UK policy framework for health and social care research:
call for comments

Please send your comments to policyframework@nhs.net by 1st May 2015. The HRA would find it particularly helpful to receive comments on the following issues:

1. Is there anything more the policy framework should say in order to meet the ambitions set out in the "Purpose" section?

X **Yes** ○ No ○ Undecided

Please provide details:

It should be specified in that the RGF Policy is compliant with the Principles of GCP and it should note that the points described there largely reflect the 13x Core Principles of (ICH) GCP, as GCP is the standard to which all involved in healthcare research should adhere.

A definition of health and social care research is desireable. This would clarify the types of research for which a Sponsor is required. There is no definitive statement, as in the existing RGF, about *when* a Sponsor is required.

Reference a Quality culture as essential to promote research.

Reference Universities – and other non NHS organisations - as employers, partners or Sponsors.

2. The policy framework will be implemented by operational arrangements that reflect and embed the principles it sets out (e.g. in England, guidance for HRA Approval, which will be made available later). Is the level of detail in the policy framework sufficient for it to be implemented? If not, how could this be rectified?

X **Yes** ○ No ○ Undecided

Please provide details:

The framework doesn't clearly state to whom it's applicable but focuses on the nature of the research. This should be set out eg applies to (but is not limited to) the public, healthcare research participants (patients and volunteers), research staff including students and their supervisors, research ethics committee members, research funders, research sponsors and health and community care professionals and organisations'.

Most of the Care Act 2014 (referenced at 5.2) deals with changes to social care in England and Wales but Part 3 Chapter 2 deals with setting up the HRA and this part does apply to Scotland and Northern Ireland also. However, as noted in 5.2 s111(6) and (7) of the Act require English local authorities and NHS Trusts to comply with the guidance etc issued by HRA. 5.2 goes on to refer to the guidance applying in Scotland "with agreement of Devolved Administrations" but doesn't explain how that agreement is effected and made binding on Scotland. This should be clarified.

There is nothing in the Care Act about powers of the HRA to impose sanctions - there should be a legislative basis. If standardisation is one of the aims then a reference to the policy which allows RECs to impose measures would be helpful.

There is a need to ensure close integration at the operational level between HRA and Scottish Government bodies, NHS Scotland and academic partners.

3. Are there any issues (e.g. obstacles to research) that the policy framework does not address? If so, what are they and how could they be addressed?

X Yes ○ No ○ Undecided

Please specify:

There is currently a gap for organisations who do not provide health or social care under contract with the NHS or with local authorities eg private opthamologists, private hospitals, private care homes. Such organisations should be encouraged to voluntary adhere to the RGF and to seek support via their local NHS R&D function where appropriate– as should partner Universities/HEI.

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

X **Yes** ○ No ○ Undecided

Please provide details:

It would be useful to align these more closely with the Principles of GCP – to avoid confusion.

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

X **Yes** ○ No ○ Undecided

Please provide details:

With the caveat that 'Information about the findings of the research should be provided to those who took part in it' where it is not onerous to the Sponsor or Funder and where it is practicable.

6. Do you think the policy framework adequately addresses the needs of social care research? If not, what needs to be covered?

Yes No Undecided

Please provide details:

Not relevant to Scotland. Insufficient information regarding community care.

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

X **Yes** No Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

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

Yes x **No** Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

Not appropriate to delegate responsibilities to a group of individuals. More effective and transparent to delegate responsibilities from the Sponsor to the CI and thereafter delegate specified responsibilities to members of the team, as appropriate.

9. Do you agree with responsibilities stated for funders?

X **Yes** No Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

10. Do you agree with responsibilities stated for sponsors?

X **Yes** ○ No ○ Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

Ensuring that mechanisms exist to protect the safety, rights and wellbeing of participants. Ensuring that a quality management system is in force.

11. Do you agree with responsibilities stated for research sites?

X **Yes** ○ No ○ Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

A system is required to allow Sites to review and/or appeal issues identified by Sites, in a streamlined manner eg access to study documentation through HARP or IRAS. It is crucial to maintain the authority of the local site to approve research locally or not.

