Cancer Research UK’s comments on the draft UK Policy framework for health and social care research
May 2015

Cancer Research UK
Cancer Research UK is the world’s largest independent cancer charity dedicated to saving lives through research. We support research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses. In 2013/14, we spent £386 million on research in institutes, hospitals and universities across the UK – including the £35 million contribution we made to the Francis Crick Institute.

We are a leading funder of clinical research in the UK, supporting around 250 clinical studies. This includes early diagnosis, prevention and epidemiological research, as well as clinical trials of investigational medicinal products. In 2013/14, over 27,000 cancer patients were enrolled onto Cancer Research UK supported trials. Cancer Research UK’s Centre for Drug Development (CDD) is the largest specialist sponsor of oncology trials in the UK\(^1\). In addition to the CDD, we provide core funding for eight Clinical Trials Units (CTUs) across the UK. These are specialist research units that have expertise in coordinating clinical trials, including their design, management and data analysis; our CTUs work closely with NHS sponsors to achieve this.

Executive Summary
Cancer Research UK supports the development of a UK wide policy framework. In producing this guidance, the Health 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)\(^2\).

Overall, we think that this document is clear and 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. To further develop the framework and ensure that it can meet its stated ambitions, we recommend that:

- The HRA, NHS England, the National Institute for Health Research (NIHR) and devolved administrations should work together to refine this framework and the operational arrangements necessary to implement it.
- Where the status of the framework is non-legally binding guidance, the key elements should be captured in a legally binding way to promote accountability and compliance.
- The HRA should set out how it intends to review and update the framework. Working with the devolved nations, the HRA should also clarify how it intends to evaluate the framework on meeting its stated ambitions.
- The framework should emphasise the importance of promoting research in the NHS. The responsibility for health and social care providers and commissioners to promote research should be set out with a clear rationale.
- The framework should clearly describe the role of health and social care providers to ensure that care users are given the opportunity to participate in research.
- There should be a section to outline a set of responsibilities that are common to all those involved in health and social care research. These should include:

\(^1\) http://www.cancerresearchuk.org/funding-for-researchers/drug-discovery-and-development/how-we-develop-new-treatments
o Ensuring, where appropriate, that care users and the public are involved in the design, management and conduct of research; and
o championing the value of research in health and social care.

- The following responsibilities for funders should be removed:
  o Establishing value for money of the research;
  o ensuring costs to all parties are identified; and
  o assessing the priorities and constraints in health and social care where research will have an impact on care provision.
- The text outlining the role of regulators is not fit for purpose. This section should clearly outline their role and responsibilities, as the framework has done for all other organisations and individuals involved in health and social care research.

Implementation, status, maintenance and evaluation of the framework

Implementation
The high-level principles and responsibilities set out in this framework have been developed by the HRA and the three devolved administrations. **We welcome this approach and strongly recommend that this joint working is extended as far as possible when developing the operational arrangements through which these principles will be met.** In doing so, the HRA and devolved administrations will fulfill the responsibility placed on them in the Care Act 2014: to co-operate with each other to co-ordinate and standardise practice in the UK relating to the regulation of health and social care research.3

We are therefore strongly supportive of section 4.3, which outlines the importance of maintaining compatible standards for research ethics, conduct and management across the UK. Furthermore, this section states that the HRA, with agreement from the devolved administrations and the UK Ethics Committee Authority, may publish policy and operational frameworks that are UK-wide. **We recommend that the HRA looks to use this provision wherever possible.**

We note the absence of both the NIHR and NHS England from the UK Wide Steering Group that was established to develop this framework. **We recommend that representatives from both of these organisations are invited to join this group.** NHS England and the NIHR should also work closely with the HRA and devolved administrations to produce the operational frameworks.

Status
The guidance clearly sets out its legal status for NHS trusts and local authorities in England. However, the legal status of the document for other stakeholders, including those in the other countries of the UK, is not made clear. **Where the status of the document is non-legally binding guidance, the key elements should be captured in a legally binding way, such as contracts, to promote accountability and compliance.**

Maintenance and evaluation
The framework is clear that the HRA is responsible for maintaining this document. **We would like to see the HRA outline the frequency and process by which this framework will be reviewed and updated.** Working with the devolved nations, the HRA should also clarify how it intends to evaluate the framework on meeting its stated ambitions.

Meeting the ambitions set out in the ‘Purpose’ section

Promoting research in the NHS

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We are pleased to see that the framework outlines a responsibility for health and social care providers to promote research and highlights their legal duty to do so as described in the Health and Social Care Act 2012. We think this responsibility should sit alongside the rationale behind the importance of research in improving patient care and outcomes and recommend that paragraph 8.25 is extended accordingly.

Research is a means to drive excellence in a care setting both in terms of the quality of clinical care that is delivered while also producing evidence to improve the future care of patients. Research continues to be pivotal to developing our understanding of preventing, managing and curing disease. Underlying progress in all key areas, is an active and vibrant research culture in the NHS. It is important that all staff are aware that the promotion and conduct of research is a core NHS function, a principle that has been set out in successive NHS Outcomes Frameworks.

