respondents were exercised by the definition of service evaluation and did not find the suggestion that service evaluations which are generalisable should be defined as research since this would encompass most evaluations. Linked to this footnotes 7 and 9 were seen to be contradictory in relation to this definition. Similar comments were made in relation to the definition of audit.

Both Wellcome, the Academy of Medical Sciences (AMS), and Cancer Research UK specifically requested the clarification around the use of ‘must’ and ‘should’ should be moved

from the glossary and brought up front in the document so that the distinction is understood form the start. They also pointed out areas of legal ambiguity, for example, 9.10 – 'all healthcare research will have a sponsor'.

On similar lines, the AMS also highlighted the need for further clarification on the legal status of the document, as well as framing the document as a minimum level of requirements.

Requests were made for a more comprehensive glossary to minimise any ambiguity and request for more examples. Where the Framework uses the phrases 'normally' or 'if appropriate', respondents would like to see clarification, possibly accompanied by examples of what is meant. Points requiring further clarification include:

- 8.2 – All the people involved in conducting a research project are qualified by education, training and experience, or otherwise competent, to perform their tasks. – how does this relate to students taking part in clinical research? Does this allow for 'or perform activities under the supervision of a person who is' to cover student activity?

- 8.4 when is 'appropriate' on the context of of involvement of patients, public and service users?

  8.5 – The MRC and ESRC suggests that dissemination should be added to the list here. The paragraph could read: '*Research is designed, reviewed, managed, undertaken, published and shared appropriately in a way that ensured quality and transparency.'*

- 8.6 when is it 'applicable' for researchers to conform to a 'standard template' design?

- 8.7 – The MRC and ESRC suggests 'follow' or 'apply' may be more appropriate than 'consider' in the following sentence *"The researchers and sponsor consider relevant legislation and guidance…' Consider almost implies that a decision could be made not to follow relevant legislation and guidance once it had been considered, when working within the law is a must and not a matter for consideration.'*

- *'A 'formal structured risk assessment' is an ambiguous term, and placing responsibility only on ethics committees to identify risks seems inappropriate. We endorse assessment of risk in all research and proportionate mitigation. This footnote would be better worded along the following lines: In all research consideration of risk and appropriate management is important and a responsibility of all, in most cases this will not involve extensive paperwork. Risks to research participants, investigators, the validity of data and research delivery, should be proportionately managed.'* (MRC and ESRC)

- 8.10 – information about research projects should 'normally' be made publically available but it is not clear what 'normally' means.

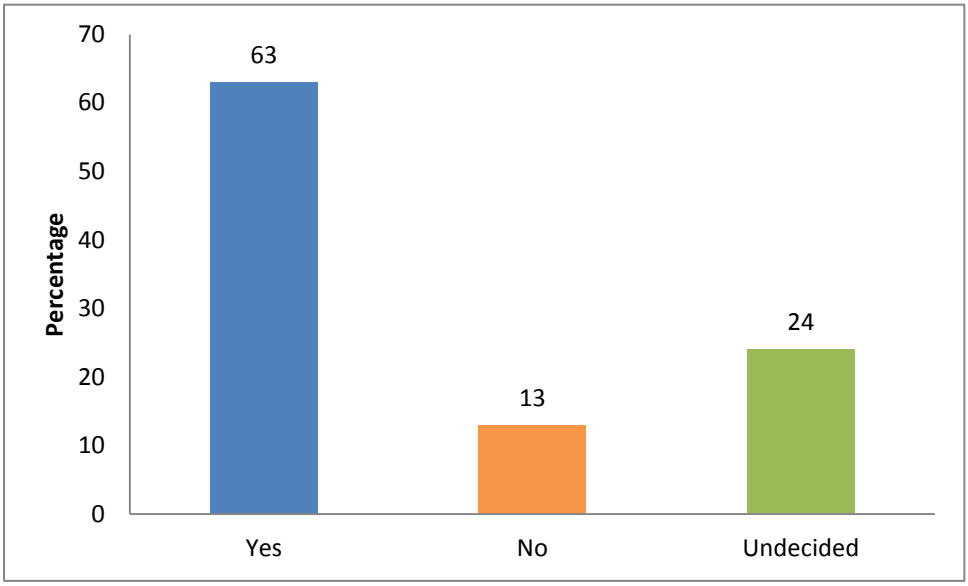
- 8.14 – Add in 'crown indemnity' as an example.

Several respondents pointed out critical wording has been included in the footnotes and this should be part of the main body of the text.

Some respondents including Wellcome felt that the section on students and supervisors responsibilities was somewhat lost in the Chief Investigator section and would justify having its own dedicated section.

Finally respondents asked for hyperlinks to be placed in the Framework to existing guidance and operational detail where this already exists. The ABPI recommended the need for clear reference to be made to links with overarching legislation, principles and regulations which are of relevance including Good Clinical Practice, European Union Clinical Trial Regulation and Data transparency requirements.

Q9. Does the policy framework place sufficient emphasis on a proportionate approach to the conduct and management of research?



We believe that this document will provide a useful framework from which operational arrangements can be developed. We are particularly pleased to see the framework emphasise the importance of a proportionate approach to the management of health and social care research. (Cancer Research UK)

The feedback recommended that a proportionate approach requires greater emphasis both earlier in the document and throughout. It was suggested should be overarching statement early on in document on the need to implement the framework proportionately. In particular there was concern that a rigid adherence to the document by sponsors and employers could result in a disproportionate and bureaucratic approach.

A number of respondents also suggested that the Framework should also make reference to a 'risk-based' approach, for example, that different methodologies required different approaches according to risk. By way of illustration, it was suggested that the principles that apply to all all health and social care research could be proportionately applied according to risk. For example, the need to register all research or use patient and public involvement in the design as of all research was seen as inappropriate for some types of studies. Similarly it was pointed out by AMS that 9.2b It is not always feasible to obtain independent expert review for smaller projects such as undergraduate projects, and so the text should be amended or removed to reflect this.

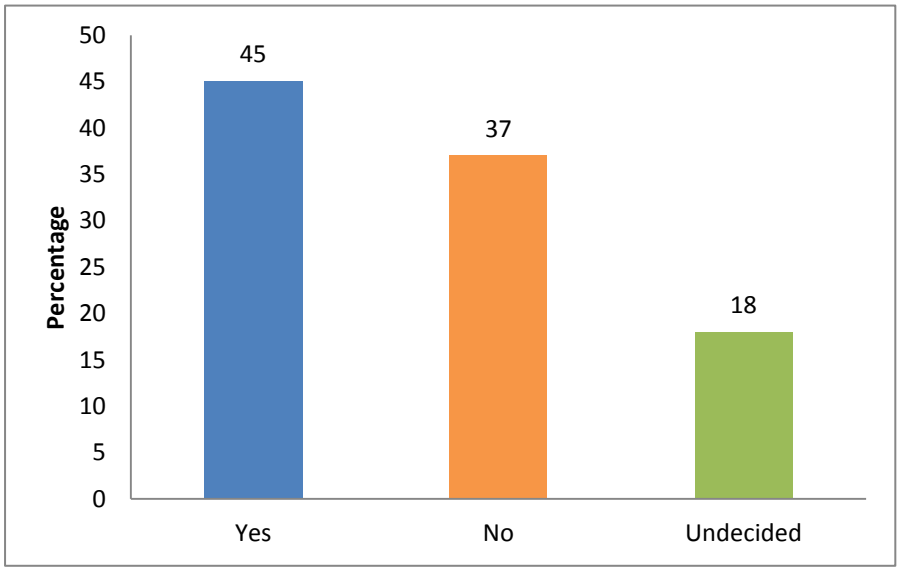
It was felt that the Framework could provide examples of how different stakeholder groups could adopt a proportionate approach.