12. Do you agree with responsibilities stated for professional bodies?

X **Yes** ○ No ○ Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

13. Do you agree with responsibilities stated for regulators?

X **Yes** ○ No ○ Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

14. Do you agree with responsibilities stated for employers?

X **Yes** No Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

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

X **Yes** No Undecided

Are there any responsibilities that you think should be added or removed? Please provide details:

16. Do you think the policy framework will help make the UK a better place to do research?

Yes x **No** Undecided

Please provide details:

The existing RGF is a more comprehensive document.

17. Is there anything more it could say in order to achieve this?

X **Yes** No Undecided

Please provide details:

It should recognise that healthcare research requires partnership across a variety of organisations – NHS, HEI, private and commercial.

18. 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:

Metrics for
the number of people participating in research – patients and volunteers in all healthcare research settings.
the number of organisations funding and/or sponsoring research.
the number of Boards/Trusts and other organisations actings as research Sites.
the length of time taken for all necessary approvals to be put in place.
the quantity and quality of outputs and impact on healthcare.

19. Do you have any other comments?

About you

Where are you based?

England Wales x **Scotland** Northern Ireland

Crown Dependency EU outside UK Outside EU Please specify:

What will we do with your response?

The HRA has a commitment to transparency. We will analyse the comments we receive, and publish a report on our website which summarises them and explains how we will address the themes raised. We will use the comments received to inform the next version of the policy document which will be sent out as part of a formal consultation later in the year.

Organisational responses: In the interest of transparency, all comments made on behalf of an organisation may normally be published and attributed unless an explanation is provided with your response as to why you consider the information should not be. (Please note the Confidentiality of Information section below.).

Individual responses: We will aim to summarise individual responses in such a way that does not identify individual respondents unless we have your permission to identify you.

If we receive comments without this form we will adopt the position that organisational responses are attributed and individual responses anonymised.

Are you responding in an organisational or personal capacity?

X Organisational

Individual

If you are replying in an organisational capacity, please note that your response may be published and quoted in the final report.

If you do not wish your organisational response, and any quotes used from it, to be identified in any report on this call for comments and any future HRA publications, or published once the comments period has ended, please explain why below:

Individual responses

I am responding primarily as a: Researcher/research team member Research support staff Member of the public Patient REC member HRA staff NHS/Social Care/HSC R&D management community Other NHS/Social Care/HSC staff Industry (mainly or only phase I) Industry (other) Regulatory body Academic Other Please write in below:
I am willing for my response, and any quotes used from it, to be made identifiable in the report on this call for comments and any future HRA publications.
I do not wish my response, or any quotes used from it, to be identified in the report on this call for comments, future HRA publications, or published once the comments period has ended.

All responses

X I am willing to be contacted by the HRA for further information in relation to this call for comments or future consultations.
If you have checked the box above please provide your contact details below. By providing these contact details, you are giving your consent for a member of HRA staff to contact you about calls for comments and consultations. The HRA takes data protection very seriously. We promise we will not pass your details on to any other organisations or use them for any other purposes.
Contact name: Catrina Forde
Email: c.forde@dundee.ac.uk

Confidentiality of information

The HRA will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties without your permission or unless required by law.

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the HRA.

UK Policy Framework for health and social care research: call for comments

General Points

1. Welcome an update to the RGF. This is a more concise document than the earlier versions but reads now more as a Guideline than a Standard and has less depth than the current RGF.
2. The drafters have clearly decided not to have a defintions section and haven't capitalised any of the terms but these additions would makes the document clearer to read.
3. The document alludes to 'health and social care' rather than the current 'health and community care. These are not equivalent.
4. A definition of health and social care research is desireable. This would clarify the types of research for which a Sponsor is required. No definitive statement as in existing RGF about *when* a Sponsor is required.

