NHS R&D Forum Consultation Response

FINAL version 1, 24th March 2016

Draft UK Policy Framework for Health and Social Care Research

V2.5 Issued for Consultation 15/12/2015 by:

- Department of Health, Social Services & Public Safety
- Chief Scientist Office
- Welsh Government
- Health Research Authority.

Introduction and Method

- Four Forum working groups have reviewed and contributed to this response; they are the Service User and Carers Working Group, the Research Strategy Working Group, the Primary Care & Commissioning Working Group, and the Research Management Working Group, as well as members of the Forum Executive committee.
- Feedback was given at working group meetings, via dedicated teleconference and in individual email contributions.
- The Forum members who have contributed were pleased to note a number of recommendations made in our early comment http://www.rdforum.nhs.uk/content/wp-content/uploads/2015/06/ForumResponseHRAConsultation.pdf *(*May 2015*)* are included in this draft document, however also note that some of our recommendations have not been adopted and we therefore reiterate those we believe remain relevant. We also raise some new issues.
- In addition to this paper we also submit to you a completed survey response and the direct feedback written by the Forum Service User and Care working group. This is to strengthen the response of this group and to highlight the importance of PPI in research and good research management. We have included a summary of their key comments in our main response here also.
- As always the feedback below should be taken constructively to aid the development of a really meaningful policy document for all. In addition members would be happy to support the ongoing development and review of subsequent publications or debates as suggested below.

Executive Summary of Key Responses:

- The 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

- The document scope describes what research is, and the principles describe what is expected of health and care research in the UK; namely that it should be ethical, high-quality, safe, transparent, accessible and compliant with the UK legislative framework. It also goes some way to describe what this looks like by specifying what is required in principle (for example indemnity provision and clear documentation of roles etc.) However, we believe the principles for *individuals and organisations* would be better described as **roles and responsibilities** as they appear to be the more detailed tasks or areas of responsibility. These roles and responsibilities (starting with the sponsor) would ideally flow down from the top-line key principles (cross referenced to ultimately form a matrix). Any statements that are genuinely statements of principle should be included in the principles section instead. **NB:** we note from the survey questions that you have framed these are responsibilities but this is not clear in the current policy draft.

- The groups generally welcomed the clarity that research evaluations of complex services are clearly within scope of the policy. However it is not completely clear from the document whether all research within the policy scope were also *by extension* comes within scope of the HRA approval process and we suggest this is made much clearer (for example social care research is not currently part of HRA approval but is within the scope of the policy).

- The definition of research has changed in the new draft, with the addition of '*an attempt at generalizability and transferability*'. Whilst the groups generally welcome any move to make the definition of research much clearer there was some concern that this might confuse further the distinction between service evaluation and research evaluations, as many service evaluations and variations in practice have transferable lessons to share. Some members were keen to promote and support a completely new debate around the definition of research however in consideration of time, we suggest at least more careful thought should to be given in the policy to the definition as it stands and to the operationalisation and communication of the differences between research evaluations and local service evaluations in practice.

- We strongly believe that the role of the Sponsor should be articulated first in the list of individuals and organisations, as the Sponsor ultimately takes responsibility for

ensuring that the principles of the policy for research are met in a research study; they will need to have systems in place to do so, and will delegate roles and responsibilities onwards. We argue this here despite accepting that other organisations have roles and responsibilities in delivering the framework separate to those of the Sponsor (for example ethics committees, funders, employers and sites) but because it is ultimately the Sponsor who is *accountable for the research* and without this recognition we believe Sponsors will not receive due regard for their critical role in the process..

- The groups welcome the inclusion of PPI throughout the document but suggest that a section dedicated specifically to PPI would help to reiterate its importance and to make clear the policy intent that PPI should be part of the entire process, from concept through to dissemination.

- We have included some additional key principles that we believe might be either missing or that are currently documented in 'roles and responsibilities' (as we perceive them) and have suggested a general categorisation to enable cross-referencing in both the policy and subsequent documents.

Summary of responses to specific sections

1. Context

- The groups suggest that the context should promote first and foremost the roles of the HRA and the UK health departments, as UK organisations that aim explicitly to "***protect*** *and* ***promote*** *the interests of patients and the public in health and social care research'*[1] This would set the scene with regards to the remit of the HRA and UK Health departments in the UK health and social care research landscape and the ultimate purpose of the policy. This role is then delivered through core values in line with the NHS constitution, (namely to promote research and to create opportunity and participation), providing the background and context for the subsequent statements concerning a 'quality research culture' to which we recommend that you add, that 'leadership and good management in health and social care research is supported and valued'.