It was also suggested that proportionality itself should be stated as a principle.

It was noted that proportionate review is already successful and could be referred to as a successful example of a proportionate approach.

Some respondents wanted to know what were the sanctions for non-compliance with proportionate approach?

Q10. 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 key issue is the need for funders to be able to arrange for early release of funding for early preparation work and PPI prior to REC approval. Many funders still have Rec approval as a condition of any funding.

Second biggest issue relates to social care research – lack of local research governance structure and confusion as to what is expected of LAs by way of research governance.

Linked to this is there no reference to forthcoming integration of health and social care – rather document treats them as two separate entities.

Social care researchers also concerned over definitions of research and how they relate to research.

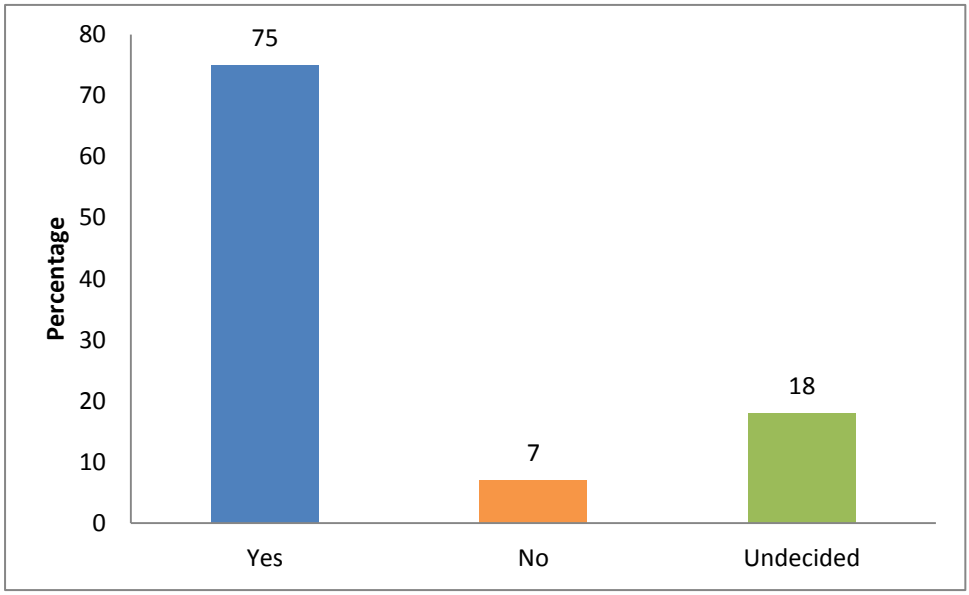
A number of researchers are concerned about the way we have changed the definition of service evaluation and when this is research.

Other issues identified are:

- ICH GCP which they say is only relevant to studies of new medicinal products.
- Lack of clarity about how principles should be applied in practice – i.e. equally to all study types of proportionately according to risk?
- Lack of detail about transparency/knowledge transfer and how this is applied
- Too much emphasis on what happens at the beginning of a study and not enough on what happens during the study, monitoring etc.
- Patient incentives

- NHS employers unwilling to release staff to sit on RECS
- Need to build evidence based research friendly culture
- IG standards imposed on low risk projects which are impossible to meet by some Trusts

Q11. Do you think the principles that apply to all health and social care research are right?



Points requiring further clarification include:

- 8.2 – All the people involved in conducting a research project are qualified by education, training and experience, or otherwise competent, to perform their tasks. – how does this relate to students taking part in clinical research? Does this allow for 'or perform activities under the supervision of a person who is' to cover student activity?
- 8.3 Several respondents including those in social care research, in particular, were unhappy with the reference to 'scientifically sound'. The Association of medical Research Charities (AMRC) suggests that this should be revised to say 'scientifically or methodologically' instead.
- 8.4 when is 'appropriate' on the context of of involvement of patients, public and service users? This is open to interpretation and variation.
- 8.6 when is it 'applicable' for researchers to conform to a 'standard template' design?
- 8.9 – Ethical review is not limited to just the proposal or protocol, other documents including the IRAS are reviewed. Furthermore 8.9 implies that ethical review is always required when there are various categories of research that do not require ethical review. Furthermore 8.9 may be taken as suggesting that early release of funding for activities such as patient involvement cannot take place before the study has ethical approval.
- 8.10 – information about research projects should 'normally' be made publically available but it is not clear what 'normally' means.
- 8.10 – Several respondents called for the footnotes for 8.10 to be incorporated into the main text.
- 8.11 – 'in a suitable form' should be changed to 'lay language' or 'plain English'.

- 8.14 Clarity is required regarding the need for indemnity for any commercialisation of findings is required as it not appropriate and is confusing as presented (e.g. if findings are commercialised by a third party who is responsible for indemnity provisions?).
- 8.16 – there were calls for greater clarity as to what compliance checks actually means.

Several respondents notes that other principles in appear under the heading of responsibilities. For example, the Health Foundation acknowledges the importance of defining the guiding principles that shape the health and social care research policy framework. However, they feel that the document conflates what might generally be considered as guiding principles with more detailed roles and responsibilities. This becomes particularly apparent when describing the principles that apply to specific groups of people. For example, principles relating to the good conduct of research in line with a research proposal or protocol are included with the roles and responsibilities of the Chief Investigator.

Similarly the NIHR proposes moving 9.4 and 9.5 (research proposals, protocols and procedures) from the Chief Investigators section to section 8.17, or adding the first sentence of 9.4 to this section (Research should be conducted in accordance with a research proposal or protocol – a document that describes clearly what will be done in the research). It should also be clear that while the creation and maintenance of the proposal/protocol is the Chief Investigator's responsibility, adherence to it is the responsibility of everyone involved in the conduct of the study. 8.9 – It would be useful to clarify how 'started' is defined, either in the principle itself or a footnote.