5. It should be specified in **1. Purpose** that the RGF Policy is compliant with the Principles of GCP and **in Section 7** should note that the points described there largely reflect the 13x Core Principles of (ICH) GCP, as GCP is the standard to which all involved in research should adhere.
6. It should be specified also that to be compliant with the RGF and with GCP that the research community requires to be compliant with statutory instruments.
7. As this is a UK wide RGF – as opposed to separate RGFs for each UK country – note the comprehensive table in the Appendix which maps out statutory obligations in each partner country.
8. The document extends the scope of what is research to general & transferable new knowledge (as opposed to generalisable) and has an statement of (some) exclusions from research in Section 2.2.
9. The emphasis on **Quality/Quality Management** which is embedded in the current RGF has been somewhat lost. I would like to see this re-emphasised in this current version. Specifically **Sponsor responsibility** re. mechanisms and arrangements to monitor, inspect, audit and risk manage are omitted which impacts on the pursuit of "high-quality research" (1.1, 1.3, 3.2, 8.4, 8.22). Note however that at 8.10b the Sponsor is tasked with 'competent project management and risk management'.
10. There is no reference to commercial outputs and the need to protect intellectual property.
11. The document makes no specific reference to Universities – or other non NHS organisations - as employers, partners or Sponsors.
12. There is a pressing need to ensure close integration at the operational level between HRA and Scottish Government bodies, NHS Scotland and academic partners.

Specific Points

1.Purpose

1.1 'care users and the public **are given, and take, the opportunity to participate in health and social care research**, and continue to feel safe when they do;'

Welcome the statement that individuals should be given this opportunity as there is no formal statement of this for the NHS in Scotland. It supports the principle of the patient/participant at the centre of research.

TASC (NHS Tayside-University of Dundee) has a Participant Experience programme to elicit feedback with a view to identifying possible improvements.

We prefer the term 'participants' rather than care users or subjects to reflect the fact that members of the public, patients or volunteers, are knowingly taking part in a study.

1.1 'researchers find it easy to do high-quality, ethical research;'
More appropriate to say 'researchers find it easy **to get approvals** to do high-quality, ethical research;

1.1 'applying to do research is simple and getting a decision is quick and predictable;'
Note that 'quick' is not always always better and predictable can imply automatic. Would prefer eg 'not time consuming and transparent'.

1.1 'industry sees the UK as a great place to do health research';
In what sense – some explanation would be useful. There is no reference to commercial partners, outputs and the need to identify IP. Note that there is reference to HRA resources at 3.1.

1.1 'commissioners and providers of health and social care appreciate how health and social care research benefits care users and staff **and the public**;
Add 'and the public'.

1.1 'money from charities and other research funders goes into carrying out research, not into **getting through unnecessary hoops** before it starts;

The inclusion of the phrase 'unnecessary hoops' is not appropriate. Governance should be proportionate and transparent but is essential to protect participants' rights, safety and well being.

1.2 'Research **should** improve the evidence base, removes uncertainties and can lead to improvements in future care, and the quality of current care….'

Add 'should' to emphasise the quality aspect and 'and change to 'Adopting research findings and being research active may also increase the quality of current care … '

1.1 'It also involves care users and the public …but also through their involvement in the design and conduct of research, or as members of research approval bodies such as research ethics committees **or patient/public engagement initiatives**'.
Add text as above as public engagement should be clearly encouraged.

2.Scope is defined by reference to both "care providers" and "care users" without being very clear if both care providers and care users need to be involved before the framework applies. Is it enough that the project is research by a "care provider" and then volunteers would be covered? Or does it have to be a "care provider" AND a "care user" before framework applies?

Footnote 2 on p1 excludes children's social care research but might be useful to refer readers to where this is covered (also footnote 11 on p5).

Typo in footnote on p2. Should be "care user" not "case user".

2.1 '…projects involving providers of care that are within the legislative and policy responsibility of any of the four UK Health Departments…'

There is currently a gap for organisations who do not provide health or social care under contract with the NHS or with local authorities eg private opthamologists, private hospitals, private care homes. Such organisations should be encouraged to voluntary adhere to the RGF and to seek support via their local NHS R&D function where appropriate– as should partner Universities.

2.1 'It also includes research involving the providers' employees or partners, either as research participants or as researchers.'

i) Whilst we welcome this inclusion it is unclear. Assume this is only relevant when employees are

involved in research and recruited because of their care provider role – as an NHS employer has a duty of care to its staff. Currently, for example, research involving NHS staff only does not require an NHS REC review and whilst staff may be NHS employees, they may be acting as volunteer participants in research.

ii) Partners should be more explicit to include, for example, Universities/HEI, private care providers or commercial partners.