- Whilst we all strive to enable research we are not clear whether it is a helpful or even realistic to suggest that researchers should find it 'straightforward' to do research, as research is often a complex endeavour with multi-organisational partners and stakeholders for good reason. Therefore we advise a revision to this statement to show that the HRA and UK health departments are perhaps committed to an environment that supports and facilitates doing high quality, ethical research and for it to be *achievable*. Alternatively you might consider re-wording to mean where researchers find it straightforward to *apply* to do high-quality, ethical research in the UK.

[1] HRA website accessed March 22nd 2016

- We suggest the word '*and evaluated*' is added to the second bullet point in the context so that is reads "new treatments, care and other services are developed *and evaluated* through ethical and scientifically sound research…"

2. Purpose of document

- The purpose is much clearer in this version of the document. As it stands we believe a few additional principles should be included in order for it to truly *'set out the principles of good practice in research and research management'* upon which all research endeavor, (within scope of the policy), should be based. We have outlined these in the principles section below. To strengthen the purpose we further suggest that you consider amending 2.1 to read, "this *policy aims* to protect and promote…by setting out the core principles to which all health and social care research should (or is expected) to adhere. These principles describe ethical conduct…"etc. We also believe the purpose of the document is to make clear the high-level roles and responsibilities of key UK organisations and individuals, to ensure that the principles can be met.

3. Scope of document

- We suggest that the document would benefit from a shorter, clearer scope removing some sections as outlined below. We also suggest a revised order for your consideration as follows:

  a) Define research first (this is usually the starting point in most discussions with researchers i.e. is it actually research or not). Please see comments below on the definition of research.

  b) Explain the types of research that are within the scope of the Policy namely 'Health and social care research in a health and social care setting or that is concerned with the protection and promotion of public health' (currently 3.5 and 3.1) **NB:** the word *concerned* could be taken to mean it is the *topic* of the research (that could for example be conducted solely in an academic setting) and not research that is aiming to actually protect and promote public health?

  c) Set out that the research that is within the scope of the policy, as research for which the four UK Health departments have responsibility.

  d) Be clear whether all research within scope of the policy will require approval or not (for example social care research, which is not current in scope of HRA approval) as this is currently not clear and 3.3, introduces the concept of 'approval' for the first time. It might be worth explicitly stating that the scope also includes studies of healthy volunteers?

- 3.4 does not appear to be relevant to the scope and might be better placed within another (e.g. 'context') section or removed.

- The groups felt that 3.6 fell into responsibilities of individuals and organisations rather than the scope. Alternatively it might also be usefully placed within the 'context' section.

- As previously argued in our early comment we believe the scope might benefit from including a statement on who is mandated to follow the policy. Alternatively we suggest bringing the audience section forward to follow on from the scope (currently it is section 7) which then leads nicely onto implementation. These are critical sections that need early sight by the reader (i.e. does it apply to them and to their research). Many policies use "who should follow this policy…?" instead of 'audience', which might be a useful alternative title.

- The current scope still doesn't explicitly include Commissioning organisations e.g. CCGs. CCGs are involved in research through the contribution of data to research studies; through their staff as research participants (for example in health management research); they may also be involved in research through their own studies or studies they have commissioned. It is not clear therefore how CCGS should apply the current Policy and it is suggested that this is addressed or made clearer in the next draft so that CCGs are sure of their responsibilities when conducting, participating in or commissioning their own research.

- The groups generally welcome the attempt to improve the definition of research and to make clearer that research evaluations of complex services are within scope of the policy, (i.e. that evaluations of services can be research, and that service evaluations are not defined by their being an evaluation of a service per se). However the new definition does not help to distinguish between research evaluation and service evaluation, and there is a risk that including transferability may cause more confusion as it can be equally applied to evaluations of local variations in practice.

- Many local service evaluations, lessons learned from audit, and service improvements are regularly disseminated on websites, in journals, via social media and at conferences and as such might be considered to be generating new knowledge, answering a question through scientific method and an attempt at transferability.