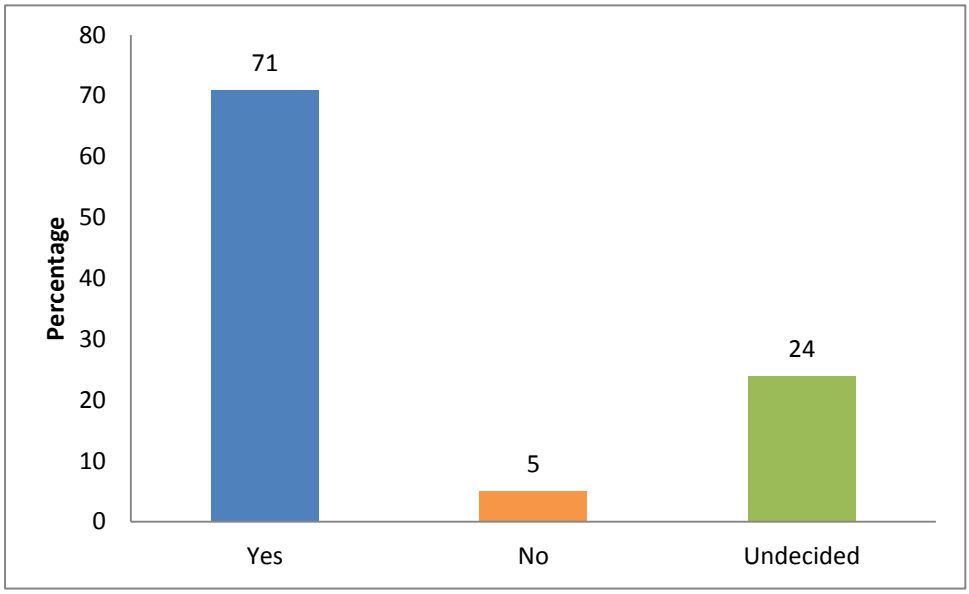
The Health foundation makes the point that the suggestion that clinical trials registers and summaries of research ethics committee applications are suitable means of disseminating information about a project also conveys a somewhat passive approach to sharing knowledge. Like many funding organisations, the Health Foundation provides a searchable record of the projects we are funding. They recommend that the HRA makes this approach a minimum requirement for all funding organisation bound by the UK UK Policy Framework for Health and Social Care Research.

Some respondents made suggestions for additional principles:

- It would be useful to capture in a general statement within the principles the need for organisations to work efficiently to avoid duplication in research governance. This will support a streamlined approach for efficient working across the UK. (ABPI)
- To bolster 8.10, an additional principle should be included in section 8.17 to outline the requirement that interventional research should usually be registered before it commences (Cancer Research UK)

Q12. 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.)



It was recommended that the definition of interventional research should be aligned with the definitions provide by Regulation (EU) No 536/2014 on clinical trials, which is very different to the one formulated in the HRS policy framework, to avoid confusion.

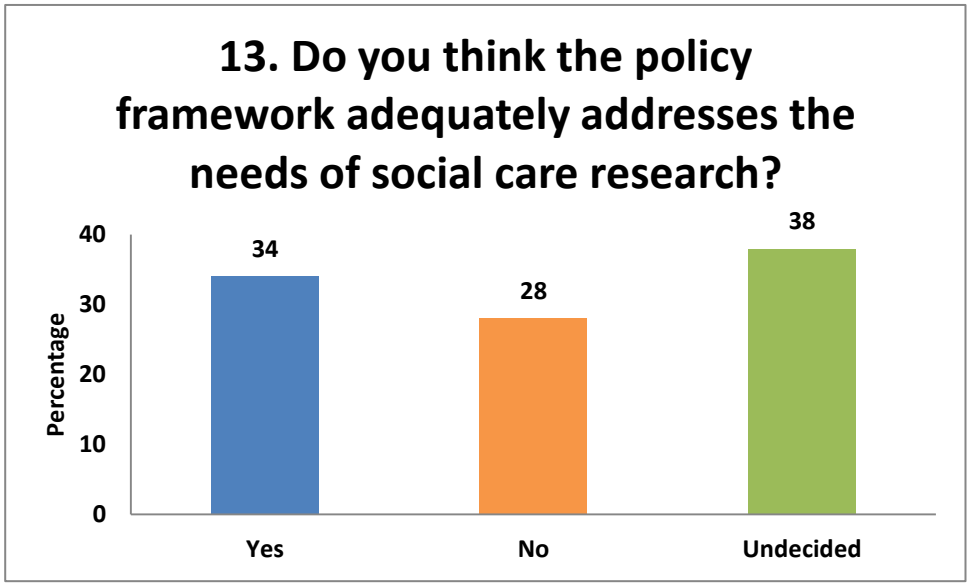
8.17 (d) According to Cancer Research UK, the wording of this principle does not reflect the involvement of patients in treatment decisions and it should be amended to do so. Treatment decisions should be made on the basis of a full and informed conversation between the clinician and patient. The importance of this was set out in the Health and Social Care Act 2012, which created a new duty on commissioners to promote the involvement of individuals, their carers and representatives in decisions about their own care and treatment.

8.17d is quite difficult to read and needs revision.

Make patient and public involvement in research a clear requirement for interventional research.

9.1: Add a note at the end which emphasises the importance of research independence, including that procedures should be in place to ensure that any conflicts of interest or partiality in research and ethics review are identified, disclosed and published.

Q13. 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?



Whilst councils and others are pleased to note the reference to social care throughout, one council asks is it worth having a paragraph added which acknowledges the distinction between health research and social care research, and acknowledges that they are often carried out in very different settings. They also note that much of what is listed here would often be done by the researcher themselves, not their employer (the local authority, presumably in the person of the researcher's line manager or head of service). If this is what we expect people to do, then there will need to be some hard work put into communicating the need for this to local authorities, many of whom do not even have a research governance lead officer, let alone any understanding of the different roles of researcher, funder and sponsor.

Other comments are as follows:

'The responsibilities are sensible with regards to professional and well-planned research. However, as noted previously, with the wide definition of research defined by the framework there may well be a group of people carrying out the research who do not operate within easily defined roles. In addition the level of knowledge and suitability necessary for work to be adequately undertaken can vary massively. Who will be responsible for ensuring that this is the case? This is particularly relevant with regards to Local Authorities in which research teams are likely to also be the research sponsors, and health and social care providers. While we agree with the statement that research staff should be able to 'demonstrate their suitability to conduct research', we know that a large quantity of research across Local Authorities is conducted by non-research staff such as commissioners or policy officers, who are acting simultaneously as sponsors, employers and researchers; often without any training in how to carry out Local Authorities in which research teams are likely to also be the research sponsors, and health and social care providers. While we agree with the statement that research staff should be able to 'demonstrate their suitability to conduct research', we know that a large quantity of research across Local Authorities is conducted by non-research

staff such as commissioners or policy officers, who are acting simultaneously as sponsors, employers and researchers; often without any training in how to carry out research. This is likely to be similar across the breadth of social care research, and in Local Authorities in particular, and is largely due to a lack of availability of specialist resource. In addition, if research teams and research leads are being called upon to demonstrate their suitability to conduct research, should guidance be issued around what the suitable level of qualification is in order to engage in different types of research activity (e.g. qualitative and quantitative) and the types of respondent engaged (e.g. vulnerable adults or children)? Although this guidance exists in professional bodies such as the MRS and BHBIA, in practice many of those undertaking 'research-like' activity detailed previously may not be aware of this.' (Kent County Council)

'Broadly, however the language and tone used in the research site section does not reflect the fact that social care research sites are often independent (private or voluntary sector) social care organisations (e.g. care homes) that have no statutory responsibilities relating to research and, while recognising the importance of research in the long term in improving outcomes, are often participating in the short term out of 'goodwill'. '(Skills for Care)

'We absolutely agree with KCL that this framework should include more of an emphasis on clarifying and strengthening local authorities' ability to respond to requests for research. At present, the system is very confused and disparate, and this slows down the progress of research projects considerably. Finally, we would like to have greater clarity on the role of the Association of Directors of Adult Social Services, in their ethical and oversight duties relating to social care research. As stated previously, consideration of the full range of research sites for health and social care (including voluntary and private sector provision) would be helpful, given the complexities of commissioner, provider, statutory and non-statutory services that may be of interest. For example, where services are commissioned by a Local Authority (or, indeed, Local Authorities) and provided by a third or private sector provider, which is the research site? We would wish to avoid the situation where organisations any of these organisations can avoid their responsibility to allow research to happen, or where it is the responsibility of the research team to resolve differences of opinion between commissioners and providers if both have to be sought. Any actions that could be taken to streamline processes between research sites, and reduce the administrative burden needed to conduct multi-site research would be beneficial to all. '(Centre for Research)