2.1 'Relevant providers include hospitals that are part of the NHS, independent contractors to the NHS (such as GPs), local authorities **and private or voluntary organisations that provide health or social care under contract with the NHS or with local authorities**.
Amend to include 'universities or other institutes of higher education and commercial organisations'

2.2 'generalisable and/or transferrable'

This is very subjective and on the current algorithm http://www.hra-decisiontools.org.uk/research/
Question 3 'Are your findings going to be generalisable?' is not helpful.
Further Guidance and links to references are necessary eg UWE Research Observatory http://ro.uwe.ac.uk/RenderPages/RenderConstellation.aspx?Context=6&Area=1&Room=3&Constellation=58

2.2 'It also includes … projects whose primary purpose is educational to the researcher, either in acquiring research skills or in obtaining an educational qualification'

Where a project's primary purpose is educational to an (NHS) researcher and it does not involve patients, specifying that it should be managed as research within the NHS thus requiring approvals, appears onerous.

2.3 Excludes "involvement of care users or the public in the design, management or conduct of research" from requiring approvals but goes on to say that this can be covered by local controls. Firstly, the statement is a bit confusing as to what is meant by saying the public being involved in "conduct" of research and secondly rather at odds with itself as the framework tries elsewhere to limit local systems etc (3.1).

Add a Section 2.5 The policy doesn't clearly state to whom it's applicable but focuses on the nature of the research. For example ''The scope of the document applies to (but is not limited to) the public, healthcare research participants (patients and volunteers), research staff including students and their supervisors, research ethics committee members, research funders, research sponsors and health and community care professionals and organisations'.

3.Implementation

3.1 'Individuals and organisations with responsibilities under this policy framework should not design

their own process for implementing the principles it sets out'.

To avoid confusion, it should be noted that those organisations will require to have in place their own Quality Management System to ensure compliance with this RGF, GCP and other standards and regulation. This is alluded to at 8.23 which provides under "Employers" that "Systems should be in place not only to enable the identification of failures or breaches but also to place responsibility with the relevant party " which is potentially at odds with the statements about not making local procedures.

3.1 could be clearer. The webpages cited contain lists and list of links on various diverse topics which may not always cover the Scottish position and could be revised and updated without our knowledge so may be difficult to stay current.

3.2 'produces findings that improve the evidence base and may lead to better health and well-being.
Amend to 'produces findings that may improve the evidence base and may lead to better health and well- being.

4.UK-wide responsibilities

4.1 'The policy framework is consistent with recognised ethical standards and with models of good practice as they apply to particular types of research involving human participants'

Amend to 'The policy framework is consistent with recognised ethical standards, good clinical practice (GCP) and with models of good research practice as they apply to particular types of research involving human participants'

5. Development, status and maintenance

5.2 'This guidance **also applies to research involving relevant care providers in Wales, Scotland and Northern Ireland,** by agreement with the Devolved Administrations'

Most of the Care Act 2014 (referenced at 5.2) deals with changes to social care in England and Wales but Part 3 Chapter 2 deals with setting up the HRA and this part does apply to Scotland and Northern Ireland also. However, as noted in 5.2 s111(6) and (7) of the Act require English local authorities and NHS Trusts to comply with the guidance etc issued by HRA. 5.2 goes on to refer to the guidance applying in Scotland "with agreement of Devolved Administrations" but doesn't explain how that agreement is effected and made binding on Scotland. This should be clarified.

5.2 'In addition, bodies that hold a contract with the National Institute for Health Research (NIHR) are required to comply with this guidance as a condition of contract'.

As it is now a condition of contract to comply with the guidance for NIHR contractors, all research partners, including HEIs need to be aware of this condition.

6.Audience

6.1' This document is **aimed primarily at those with responsibilities for the conduct and management of research**, to help them fulfil their duties to care users and the public'.

It would be helpful if organisations with these responsibilities are specifed ie Sponsors and research Sites – both commercial and non-commercial and NHS and non-NHS.