- Some members of the groups have argued that distinguishing between the two evaluation types (research evaluation and service evaluation) might not matter so much for the purposes of the policy scope *if* the principles were to be adapted to type accordingly (i.e. all evaluation is within scope but not all of the principles need necessarily apply to each type of evaluation), and if we can be clear about the type of evaluation that falls into the scope of the *approvals* process. However if the distinction is to be drawn as an entry point for inclusion in the policy then there is an opportunity to make more explicit the differences between the two and further careful consideration is therefore required.

- NHS organisations are increasingly receiving Freedom of Information (FOI) requests for data and information for the purposes of research, which has by- passed usual approval processes for research. NHS organisations are obliged to provide information to the FOI requestor if it meets FOI requirements but this puts NHS organisations in a difficult position and is a loophole that seems to be increasingly utilised by researchers (to by pass the need for HRA approval), often from the University sector. A policy statement on this issue within the Framework would be very helpful for all parties. Forum members to aid debate in this matter can provide further examples.

4. Implementation

- This section is clear however it should still be acknowledged that systems might need to be developed (and these might be new not just existing procedures) by Sponsors in particular, in order to meet their legal responsibilities. Indeed we propose that ensuring operational procedures are in place is a principle that is perhaps missing from the current set. However it is good to note that these procedures should be proportionate to study type and reflect the policy and its principles at all times.

- We suggest you remove references to HARP as this is not understood or used by the wider community and may cause some confusion; the first sentence is enough to make the point.

5. Principles (*Sections 8 & 9 combined*)

- This section is the essence of the policy and it would be good to really ensure they are clearly highlighted in the final published version.

- Many similar documents number their principles, 'Principle 1, 2 3 etc' so that they can be further referenced in SOPS and subsequent documentation, which is worth considering here too. It is also helpful to provide a summary title for each principle so that the community can make easy reference to them. An example might be as follows, which we have attempted as a starter-for-ten, using the current principles in the draft:

    - **Principle 1:** Safe and Ethical Research (8.1) **NB:** We believe this should place greater emphasis on the concept that that research should be safe and this may be a separate principle or an additional statement to 8.1
    - **Principle 2:** Qualifications, Education & training (8.2)
    - **Principle 3:** Scientific and Ethical Conduct (8.3)
    - **Principle 4:** Patient, service user and public involvement (8.4)
    - **Principle 5:** Integrity, Quality & Transparency (8.5)
    - **Principle 6:** Protocol (8.6)

- **Principle 7:** Sponsorship & Chief Investigators* (8.7, please see note below about Sponsorship)
- **Principle 8:** UK Legal Framework (8.7)
- **Principle 9:** Risk Identification and benefit-risk assessment (8.8)
- **Principle 10:** Review by a REC and regulatory body/ies (8.9)
- **Principle 11:** Publically available research/Transparency (8.10)
- **Principle 12:** Accessible and understandable research information (8.11)
- **Principle 13:** Informed consent (8.12) (possible 9.7)
- **Principle 14:** Respect for Privacy (8.13)
- **Principle 15:** Indemnity and Insurance (8.14)
- **Principle 16:** Information, records and data management/ or Verifiable and reproducible research (8.15), (9.5)
- **Principle 17:** Compliance with the Policy (8.16)
- **Principle 18:** Justifiable new treatment
- **Principle 19:** Ongoing provision of treatment at the end of a study
- **Principle 20:** Information about treatment. Verifiable & transparent research
- **Principle 21:** Duty of Care

- **Missing Principles:**

  We believe the following principles (that are either completely new or currently specified under individual roles and responsibilities), should also be considered for inclusion.

  - **Principle 22**: Continuing review/ongoing benefit-risk assessment
  - **Principle 23:** (Proportionate) Quality Systems
  - **Principle 24:** Protocol Compliance (9.4)
  - **Principle 25:** Sponsorship*. That all health and care research should have a Sponsor (if this is indeed the policy)
  - **Principle 26:** Clear Roles and Responsibilities (currently 9.1)
  - **Principle 27:** Research Waste

- **General comments on the principles/responsibilities**

  - 8.1 We suggest that you add the *'dignity, right's*… safety and well-being of the research participant prevail over the interests of science and society. Greater emphasis should be placed on the fact that research should be as safety as possible balancing risk and benefit.

  - 8.6 We feel strongly that the term proposal should not be used interchangeably with protocol and we ask the question whether a proposal will be accepted as part of the HRA application process? We believe a protocol has a defined meaning that is fundamentally different to a proposal as it states what *must* be done and how the study *is* going to run. It will be published and deviations from or amendments too must be appropriately managed. The word proposal by its very nature suggests something that can be changed and although we accept this is common language for academic student work, when conducting research in health and social care they will still require a protocol which can be very easily based upon much of the content of an original proposal for funding, student study or otherwise.