'As a Local Authority, under the current guidance we retain responsibility for a range of potential research sites. If this continues then the requirement to make information available about our capacity to and capability to support different types of research needs fleshing out. In the case of some health sites this may be feasible, but the range of potential research projects applicable across a multitude of locations for which we have some responsibility through commissioning (e.g. care homes) in Kent makes this unrealistic. If the intention is to remove this duty from Local Authorities and class (for example) care homes as individual sites, then they will all need to have their own governance arrangements in place – this is a massive and unrealistic burden for what are often small-scale private enterprises. In this case what is appropriate for them to demonstrate the location is suitable, or ensuring that favourable ethical approval is in place or that appropriate insurance and liabilities are in place? The movement of responsibility from Local Authorities to individual Care Home managers in such a manner is likely to result in a dramatic fall in the number of homes willing to engage with researchers. In addition to the above, if the devolution of health and social care budgets continues this could have significant implications on the complication inherent in such a system, removing authority from Local Authorities and placing them elsewhere.' (Local Authority)

There are references to Excess Treatment Costs in several places in the document, but they will not mean anything to those in social care. They need to be explained and perhaps should be set in a section which is clearly for health.

Because no explicit reference is made to Local Authorities, many respondents are under impression that the none of the responsibilities listed apply to them. There needs to be clarification of the roles that a local authority or council could take. Most councils no longer employ in-house researchers so it would be difficult to apply the responsibilities of employees to most Local Authorities.

Other points:

- The Framework should include reference to carers
- Research in social care is often conducted by independent research consultants and it is not clear how they would be accounted for under the proposed Framework.

Q14 – 23 – Responsibilities by role

Do you agree with the responsibilities for:	Yes	No	Undecided
Chief Investigators	69	15.5	15.5
Research Teams	77	13	10
Funders	82	9	9
Sponsors	59	3	10
Contract Research Organisations	79	1	20
Research Sites	72	12	16
Professional bodies	86	4	10
Regulators			
Employers	83	4	13
Health and Social Care providers	76	6	18

Q14. Chief Investigators

Key points raised by respondents included:

- 9.2.a – several respondents did not like the reference to scientifically sound and would like to see this changed to 'methodologically sound'.

- In early phase/ novel research, it may not be possible to establish that the research is safe or feasible; this is part of the process.(UKCRC) UKCRC CTU suggest the words 'the benefits are considered to outweigh the risks' rather than 'safe'.

- 9.2b AMS pointed out that it is not always feasible to obtain independent expert review for smaller projects such as undergraduate projects, and so the text should be amended or removed to reflect this. Others noted that 'independent expert review' should be defined in the glossary.

- 9.2b – It is important to distinguish between independent expert scientific review and ethical review (MRC and ESRC).

- 9.2 Cancer research UK stated that for non-commercial trials, some of the activities listed in this section, for example 9.2 and 9.5, are often carried out by Clinical Trials Units (CTUs). In its role as trial sponsor, CRUK's Centre for Drug Development (CDD) may also carry out some of these activities. They recommend that the wording of 9.2 is amended to reflect that, although ultimately responsible, the chief investigator will often work with the research team and sponsor to design, conduct, analyse and report a research study. Funders will review information about cost attribution, but it is the responsibility of the chief investigator to identify and attribute these costs. Section 9.2 should be amended to include a responsibility for chief investigators to 'identify and attribute the costs of the research study'.

- 9.2 b – Needs to be applied proportionately rather than across the Board. It was suggested that it is not always feasible to obtain a truly independent review for smaller projects (for example student projects) and a sensible approach is required

here.

- 9.2d – Several respondents noted that ensuring the competence of every research team at each site in a multi-site study is an onerous task for the CI and is better delegated to the PI. Should the responsibilities of the PI be spelt out under the Research Site section?

- 9.2f should be separated out into three distinct statements; one relating to registering the research, the second relating to making the findings available in a public arena, thirdly sharing individual level data and tissue.

- NIHR suggest rephrasing 9.2 h to set a clearer expectation that findings should be available to research participants as a matter of course. Using the term 'normally' instead of 'as appropriate' may be helpful here. Should be applied proportionately as may not be applicable to some types of research e.g. laboratory research.

- 9.3 Several respondents think that it would be better to place this section on students outside of the section outlining the responsibilities of chief investigators. Some of the responsibilities set out in the section refer to the student's supervisor who might not be the chief investigator. Cancer Research UK make the point that Footnote 28 is important to understand the type of students (and type of study – as would not apply to CTIMPs) this text refers to and should be included in the main text. There are other instances throughout this document where the main text would be clearer and benefit from the extra information supplied in the footnote (for example footnote number 21). The HRA should review this framework and move footnote text into the main text where possible. It is suggested that a section on students would sit better under the general principles section.

- 9.3 – section on students should make clear up front that this relates to undergraduates, Masters level and PhD level students. This is in the footnote below but needs to be included in the main text but because the sub-sections of 9.3 relate only to Masters and undergraduate students, it implies that this section does not encompass doctoral students. This was noted by several bodies including AMRC, Parkinson's UK, College of Occupational Therapists and NIHR as well as individuals.

- 9.4/9.5 – Similarly 9.4/9.5 which focuses on the research proposal or protocol is seen as a standalone piece which should not sit under CI responsibilities. In addition 9.4/9.5 was seen as a level of detail not appropriate for what is supposed to be a high level document.

- 9.3 – In relation to the section on student research, several respondents want further clarification as to what is an acceptable supervisor to student ratio.

- 9.5 it states 'they (newly approved documents) are introduced uniformly across all relevant sites.' A CTU writes *'For some of our large Phase III studies we have 95 site across the UK. In England there is the 35 day implementation, in the other nations there is not. Some Trusts approve document on Day 1 and other can take weeks. Therefore running large multi-centre trails becomes a challenge when every site is on different versions of documentation. Can the 35 day rule be applied to all?*'

Adverse events

Some respondents noted the responsibilities listed do not cover those ongoing for the duration of the study such as alerting, reporting and investigatory responsibilities including submitting annual and final reports to the REC. In particular several respondents would like to see a specific responsibility around the reporting of adverse events in both CTIMPs and non-CTIMPs. Specifically it is the role of the CI to establish the 'relatedness' of the event.

Finally some respondents including those in attendance at the consultation events noted the difference in terminology in the EU Clinical Trials Regulations and suggested that the Framework makes clear what is meant when they refer to a CI and explain how this differs to the EU Clinical Trials Regulation's definitions and the role of a principal investigator.

Q15. Research Teams

- As above, the role of the PI should be made more explicit.

- 9.7a – The level of information required here is seen as disproportionate and unfeasible especially the reference to 'including the summaries of systematic reviews of existing treatments' and in all likelihood would be beyond the comprehension of most participants and is seen as excessive and disproportionate by many respondents (AMS, NIHR, Marie Curie, BHF etc and individuals.).