The framework should also include a section, to follow 8.25, which outlines the principles that apply to health care commissioners. This should include the legal duty for commissioners in England to promote research into matters relevant to the NHS.

These amendments would make the framework better placed to meet the ambition set out in 1.1: for commissioners and providers of health and social care to appreciate how health and social care research benefits care users and staff.

Giving care users and the public the opportunity to participate in health research
One of the core ambitions of the framework is for care users and the public to be given, and take, the opportunity to participate in health and social care research, and continue to feel safe when they do (1.1). However, as drafted, the framework does not outline who is responsible for ensuring this or how the service could be better set up so that more individuals are given the opportunity to participate.

We are concerned that there is inequitable access for patients looking to participate in research in the NHS. Responses to the 2013 national cancer patient experience survey clearly demonstrate a willingness on the part of cancer patients to take part in research. However, while 85% of patients said they had seen information about research, only 32% of patients said that taking part in research had been discussed with them. Furthermore, there was significant variation between Trusts ranging from just 11% of patients in the lowest scoring Trust having their involvement in research discussed with them, to 62% in the highest scoring Trust. Of those patients who were asked to take part in research, 64% went on to do so.

As there is a clear desire by patients to take part in research we believe that not having any opportunity to take part or even be asked about research is unacceptable.

We think that it should be the responsibility of the health and social care provider to ensure that patients are given the opportunity to participate in research. The framework should reflect this by amending section 8.25, which currently only states that providers ‘may identify potential participants for research sites’. This section should describe the role of providers to ensure that care users are given the opportunity to participate in research and should outline the importance of them doing so.

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Principles that apply to all health and social care research

We are broadly supportive of the principles outlined in this section (7.5-7.15) and have recommended some amendments to those where we have concerns below. As a general point, we would suggest this section is divided in 2 parts to separate the broad principles (7.1-7.5) from the more specific requirements around the conduct of the research (7.6-7.15).

7.10

*It is not clear from this principle what information should be made publically available before the start of the research.* To add clarity and to meet the ambition of the framework for research projects to get registered (1.1) we recommend that 7.10 is amended as follows:

> *Information about Research projects must be made publically available should, in most instances, be registered before they start, and their findings must be made available and accessible to the public after they have finished*  

Section 8.2 (g) and 8.10 (f) should also be amended based on this recommendation.

7.11

This principle should be amended to reflect a situation where a research participant is not competent to give consent, and this is instead provided by someone else who is empowered by law to do so.

It is important that there is a proportionate approach to patient information and consent, which is generally taken throughout the framework. We recommend that 7.11 is amended to be consistent with this approach and to reflect that participants’ *autonomy, choice* and *privacy* are not absolute rights.

7.13

It is our understanding that some research, for example some non-interventional health and social care research, will not require insurance or indemnity to cover any liability which may arise in relation to the design, management or conduct of the research project. Our grant conditions require host institutions (employers of staff in receipt of a CRUK grant) to hold appropriate policies of insurance covering personal indemnity, public liability, and employer’s liability. These should be maintained throughout the project and any commercialisation of the results. We would therefore suggest amending this principle to read:

> *Appropriate provision must be made for insurance or indemnity to cover any liability which may arise in relation to the design, management or conduct of the research project, or any commercialisation of the results*.

Principles that apply to interventional health and social care research

7.16

An additional principle should be included in this section to outline the requirement that interventional research should usually be registered before it commences.

7.16 (d)

*The wording of this principle does not reflect the involvement of patients in treatment decisions* and we suggest it is 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.
7.16 (e)
We support the inclusion of this principle. However, it is important to appreciate that feeding back the findings of research to those who took part is not always achievable or appropriate and some participants may not wish to receive this information. Furthermore, where this information is provided, for it to be of value to participants, it should be accessible to them. We recommend that the wording of 7.16(e) is amended as follows:

‘Information about the findings of the research should be provided to those who took part in it in an accessible format, where this is possible and where the participant wishes to receive it.’

Principles that apply to individuals and organisations

We welcome that the framework has outlined the roles and responsibilities of individuals and organisations involved in research. In addition to some specific amendments to these responsibilities as outlined below, we recommend that this part of the framework also has a section outlining a set of responsibilities that are common to all those involved in health and social care research. These should include:

- Ensuring, where appropriate, that care users and the public are involved in the design, management and conduct of research – in the framework, this is currently only described under the role of the chief investigator (8.4)
- Championing the value of research in health and social care – in the framework this is currently only a responsibility for research funders (8.9 (b))

Our rationale for these being described as common responsibilities is set out in our discussion of 8.4 and 8.9 below.

Chief investigators

For non-commercial trials, some of the activities listed in this section, for example 8.2 and 8.5, would be carried out by Clinical Trials Units (CTUs). Furthermore, CRUK’s Centre for Drug Development (CDD) will often carry out some of these activities in its role as a trial sponsor. We recommend that the wording of 8.1 is amended to outline that chief investigators may collaborate with CTUs and research sponsors on the design, set up, delivery and reporting of a study.