  - 8.7 The researcher and sponsor *should* consider *and evidence* compliance with relevant legislation and guidance with respect to conducting and managing the research.

  - 8.9, please add that a project is *'only started at a site where capacity and capability has been confirmed by that site and the site and sponsor agree all is in place to begin'*

  - 8.10, please explain what is meant by normally? We feel this is rendered meaningless without a further steer on when studies should or shouldn't be made publically available.

  - 8.11 As above

  - 8.14 Indemnity. This principle is fine as a principle but we believe it is time to initiate further discussions to ensure that the NHS has full indemnity provision for its role in clinical research, for example as a Sponsor overseas or when signing non-disclosure agreements for research protocols to be released (for example).

  - 8.15 All information …*and data*? Appropriately stored…*and archived*? Archiving has a definition that is understood to be different to storage and so this could be reflected here.

  - 8.17b The groups suggest that this should also state that any continuation of treatment/care/services must follow prior agreement to fund that treatment of

service from the commissioners/funders (it would normally be the role of the Sponsor to ensure this agreement was in place in advance of the research beginning)

- 8.17d is quite difficult to read. We suggest the following amendment "A relevant health and social care professional retains responsibility for the treatment, care or other services given to patients and service users as research participants and for decisions about their treatment, care or other services… *outside the research*."

- 9.1 reads as a general principle and so we advise that Section 9: 'Principles that apply to individuals and organisations' is changed to '*Roles and Responsibilities of Individual and organisations'.* Each set of roles and responsibilities can be cross-referenced to a general principle to justifiy the expectation.

- As above we believe that the Sponsor should be specified first as overall accountable organisation for the research.

- 9.2. We advise that you avoid detail such as '*submitting* research protocols' and amend to 'ensuring that research protocols are submitted' as the Sponsor may decide that the Sponsor team is responsible for the actual submission and this would be stipulated in Sponsor SOPS. This is also likely to be true of 9f and so the wording should be written to demonstrate this flexibility. As the Sponsor can delegate many responsibilities and so you could add a role that is to '*adhere to the processes and procedures of the Sponsor and any delegated duties.*

- 9.3 also seems to fit better as a general principle, (perhaps Principle 7 as we have categorized above) 'Sponsor and Chief Investigator'. That students ought not to take on the role of Chief Investigator, (unless they are an experienced clinical practitioner) is a policy decision and a principle, not a role and so if you accept our suggestion that section 9 becomes roles and responsibilities then this detail can be moved. The role of the Chief Investigator and what they are responsible then for provides the reasoning for this policy decision. In addition some concern has been expressed from our Service User and Carers group about the appropriateness of this principle.

- 9.4, is a general principle and again we are not clear why it is only relevant Chief Investigators. This would fit nicely under a new principle that we have suggested, namely 'Protocol compliance'.

- 9.5 Good document management and version control is a general principle and not exclusive to the Chief Investigator or a role/responsibility. This fits well under Principle 16 above or you could divide this principle up to create two.

- 9.7a 'potential research participants should be provided normally by the research team, with the information they need to help them decide…including *summaries of systematic reviews of relevant existing research evidence'.* Whist the groups agree this is valuable information they had concerns about the practicalities of providing this information and whether it would be built into the patient information sheet process. Clarity of how this will work in practice would be welcome. 9.7a research teams should also be able to clearly explain alternative options.

- 9.7, 9.8, to note again that if you accept our suggestion to turn these into roles and responsibilities only that this section will need either re-wording (teams are responsible for ensuring 'a, b, c' information is provided) or including in the general principle (about consent (principle 13 above).

- 9.9d, it would be helpful to make this statement a little smarter to support a stepwise release of funding in support of early set-up prior to research approvals being in place. Subsequent funding can be conditional on approval but this statement suggests that funders should not issue funding until approvals are in place.

- 9.9e, it would be very helpful to note that model agreements should be promoted and used wherever possible.

- 9.10, we advise that you add an extra responsibility, which is to ensure adherence to the principles in this UK policy and to have proportionate systems processes and procedures in place for the design, initiation, management, conduct, reporting and archiving of the study.

- 9.10 (i), we suggest that you include the word 'oversight' and make reference to audit as well as monitoring procedures. If it is agreed that Sponsor organisations are *accountable* for the research then this might also be made explicit here.