  '*The assumption that greater amount of information delivered through PIS results in a greater understanding of research participant is invited to participate in is not necessarily correct and therefore there is a need to ponder over as to how the principle of proportionality could be satisfied in this context.' (Individual)*

  This requirement for this level of detail contradicts 9.8. This issue was also identified in the consultation workshops. Respondents felt that the results of systematic reviews should be a point of discussion with the funders, sponsors and the REC, not the participants. Respondents would like to see a proportionate approach taken to the amount of information placed in a PIS. For example, *'the PIS should be as concise and accessible as possible without compromising the accuracy or completeness of the information.'*(CTU)

- 9.7 onwards is not written as a responsibility (it is more like a principle). In addition research teams are multi-disciplinary, not just at site, and are not just concerned with the consent process so it is unclear why this specific detail is included in this section. (R&D Forum). Furthermore the content of the PIS is not the responsibility of the research team so some of the text in this section would be better placed elsewhere.

- 9.7c – could be re-worded to say ' Evidence of an appropriate and approved consent process is documented and available.

- 9.8 – there is a risk that this could be interpreted as meaning that in higher risk trials a high volume of documentation is required in the PIS when in fact the emphasis needs to be on how researchers can most effectively communicate the key issues to the potential participant and should not be dependent on length. This point was made by several respondents.

Q16. Funders

Para 9.9d attracted most comment with respondents pointing out that implies that funding is conditional on relevant approvals being in place and that this would inhibit various early activities which are often funded by early release of funding for pre-approval activity including patient and public involvement. Several funders are moving to this model and the text here needs to make it clear that this approach of releasing pre-approval funding is supported.

9.9a – Text should be amended to show that the funder should consider whether or not involving patients and the public in funding decision is appropriate. The AMRC stated in particular that

'We are particularly concerned that the requirement for involving patients, service users and the public effectively in funding decisions is seen as absolute in this framework (9.9a). Involvement happens in many ways. Some funders have patients/service users on panels, whilst others do not directly involve patients or the public in their funding decision making, although they will have research strategies that respond to the needs of people affected by the conditions they are interested in. It is for the funder to decide which is most appropriate for them, for both their funding call and the patient group. To mandate one particular method of involving patients in decision making does open up the potential for this to be a tokenistic gesture. We recommend patient and public involvement is encouraged where appropriate, and in a meaningful way.

- 9.9a Cancer Research UK suggest that this text is split into two parts as follows:
  i) Assessing (or arranging the assessment of) the scientific quality and, where appropriate, value for money of the research proposed
  ii) Involving patients, service users and the public, where appropriate and in a way that meaningfully informs funding decisions.

- 9.9b – This sentence is daunting and might not be understood by some small charities. In addition where an investigator-initiated trial (i.e. non-commercially sponsored trials) receives funds from a commercial company), the funder would not currently expect to review attribution of costs. This was noted by several respondents.

- 9.9c – should remove the word 'really'. The funder may not be well placed to make this judgement. Perhaps should be moved to the providers section. The AMRC noted that research applications do not usually name all the sites where a study will be based, so it is not possible for funders to assess whether or not the research is achievable in all settings

- 9.9d – Should this read 'appointment of a sponsor'?

- 9.9d – The R&D Forum recommend that this should include a reference to 'step-wise funding provision'.

- 9.9e – the requirement for CIs to make 'accurate findings, data, and tissue accessible, as appropriate' has significant implications of tissue banks and long standing datasets.

- It is not clear what the implications are for funders in the event of non-compliance.

Q17. Sponsors

Some respondents noted this section should have been given a higher profile in the document as they see it to be the key role.

Some key points:

- 9.10 we often sponsor studies where the CI is an honorary, not substantive, member of staff. The wording of the policy does not seem to preclude this but we wanted to draw this to your attention. 9.10 a. replace 'everything' with 'all which is necessary' 9.10 i. replace 'monitoring' with 'overseeing' but monitoring could be added as an example of a sponsor exercising oversight. Please note 'adverse event' again and give an example of 'other developments' which is otherwise vague.

- 9.10d The AMS noted that 'Ensuring that the research proposal or protocol is scientifically sound (e.g. through independent expert review, if appropriate) and that the investigators, research team and research sites are suitable' may be beyond the capabilities of university research offices and could create difficulties if there are multiple bodies with different perspectives scrutinising research in this way.

- 9.10 – Whilst the sponsor may be the employer of the Chief Investigator, as stated here; for multi-site clinical trials run through an academic Clinical Trials Unit (CTU), where the CTU is effectively managing the trial on behalf of the Chief Investigator, it may also be appropriate for the host institution of the CTU to accept the role of sponsor. We would welcome a caveat to clarify this. (UKCRC).

- Many of these responsibilities appear to duplicate the responsibilities of other actors in research, CIs, research teams, research sites and funders. This can create duplications and delay the process of research, without adding to the quality of scientific or ethics review. There are some roles that research employers need to take, in relation to HR and also the reputation of the organisations, but we urge the HRA to rethink and limit the scope of this role. If it is be continued largely as it, we think that, some of the responsibilities in 9.10 may be problematic for adult social care department sponsors. Local authority research and third sector research typically do not have a research support infrastructures equivalent to those available for NHS research or much university-based clinically related research.

- It should be noted that some CIs delegate some aspects of their roles to individuals who may not be competent to carry them out.

- Query burden placed on LAs who do not have the same R&D infrastructure as NHS?
- One respondent thinks that the supervisor should not take the role of CI where the student is distance learning.
- Need to stress proportionate approach by sponsors.
- There should be a clear message that Sponsors should show proportionate and pragmatic approach to training, for instance for clinical and support service staff undertaking activities no different to their normal role, indeed they are undertaking the activity as part of a normal.
- clinical service rather than research specific.
- Not clear who has responsibility for scientific review.

Q18. Contract Research Organisations

Interestingly no comments were made on this topic by industry bodies or CROs themselves. A number of respondents on behalf of social care made comments, assuming that this related to commercial companies delivering research under contract. It is not clear if that was the intention here.

9.13 Cancer research UK recommends a separate definition of CTUs in the Framework. CRO involvement in research is usually as a commercial service provision, whereas academic involvement is usually as an academic collaboration. CTUs managing trials on behalf of an external sponsor provide intellectual input into the design and analysis of the trials and expect research recognition as the main output; they are not service providers and as such it is not appropriate to identify or define academic clinical trials units as CROs. Other respondents supported this suggestion.

Q19. Research Sites

Several respondents commented on the negative overtones of this section; in particular the focus on research waste and the focus on the research site's role in this. It was also criticised for being overly secondary care focused. The wording was seen as less applicable to general practices or social care settings such as care homes. Do all these responsibilities really apply to general practices?

9.15 – The issue of liability of the approval body is questioned in relation to social care research where most research is not reviewed by an ethics committee managed by the HRA. Where research is approved by a university research ethics committee, is a Local Authority expected to accept that the University will be liable if there is a problem? Or does this section only apply to NHS sites? Under current arrangements, the context for a local authority is very different to that in the NHS.

9.15 is thought to be overlong and would benefit from breaking into separate paragraphs.

9.15 – need to consider the applicability of this section outside of England.

9.15 – There is a lack of clarity as to who the term 'approval body' applies to.