Footnote 10. P5.

'Under the Medicines for Human Use (Clinical Trials) Regulations 2004, UKECA is the body that establishes, recognises and monitors research ethics committees and approves their operating procedures. UKECA's members are the HRA and the Devolved Administrations'.

As the EU Clinical Trial Regulation entered into force on 16 June 2014 and is expected 2016, this should be noted in the footnote.

7.6 '… in a research proposal or protocol, **conforming to a standard template where applicable'**.

I note the template protocols available on the HRA website. TASC have had template protocols, and other documents, in use for a number of years. I would not wish to see any HRA templates, including protocol templates, becoming mandatory as local templates provide the essential flexibility required.

7.7 'The researchers and sponsor should consider relevant guidance with respect to commencing and conducting the research project.

Amend to 'The researchers and sponsor should consider relevant guidance, including local, national and European (refer to the Appendix), with respect to commencing and conducting the research project'.

7.8 'A research project should be started and continued **only if the anticipated benefits justify the risks**.'

The nature of research is such that benefits cannot be known. Amend to ''A research project should be started and continued only if the anticipated benefits justify the risks and when a risk assessment has been conducted to minimise risk'.

7.10 'Information about research projects must be made publicly available, **normally before they start**, and their findings must be made **accessible after they have finished**.'

Information on studies which are eligibly funded or adopted onto the Portfolio will be publicly available on the UKCRN Portfolio Database, when approved. Where appropriate, protocols are published – refer for example to the TASC Policy on Publication. Many studies are published on public databases eg EudraCT, ISRCTN, clintrials.gov We note also that RECs publish research

summaries. However, not all studies have an appropriate vehicle for publication and many will not be published prior to start. Dissemination of results is strongly encouraged but it must be recognised that not all projects will find a suitable vehicle for publication in a public forum.

Amend to read
7.10 'Information about research projects and their findings should be made publicly available, as early as is possible and after they have finished.'

7.15 'Non-compliance with the principles or requirements set out in this policy framework may be subject to administrative measures available to research ethics committees or the HRA'.

Unclear what this means. Compliance to standards and policy is generally managed by Sponsor and non-compliance requires notification to the Sponsor.

What are the measures the HRA can impose. There is nothing in the Care Act about powers of the HRA to impose sanctions and I would have thought these should have some sort of legislative basis. If standardisation is one of the aims then a reference to the policy which allows RECs to impose measures would be helpful.

Note also that R&D Offices can also halt or stop studies where they are conducted outwith the terms of their local approval.

Footnote 12. P6.
'The terms 'research proposal' and 'protocol' are meant interchangeably'.

Proposal and protocol are different things. Proposal generally relates to a research plan, primarily written as part of a funding application. Protocol is the study document which specifies how the study will be conducted, in detail, and which requires all appropriate approvals.

7.16 d.'The duty of care owed to all care users continues to apply when they take part in research'.
Not just to 'care users'. To all participants in research so amend from 'care users' to 'participants'.

'7.16e 'Information about the findings of the research should be provided to those who took part in it'.
This is desireable but may be difficult where the project is a large population based study and/or where it has significant cost or resource implications.

8.Principles that apply to individuals and organisations

8.2e Chief Investigator '…ensuring that they and the research team they lead are qualified by education, training and experience to discharge their roles in the study;'
Welcome this change from a responsibility of the main funder in the current RGF.

8.3 ‘Students should not normally take the role of chief investigator at any level of study’.
Welcome this clarity. TASC has had this policy in place locally for some time.

8.5’. It is important to ensure that changes to the research proposal or protocol are submitted for review, if required, by a research ethics committee and any other relevant approval bodies …’

Whilst accurate this has the potential to be confusing. Amendments require to be specified as substantial or non-substantial and approved initially by Sponsor. They also need to be reviewed by R&D Offices. Also, non-substantial amendments do not require review per se by REC – but acknowledged by REC and other bodies.

8.6 Research teams

Not keen on certain obligations being placed on a research team as a group as this could easily lead to no-one taking responsibility. Better that obligations are assigned to the CI and then delegated.