- 9.16, we advise that the words 'poor information or processes *at site*', is not helpful as the whole system is hampered if there is poor information or processes in any of the respective organisations. This should either be broadened as a general principle (perhaps on research waste) or re-worded as an expectation/role to provide good, timely information.

- 9.16 should include 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.

- 9.20 Is also a general principle

- 9.22 Please note that providers may agree to Sponsor non-commercial studies where the Chief Investigator is not an employee (particularly in low risk studies) and although more usually they are employees the wording here should better reflect it is possible. The rest of the paragraph is also a little unclear and clarification would be welcomed "Health and social care providers may also provide services to research sites, such **as** identifying potential participants or *making information available for research elsewhere*".

- 9.22 b (page 18) the reference to excess treatment costs doesn't seem to fit here and appears to be an after thought or 'add-on'. We think this would be better as a separate bullet point in relation to health and social care providers' responsibilities in relation to excess treatment costs, which is such an important topic.

- As previously noted the policy might also consider the inclusion of broader confidentiality terms to cover commercially sensitive information *as well as* patient confidential information. Intellectual Property is no longer in the policy but was previously in the Research Governance Framework and it is unclear now how this fits. However if the Policy were able to make provision for enabling the protection of confidential information then better assurances might be provided to Sponsors and the need for onerous non-disclosure agreements might be avoided.

UK Policy Framework for Health and Social Care Research:

Consultation Questions & Forum Responses

1. Is the level of detail in the policy framework sufficient for it to be implemented? If not, how could this be improved?

- The document is high-level and as such operationalisation of the policy remains open to some interpretation and variation in practice. This variation may be reduced through issue of subsequent operational guidance or codes of conduct linked to the principles.
- The policy document could be improved by:
  (a) Clearly referencing the principles,
  (b) Linking the principles to a few key general roles and responsibilities for the main organisations and individuals in research, being mindful that this cannot be a truly exhaustive list
  (c) Starting with the Sponsor as the accountability body who will delegate responsibilities to other individuals and organisations accordingly,
  (d) Providing the structure and commitment for subsequent operational codes of conduct that will set out in more detail what is expected in order to deliver for different study types.

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

- Yes in general, although it could be explicitly stated as a principle. In some places the case for proportionality is over-simplified and does not take into account the full complexity of large multicentre, multidisciplinary research (see 1.1) therefore more emphasis could be placed on proportionality in relation to study type, rather than a general statement that all research should be 'straightforward'.

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?

- As this is a high-level policy document we don't believe it is able to truly address all the obstacles to good practice and management. However it can and does make clear the key principles for good practice (we have suggested some additions). It also can set out values and the expectations of the Four Nations regarding how research should be conducted; that it should be supported, and that is should be conducted with management practices that are proportionate (it should however be made clear what this approach should be proportionate to, (for example risk/scope of research question/impact of the research). It can also identify those principles that might in themselves remove barriers to a quality research culture.

- One significant barrier to good conduct is considered to be a lack of clarity on how best to *apply* the principles to all study types in practice, which can lead to variations across the country and confusion. Further codes of conduct or operational guidance might overcome this.
- Further clarity on the definition of research is needed in the policy to ensure the entry point to the policy scope and therefore the quality of research is not arbitrary. Please see our comments on the addition of transferability in our full response. Furthermore without this and some additional operational clarity that is adapted to study type, the policy might itself be considered to foster disproportionate practice for some projects (for example if all research needs a Sponsor, what do the Sponsorship responsibilities look like for all research types and what does the implementation of the principles mean in practice for small but transferable evaluations vs large, multi-centre studies)
- The expectation that training for some study roles and duties adapted to study type, would help to prevent sometimes onerous training requirements for research purposes from Sponsors, that might otherwise be reasonably served and evidenced through usual clinical training.

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

- We think they are generally right but they do require some revision. We have suggested some alternative wording and additional principles in our full response. We believe some of the principles for individuals and organisations are actually roles and responsibilities.

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

- Yes, they seem to be right.

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?

- Social care research is not currently within the scope of HRA approval and therefore being in scope of the policy does not necessarily mean in scope of the approval processes? This is currently unclear in the document.

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

- No. The responsibilities are written are not all exclusive to Chief Investigators and we believe some are more general principles. In addition the Sponsor may decide to retain some of the duties in the Sponsor office and so this should be considered in the wording of this section. Please see our full written response.