9.16. The R&D Forum recommend that the words 'poor information or processes at site' should be re-phrased. Good processes and information provision is important for all organisations and individuals involved in the research process and this is not exclusive to sites. 9.16 should include that research sites are responsible for confirming capability and capacity and together with the Sponsor confirming all arrangements are in place to start the research at site. Reference should be made to different sorts of site type such as PIC and shared care. (R&D Forum)

9.16 – Should also include that research sites are responsible for confirming capacity and capability.

9.16d – NIHR have suggested that this sentence should also make reference to patients, service users and public who might also form part of the research team. 9.16d is repetitive of 9.15.

9.16f – This section needs rewording for clarity. Comment from Efficient Trial Conduct Group – '*it is unclear whether this section refers to a 'research site' which is already participating in that particular trial or that the site is just 'research active'. It would be unfeasible to transfer a patient to a research site not participating in that trial and expect them to continue participation if it relied upon staff and services during their stay*.' Additional comment re: 9.16f from NPEU CTU, University of Oxford: '*We feel point 9.16 f within the policy document is required as it addresses the need and recognition for continuing care sites/shared care sites sharing responsibly. This is a particular issue within our Neonatal trials as approximately 50% of our recruited participants are transferred to different hospitals sites. Historically it has been difficult to engage or get approvals from these continuing care/shared care sites'.*

9.16g – Should be applicable to all sections, not just research sites. Maybe should be a general principle?

Finally it is not clear to what extent private providers delivering NHS services would be defined as a research site and would be able to accept the assurances of the approval bodies.

Q20. Professional bodies

The list of professional bodies excludes social worker professional bodies. It should be noted that the regulatory bodies for social workers in the rest of the UK are different. One council suggested that many researchers in a social care setting do not have a professional body and this concept is less relevant in social care research.

It is also unclear if this section also includes the Royal Colleges. It was felt that the Framework overlooks the important role played by Royal Colleges in setting standards. The Royal College of Paediatrics and Child Health suggest the text should be amended as follows:

'Professional bodies such as the General Dental Council, General Medical Council, Health and Care Professions Council, Nursing and Midwifery, Council General Pharmaceutical Council and Medical Royal Colleges are responsible for professional standards in healthcare and ensuring compliance with these standards. These bodies should (a) include basic research-specific skills in the competencies necessary during training (b) include research involvement as part of quality standards against which clinical services are measured.'

The Council for Allied Health professionals stated that *'The Health and Care Professions Council is a regulator rather than a professional body and covers compliance with professional standards as described in this section. Each of the 12 allied health professions has a separate professional body which is a membership body providing services to and campaigning on behalf of its members. Therefore this guidance should refer to the responsibilities of the professional regulatory bodies rather than professional bodies'.*

One researcher noted '*Professional bodies should include facilitation of research, e.g. making patients aware of research opportunities, as part of their professional guidance'.*

Q21. Regulators

The text currently describes the different regulators and their purposes, but not their responsibilities. This is at odds with all other sections describing the roles of different organisations and individuals involved in Health and Social Care Research. (Cancer Research UK). Others suggested responsibilities for regulators such as:

- a responsibility to avoid any delays in dealing with research proposals etc.
- an ongoing responsibility for ensuring standards of effectiveness as well as being able to help and support whistleblowers who may uncover wrongdoing.

It Is not clear whether regulators have powers to act against those not complying with the Policy Framework, if so this should be made clear (NIHR).

Should the list of regulators include DEFRA?

Q22. Employers

Comments received were as follows:

- There was some confusion as to whether the term 'employer' means 'substantive employer' or could it encompass employees with honorary contracts?
- There was suggestion that 9.19 a should be split into separate points.
- 9.19b was seen as too vague.
- There was a sense that 9.20 is too prescriptive as to the type of training required and is disproportionate especially for low risk research. For example the requirement for measurable learning outcomes might be regarded as burdensome. 9.20 is overly long and needs to be broken into bullet points.
- 9.20 – NIHR suggested that the word 'role' should be substituted with the word 'duties'.
- 9.20 – The MRC notes the this is an opportunity to explicitly *'dispel the widely held misconception that GCP training is required every 2 years. This could be facilitated by adding a footnote which outlines this specific example and also links to the HRA Training requirements for researchers – progress update.*
- 9.21 was seen as unnecessarily explanatory and should be more concise. 9.21 could be seen as conflicting with 9.20.
- Nuffield pointed out the role that employers have in allowing staff to attend as members of research ethics committees: *'We understand from health professionals and others engaged in research that difficulties are often encountered in convincing their employers that the time required to serve as a research ethics committee member is worth committing. â€¢ Our report therefore recommends that that the UK Departments of Health, NHS Employers, Universities UK and the Health Research Authority should jointly consider what steps they can take to protect the professional time needed for research ethics committees to work effectively.'*
- The reference to recognising existing experience and expertise, rather just giving training was appreciated but was not thought to be strong enough. It was suggested that the

Framework needs to explicitly make reference to the inappropriate use of ICH-GCP training especially where the research does not take the form of a CTIMP.

- It was suggested that it might be useful to make reference to training for academic supervisors and the need for them to be trained in approval processes.

- The Royall College of Anesthetists felt that there may some duplication in responsibilities between the employer and the sponsor.

- It was not clear to respondents how the principles for employers would be applied in a social care environment where the infrastructure for research is variable.

Q23. Health and Social Care Providers

The R&D Forum would like the issue of excess treatments to be identified much earlier in the process so conclude that it might be better if it is identified at the grant application stage and is covered under the CI/PI responsibilities.

The AMS welcomes the additional point in the new draft which outlines that health and social care providers are expected to be 'promoting opportunities to take part in health and social care research' , but go on to say that this should be highlighted more strongly and that all stakeholders such as researchers and research funders, not only providers, have a responsibility to do this, and that this expectation is outlined at the start of the document to underline its importance.

Cancer research UK stated that the responsibility excess treatment costs is distinct from that to promote research opportunities and 9.22 (b) should therefore be split into two parts.

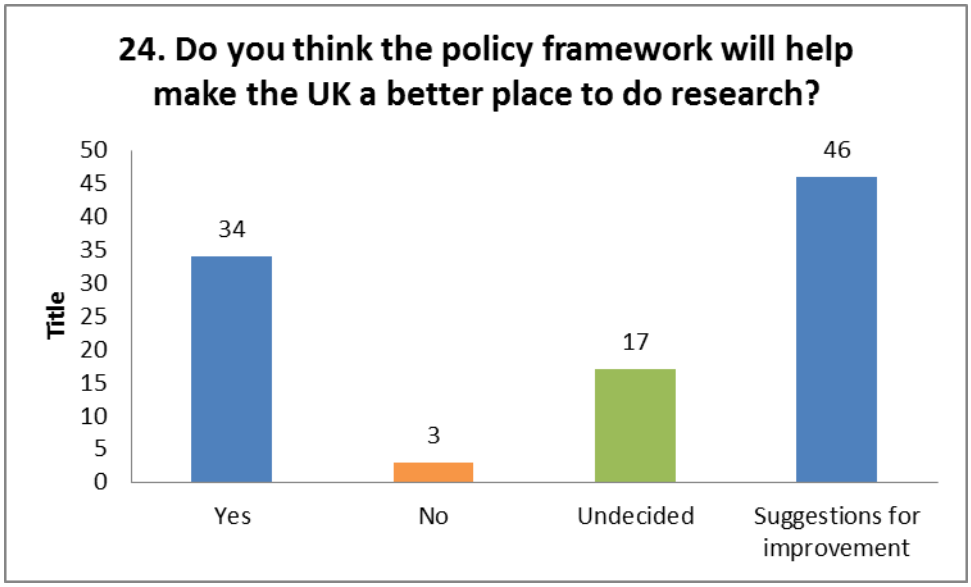
The responsibility for providing excess treatment costs should be shown separately to the responsibility to promote research opportunities. There should be a link to the guidance on Excess Treatment Costs.