We welcome that the framework includes the principle that care users and the public should be involved, where appropriate in the design, management and conduct of research (7.4) and outlines the importance for doing so under the role of the chief investigator (8.4). However, there are other individuals and organisations that also involve care users and the public, including funders, research teams, sponsors and regulators and this should be acknowledged in the framework. As a funder, we involve patients and the public in many aspects of our work. This includes their involvement in our funding decisions, our strategic direction and the development of content for our CancerHelpUK cancer trials database, which contains trial summaries that are written primarily for a lay audience.

We recommend that the description of public involvement and its importance is removed from the section that describes the chief investigators role and is placed in a separate section that details responsibilities common to all individuals and organisations involved in health and social care research.

We would also welcome clarity over what is meant by ‘local controls’ that the involvement of care users and the public may be subject to (2.3).

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8 http://www.cancerresearchuk.org/funding-for-researchers/how-we-deliver-research/our-research-strategy
9 http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial
Research funders

8.9 (a)
There may be instances where the scientific quality of the research proposed is assessed by experts that sit outside of the funding organisation. We would therefore suggest amending this responsibility as follows:

‘assessing ensuring that the scientific quality of the research proposed has been appropriately assessed’

8.9 (b)

Although funders will review cost attribution, it is the chief investigator who is responsible for identifying and describing attribution. We therefore disagree with the draft framework’s requirement for funders to ensure that costs to all parties are identified. This requirement should be amended to read: [The funder is responsible for] ‘reviewing cost attribution’ and a new responsibility for chief investigators to ‘identify and describe the attribution of research costs’ should be inserted into 8.2.

‘Establishing value for money of the research as proposed’ should not be included as a requirement of funders within the policy framework. As an NIHR non-commercial partner\(^{10}\), we recognise our responsibility to ensure that our research is of value to the NHS. However, neither AcoRD\(^{11}\) nor the underlying guidance on responsibilities for meeting research costs (HSG (97)32)\(^ {12}\), refer to a requirement to establish value for money.

Value for money is likely to mean different things to different organisations and individuals involved in research, it is therefore important that this term is adequately defined. An assessment of value, if too narrow in its consideration, could jeopardise the funding of studies that might produce effective interventions and important knowledge in the long run. Furthermore, we are concerned that there is increasing pressure for funders’ research priorities to align to local commissioning goals. While not all clinical studies undertaken in a Trust will match local commissioning priorities, overall research will deliver the treatments of the future and patients welcome the opportunity to participate in research.\(^ {13}\)

‘championing the value of research to health and social care’ is a common responsibility and should either be inserted under the responsibilities of all those involved in research, or else removed from this section and inserted into a separate list of common responsibilities as suggested above.

8.9 (c)
It is right that funders assess the suitability of the research environment in which the research will be undertaken to determine that it is fit for purpose. However, the funder is not well placed to assess ‘the priorities and constraints in health and social care where research will have an impact on care provision’. This should be the responsibility of the research sites and health and social care providers. We would therefore recommend removing this wording and inserting this responsibility in 8.17 and 8.25.

Sponsor

The description of the sponsor is not reflective of the current sponsorship arrangements in place for many non-commercial trials in the UK. Trials run by CTUs are often sponsored by the host

\(^{10}\) http://www.crn.nihr.ac.uk/wp-content/uploads/About%20the%20CRN/Eligibility%20Criteria%20for%20NIHR%20CTUs%20Support.pdf


institution of the CTU, not the employer of the chief investigator. Furthermore, Cancer Research UK both sponsors and funds non-commercial trials through our Centre for Drug Development. We recommend the wording is amended as follows:

‘The Sponsor is normally expected to be the employer of the chief investigator, the host institution of a Clinical Trials Unit, or in the case of non-commercial research or the research funder in the case of commercial research.’

Research Sites

8.18
We strongly support this principle. Its inclusion in the framework is important to underpin the work that is currently underway to streamline the approval and set up of research, for example, the HRA Approval. The text explicitly states that approval bodies are liable for any harm to a research participant that arose from failure to carry out checks that they undertake. **We welcome this statement, which should give research sites the confidence necessary to ensure that they do not repeat or duplicate these checks.**

8.19 (d)
We seek clarity over what is meant by ‘inappropriate HR processes’.

Regulators

Section 8.21 should be revised to outline the responsibilities of regulators. As it stands, this 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. As an example, 8.18 describes the responsibility on Research Sites to rely on checks carried out by approval bodies such as the HRA, MHRA and HFEA. However, the responsibility on Regulators to carry out such checks is not described in section 8.18.

Health and social care providers

As explained above, we recommend that the responsibility on health and social care providers to promote research sits alongside the rationale behind the importance of research in improving patient care and outcomes. Paragraph 8.25 should be extended accordingly.

In addition, we would like to see this section include a responsibility on health and social care providers for opportunity costs. If research doesn’t go ahead due to costly or unnecessary delays through research governance processes, it is NHS providers that are responsible for the delay in the generation of scientific knowledge and accountable to patients who have to wait to be entered onto a clinical trial as a result.

Other suggested amendments

1.1
6th bullet:

“money from charities and other research funders goes into carrying out research, not into can be spent effectively and is not wasted on getting through unnecessary hoops before it starts during the set up and conduct of the research.”

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