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

- In general terms yes but 9.7 onwards is not written as a responsibility (it is more like a principle). In addition research teams are muli-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. Again please refer to our full written response.

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

- Yes with additional reference to model agreements and an amendment to 9.9d in support of step-wise funding provision.

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

- Yes but with some additions and amendment however we strongly believe the responsibilities of the Sponsor should be made more prominent in the document, i.e. they should be first in the list of roles and responsibilities.

- The roles and responsibilities of the Sponsor throughout the lifecycle of the study are not adequately reflected and there is no reference to Sponsor oversight. This should be amended. Please refer to our full written response.

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

- Yes the responsibilities are reasonably clear for a contracted service with responsibilities and duties delegated from the Sponsor. However they should also have quality management systems in place proportionate to their role. Clarity of role, delegation, liability, SOPS, availability for audit, and oversight are critical. Subcontracted services might also be provided by organisations not traditionally referred to as CROs (for example laboratories, pharmacies or scanning facilities) for example, who should equally be supported with written agreements.

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

- Yes in principle however some of the wording in 9.16. and we advise 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. and o processes in any of the respective organisations.

- 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 for example.

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

- Yes they seem to be appropriate

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

- Yes they seem to be appropriate

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

- See appropriate, though lessons learnt should also be extended to Sponsors, the Chief Investigator and the research teams.

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

- Yes they seem to be appropriate although specific bullet point should be given to enabling excess treatment cost provision.
- Providers may agree to Sponsor non-commercial studies where the Chief Investigator is not an employee (particularly in low risk studies) and although more usually they are employees the wording here should better reflect it is possible.

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 policy sets out laudable expectations and principles of good practice. It sets an onus on employers and health and care organisations to support research, and helps them in doing so by making their roles clear. However the operationalisation of the policy could make the difference to whether the policy is helpful or not, and some of this detail is not yet clear. As we have suggested above, additional codes of conduct adapted (perhaps to study type) would be helpful.

- The policy decisions around the definition of research and what is in scope of the policy and the approvals processes are critical to ensuring that the generation of high quality, ethically obtained new knowledge in the UK is possible. We are not certain this has yet been achieved in this version of the document. Please see our written response for further details.

- Further explicit support for patient and participant involvement in all aspects of the research endeavour could be made.

- The inclusion of commercially sensitive confidential information in addition to patient confidential information.

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

- Not specifically although we have suggested ways that it could be re-structured to be smarter. We have found it to be confusing in places due to a mix of principles, roles and responsibilities, and some operational detail.

19. Do you have any suggestions about how to measure the policy framework's contribution to achievement of the ambitions set out in paragraph 1.1? Please provide details:

- Not at this point but we would be happy to take part in discussions.

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)?

- Ideally there would be consistency of approach and the argument for excluding certain studies from the policy should not *in principle* be based on any concern that it might be too onerous to include them, although we accept there will be pragmatic considerations to be taken into account from a systems and implementation point of view. However the policy is a principles document and therefore these principles should in theory either apply or not (using the argument, if it matters then it matters!). The subsequent systems put in place to implement the principles should then aim to be smart and adapt to ensure they are able to manage the different types/risks/and impacts, so that the first question might be whether the principles apply and the second question, 'how might that principle be delivered in a proportionate way?' (Being clear what is meant by proportionate to…risk for example?)

- Therefore any decision to include or exclude research in scope should be based upon consistent reasoning and robust moral decision-making. This is because the policy is based upon principle decisions and these principles should, in theory, either apply or not: they might apply because it is research or they might apply because it is a certain type of research. For example, if the principles are important for health research in a health care setting, the question might be asked 'do they apply because of the circumstances specific to that setting or do they actually apply to all health and care research because of their important contribution to new knowledge. This question might also be asked again for some of the service evaluations excluded from the current scope.

- Whilst accepting there may be negative practical and logistical reasons why research in certain settings should be excluded from the policy (because it would flood the system for example) we should be mindful that there may be an equally negative impact on the value of the policy if there is a seemingly arbitrary line drawn between them. This might also be true of some evaluations and therefore we argue that further discussion or at least clarity in the document is required on the definition of research.

- There is currently no mention of NHS staff undertaking research in non-NHS or social care sites.

21. Do you have any other comments?

- Please see all our written comments from the Forum working groups and also a separate documented provided by the Forum Service Use