There are references to Excess Treatment Costs in 9.22, but they will not mean anything to those in social care. They need to be explained and perhaps should be set in a section which is clearly for health. The phrase 'acknowledging the acceptance of excess treatment costs' could be seen as off-putting. Should there be a description of a social care equivalent: perhaps explaining the need to accept the extra costs involved in hosting research?

Providers may also choose to act as a sponsor where the CI is not one of their employees but this is not spelt out as an option in section 9.22.

Respondents would welcome some guidance on excess treatment costs in relation to public health research and local authorities.

Q24. 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?



There are a variety of bodies in the UK which possess great collective experience of, and expertise in, issues of good research practice and regularly share this with the research community through various means. To help the policy framework in its aim to help make the UK a better place to do research, it would seem sensible if highlighted the sources of help and advice available to researchers and research organisations, to help ensure that they meet its requirements, and also to patients and other participants in research. These sources of help might include relevant learned societies, professional bodies (already noted in 9.17 though with a different focus), the UK Research Integrity Office, the Association for Research Ethics and other advisory bodies on issues of research integrity, practice and ethics. (UKRIO)

We consider the harmonisation of the research framework across all UK nations to be an important positive step, and is likely to make it easier and more appealing to carry out research in the UK. (The Genetic Alliance)

'The old SCIE Research Register was a useful way of recording health and social care research completed in the UK. Could something like this be recreated? It would enable us to monitor research being done, and provide a quick and easy way to contact researchers (and perhaps some of their participants) to audit their experiences of conducting their research.' (Newcastle City Council)

Q25. Is there anything the policy framework should leave out?

Various comments were made but only one issue was suggested for omission and that was the reference to ICH-GCP. However some respondents might want the Framework to explain why ICH-GCP is not always appropriate.

Q26. 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? Please provide details:

The improvements in REC performance have been measured in terms of timelines and consistency; the same parameters should be applied to the Policy Framework. Other suggestions include a public consultation and a survey of stakeholders.

In addition the UK Research Integrity Office (UKRIO) has suggested that they could feed back to the HRA based on their interactions with researchers -anonymously and in confidence- about *'what we hear about what works well and what perhaps might need revision'*. UKRIO would be happy to work with the HRA in this fashion to support the implementation of the new policy framework.

Q27. 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)?

The scope of the Policy Framework includes:

- **research concerned with the protection and promotion of public health;**
- **research undertaken in or by a UK Health Department, its non-Departmental public bodies or the NHS and social care providers; and**
- **clinical and non-clinical research, research undertaken by NHS or social care staff using the resources of health and social care providers and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services.**

Some areas are currently excluded from this scope. For example, sports research, Phase trials in private units etc.

- There is ambiguity as to what is within scope under status quo.
- Many responses here address definition rather than scope.
- Some respondents are under the impression that public health is outside the remit.
- 'Phase 1 trials will continue to comply with the law – they should not be disadvantaged by introducing additional administrative burden above and beyond the lay'/Already heavily regulated and could encourage some industry to leave UK.
- No mention of NHS staff research and confusion as to where this lies.
- Is there an evaluation of the baseline to demonstrate what difference would be made by widening the scope? Would anything change?
- Concern over omission of children in social care research – request for joint working with DE to establish a RG system for children.
- Some suggestions that Universities and their RECs have a robust system and do not need any additional oversight/others note the disparity in standards.

The Executive Group (EG) of the NIHR School for Social Care Research (SSCR) made the following comments in relation to scope:

Our main area of concern with the draft is ensuring that the scope is well drawn from our perspective as both funders and providers of research in adult social care in England. We are not sure that the current definition of the scope adequately captures the (growing) complexities of adult social care in England and, hence, of what research ought to come under the remit of the policy framework.

The social care context we are concerned with is not well defined as 'social care providers' and not as easily drawn as 'the NHS' (where it is essentially care funded through statutory/NHS funds). Adult social care in England that is funded through the state is largely provided through independent (i.e. for-profit) and third sector organisations, with a fairly small amount being delivered directly by local authority services. Local authorities though, commission much of the care provision, either funding it themselves from council tax and other local resources, or on behalf of people who pay for their own services. Some purchasing of services is undertaken directly by those receiving the care and support from their own resources or from their personal budgets (i.e. local authority (statutory)-sourced money that is managed by the service user, or someone else on their behalf).

We believe that research on social care delivered in any sector and funded from any of the sources that we have described should definitely be included in the research policy framework. However, we also feel that the framework should be clearer about these organisational arrangements for adult social care to help people understand exactly what is in scope.

We are particularly concerned that self-funded social care should be within the scope of the research policy framework. People are using their own money to purchase social care (e.g. home care, personal assistants or places in care homes) but statutory services may have no part to play in the commissioning, provision or management. This is a fairly rapidly growing aspect of social care provision and, as such, one that is of increasing interest to policy-makers, research-funding bodies and researchers. Whilst state funding is not used to purchase these services, we suggest that the scope of the research policy framework ought to be drawn to include people who are self-funders for a number of reasons:

- *Under legislation (i.e. the Care Act 2014), local authorities retain some responsibilities for self-funders, including providing assessments, information and advice.*

- *When researching in some services and settings, e.g. communal areas of care homes, it may not be possible to draw a clear boundary between those who are state-funded and those who are self-funders.*

- *The Care Quality Commission has a regulatory responsibility for these services that may be self-funded.*

- *Some studies may be concerned with including both state- and self-funded users of adult social care, and it would be inappropriate to have one group included in the remit of this framework and not the other.*

- *Changes in national policy (e.g. in relation to eligibility) could mean that some people who are now self-funders would previously have been eligible for state-funded adult social care, or*

vice versa. Similarly, differences in local policy (e.g. in relation to prioritisation of care and support) could mean that one individual would receive state-funded support, whilst another individual with identical needs and assets and using identical services but living in another council area would be self-funded. It would be odd for one individual to be covered by the new UK policy framework for health and social care research, and the other to be excluded. Some self-funders of social care support will be vulnerable people and the additional safeguarding provided by their inclusion within the scope of this policy framework would be helpful.

We feel that the combination of these points suggests a need to ensure that the scope of the policy framework explicitly includes self funders of adult social care. We do not feel that this would add a huge extra burden to the system of research ethics and governance in the immediate future as there is not a lot of research in the area of self-funding. Over time, however, self-funding will surely attract more research attention.

Q28. Other comments

Compliance

A number of respondents wanted to know how compliance would be ensured and and what sanctions would apply in the event of non-compliance or breaches of the Framework.