8.7 ‘Where consent is required’
Not much detail on consent. Sets out certain requirements but little information on when consent is required or any reference to guidance on consent.

Funders at 8.9
How can obligations can be imposed on funders as legislation doesn’t reach through to them.

8.10 ‘The sponsor is normally expected to be the employer of the chief investigator’.
Welcome this clarity. TASC has had this policy in place locally for some time.

8.10a ‘The sponsor is responsible for ‘confirming that everything is ready for the research to begin;’
Recognising that the Site must have in place a process to assure the Sponsor that the Site is ready to commence.

8.11 There is an acknowledgement here that Sponsors of CTIMPS have “particular legal duties” but a clearer statement would be welcome.

8.12 ‘Universities and colleges should accept the role of sponsor for all educational research conducted by their own students …’

Welcome this clarity. TASC has had this policy in place locally for some time.

8.12 ‘Sponsors of educational research should ensure that their supervisors can and do carry out the activities involved in fulfilling this role’.

Welcome this clarity but recognise the potential impact on University Sponsors. A requirement for GCP training will be involved.

8.13 ‘A research culture should be fostered amongst undergraduate students…’
Agree. Requires discussion with the appropriate staff - particularly in University Medical, Nursing and Dental Schools.

8.14 For projects with no material ethical issues (see www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-proportionate-review-service), academic staff are expected to make a single ‘batch’ application for ethical review on behalf of a number of different students.
An interesting idea and one which will need discussion with the appropriate staff - particularly in University Medical, Nursing and Dental Schools.

8.15‘Undergraduate students leading individual research projects in isolation which involve direct contact with care users should normally be discouraged ….’
Requires discussion with the appropriate staff - particularly in University Medical, Nursing and Dental Schools. We would not with to instill a risk averse approach to student research and appropriate supervision minimises risk.

8.16 ‘Students from non-health related courses …. should be offered a co-supervisor with a relevant care-related background’
Agree. Requires discussion with the appropriate staff - particularly in University Medical, Nursing and Dental Schools.

8.18 ‘Research sites …. must not duplicate or repeat checks undertaken by research ethics committees or other approval bodies **such as the HRA, MHRA or HFEA’**.
i) This should also specify the Sponsor.
ii) Whilst recognising that duplication is unwelcome, local review of the study can identify errors in version control. Therefore a system is required to allow Sites to review and/or appeal issues identified by Sites, in a streamlined manner eg access to study documentation through HARP or IRAS. A good sponsor/CI/research team/REC are key to ensuring quality and confidence in the research and associated documents.
iii) It is crucial to maintain the authority of the local site to approve research locally or not.

iv) “Because it is reasonable for research sites to rely on checks carried out by these bodies, liability for any harm to a research participant that arose from failure to carry out those checks properly would shift from the site to the approval body.”

This can’t be viewed as a binding or legislative provision as this framework can’t change the law in this respect- more just an acknowledgement that the law might find the approval body liable in that situation if negligent. Same applies at 8.19d.

8.19 a ‘Research sites are expected to make information available about their capacity and capability …’
This highlights the increasing importance of the role of the research facilitator and feasibility process.

8.19d ‘Research sites are expected to accept reliable assurances from recognised authorities and each other and must not repeat checks that have already been carried out’**.**

Refer to points above in 8.18.

8.19d **'**This includes assurances about …the legal compliance of the proposed research project, the acceptability of contracts and costs …'

Confidence is required re. contracts, costings and budget attribution and the impact of different funding mechanisms across the UK. Particularly where studies have already commenced at other sites.

8.20 Professional bodies

Welcome this addition.

8.24 'It is important to encourage open and honest reporting' and '…a focus on improvement rather than blame'.

Welcome these comments. This fits well with the equality and diversity principles of the NHS - and other public sector organisations - acting as Sponsor who have a duty of care to healthy volunteers and patients participating in research. A culture of openness and honesty and learning from lessons learnt, a move away from a blame culture and a focus on continual improvement and learning is desireable. Note that in 8.23 it appropriately states that '… Systems should be in place not only to enable the identification of failures or breaches but also to place responsibility with the relevant party …'