> *The Health Foundation notes that compliance with the policy framework is critical to ensuring good practice in the management and conduct of health and social care research. Of concern, however, is the lack of detail in the policy document regarding the monitoring and measurement of compliance with the framework. It is unclear whether the HRA or others, such funders, are responsible for monitoring compliance, and who is responsible for initiating sanctions if breaches occur.*
>
> *Like many funding organisations, the Health Foundation has minimum standards of conduct included in its funding agreements, to which awardees are expected to adhere. Whilst the policy framework states that consideration will be given to actions or sanctions available to others (e.g. the funder), lines of precedence are not defined. It is also worth noting that the policy framework makes no mention of sanctions should funders or other organisations (e.g. employers) breach the minimum standards set out in the framework document.*

> *We believe a primary aim of the framework should be to streamline and simplify the research governance process by setting out expectations and ensuring compliance with these expectations. We would like to see these feature more prominently in the 'Principles' section – especially with reference to sections 9.8 and 9.16.* (ABPI)

> We strongly support the principles within the policy framework and the coordinated approach to harmonise and simplify the regulatory and governance processes for health research across the UK. We welcome the emphasis on research as a core function of health and social care, and that conducting research should be simple with quick decisions and where possible, minimal duplication of effort. (Academy of Medical Sciences)

> *We are concerned about the implementation of the framework, especially given that similar frameworks have been set up in the past with apparently limited success in terms of implementing more streamlined and efficient governance processes. The framework document states that, 'Individuals and organisations…are expected to adopt these operational provisions wherever relevant' (4.1). We would like to know what reporting and audit standards will be in place to ensure that this expectation is met.* (City University London)

Duplication of roles

Both the ABPI and the AMS believe that the Framework could do more to encourage organisations to work together to minimise duplication in research governance.

Promotion of research

Several respondents recommended that the Framework emphasises the the overriding responsibility of stakeholders , including all health providers, to promote research in the UK.

ICH-GCP

Para. 3.4 makes reference to a number of other sources but there is some contention as to whether the ones cited are the correct ones. The AMS suggest that instead the footnote could link to a HRA webpage on resources on good research practice which could encompass a much wider range of references than those listed in the footnote. In particular some respondents (in particular AMS, MRC and ESRC, Nuffield Department of Population Health) noted concern with the focus on ICH-GCP. It was noted that ICH-GCP is frequently applied inappropriately in non-clinical trials and is not always appropriate in non-commercial trials.

'We do not support any reference to ICH GCP (footnote 11), as there is significant evidence that this does not promote high-quality research and needlessly increases the complexity and costs of trials. It would be preferable if the Principles of GCP were mentioned, which are risk-based and more appropriate for research, including CTIMPs.' (MRC and ESRC)

'*We and others have drawn attention to fundamental problems with ICH-GCP, and although the ICH has acknowledged that its guidance requires revision*[1]*, it has failed to address the major issues in its recent update. The ICH-GCP guideline hampers rather than promotes high-quality research and needlessly increases both the complexity and cost of trials. Therefore, reference to it should be removed.'* (UKCRC CTU and Nuffield Department of Public Health)

Use of routine data

The AMS note that there is an absence of references to the routine use of health records for research. It is suggested that it might be helpful to map the role of key players here such as the HSCIC. This point was supported by NIHR. Other bodies, such as the MRC and ESRC, also called for the HRA to include a section dealing with researcher access to routine data across a range of organisations such as HSCIC, CPRD and Public Health England. It is important to acknowledge these issues in this context as research governance and information governance can be closely connected as both aim to ensure the appropriate use of data and that peoples personal data is protected but also need to ensure that valuable information is made use of to improve services.

Role of Principal Investigators (PI)

The document does not adequately refer to the role of the PI or define their role in relation to the CI.

Role of commissioners

Cancer Research UK and others think there should be a section outlining the responsibilities on commissioners, particularly CCGs, which includes their responsibility to communicate

their priorities. It should state a responsibility on NHS England to publish its research plan as supported by the mandate as well as a duty to pay excess treatment costs.

Transparency

The AMS would like to see the issue of data transparency given a greater profile throughout the document.

The first bullet point in section 1.1 refers to three different issues which would benefit from being separated out.

Alignment across the four nations

One pharmaceutical company expressed concern that, '*while intent of the research governance framework is to ensure that there is alignment across the whole of the UK, the operational processes within the four separate nations are actually diverging. Northern Ireland, Scotland and Wales have elected to continue with the current SSI forms and individual comprehensive governance host organisation review at a site level whilst England is moving to the new HRA process where governance review is done once centrally. This is clearly going to reduce efficiency for the whole UK.*

Furthermore, this means that industry will have to adopt differing processes for each nation which is time consuming and inefficient. It will also affect our competitiveness at a global level if other nations are able to offer a faster and more effective service.

This is exacerbated by diverging clinical research strategies amongst the four nations. The Scottish Chief Scientist Office (CSO) recently published Delivering Innovation through Research detailing the steps that CSO will take to improve the research environment in Scotland. In addition, the Accelerated Access Review is expected to publish its final report soon, which may have potential consequences for the clinical research environment in England. These developments suggest that there will be further divergence between England, Wales and Northern Ireland.'

Appendix 2: The Freedom of Information (Scotland) Act 2002 is missing; Section 45 of the Human Tissue Act 2004 applies to Scotland as well as the rest of the UK; and the Nursing and Midwifery Council (midwives) Rules Order of Council 2004 may be an appropriate addition.

Evaluation of the Policy framework

As above several respondents noted the absence of references as to how the implementation of the Framework might be evaluated and monitored. Cancer Research UK suggests equity of access could be an indicator of success:

Equity of access for patients looking to participate in research in the NHS. *Responses to the 2014 national cancer patient experience survey clearly demonstrate a willingness on the part of cancer patients to take part in research. However, while 86% of patients said they had seen information about research, only 31% of patients said that taking part in research had been discussed with them – 2% less than those surveyed in 2012. Perhaps most concerning, there was significant variation between Trusts: only 10% of patients in the lowest scoring Trust said that taking part in research had been discussed with them, compared to 61% in the highest scoring trust. Of those patients who were asked to take part in research, 63% went on to do so. Again, this proportion varied by Trust, with scores ranging from 33 – 80% (Cancer Research UK)*

Children in social care research

Several respondents noted that whilst they understood that children in social care research was outside the remit of England, that steps should be taken to request that this position is re-considered or that the HRA should work with those that are responsible for children in social care research to establish an equivalent research governance process.

Updates

Several respondents suggest that the framework should specify how the document will be reviewed and updated.

Some general points for consideration:

- Whilst they accept the need for a high level document, there is a need for detailed operation guidance to stop variation in interpretation and disproportionate approaches.
- Reference might also be made to the updated NHS Constitution,[2] which emphasises the importance of research in providing the highest quality care. (MRC and ESRC, Nuffield Department of Public Health)
- Need to consider the definition of research and what is not research, in particular around service evaluation.
- Need for cross-referencing between Policy Framework and underlying guidance.
- Need to address increase in integrated health and social care research in the future and how this will be handled.
- How will compliance with the Policy Framework be assessed?
- Could say more about big data and use of data.

Improved glossary

There were a number of suggestions for terms which needed including in the glossary. Some of these were as follows:

- Generalisability
- Transferability
- Audit
- Service evaluation
- Interventional research
- Excess treatment costs
- Educational research (lots of confusion here; it is not assumed to equate to student research)
- Provider to make clear that this encompasses both public sector and private providers
- CI/PI
- Transparency.

The glossary also needs to include a list of relevant Acronyms.

Next Steps

In addition to this call for comments, we also conducted a series of workshops[3] to debate the the detail of the Framework. The feedback from this exercise will be considered alongside the responses to the consultation in the revision of the document.