UKCRC Registered CTUs Network Response

HRA Consultation UK Policy Framework for health and Social Care Research

The Clinical Trials Units of the UKCRC Registered CTUs Network welcome the steps which have been taken forward by the Health Research Authority in developing one compatible set of standards for NHS research across all four nations of the UK. The Policy has been well informed by a number of previous consultations and proposes, in general, a balanced set of principles for conducting high quality, ethical and transparent research within the NHS. It is encouraging to note the focus on ensuring the real risks of an individual research project inform its authorisation and management and a clear note to employing organisations of the important role staff development and training plays in supporting employees in understanding the purpose of their activity and therefore how best to apply legal and best practice standards. We are supportive of the principle that duplicate or repeat checks must not be undertaken by research sites and hope that the reassurance provided by the HRA in terms of liability will give rise to the envisaged efficiencies

Practical application of the Policy seems well supported by additional work-streams led by the HRA, for example the current consultation on a draft Protocol Template. Further work would be welcomed in the areas of:

- Informed consent, in particular with a review of the value, potential burden of and proportional approaches to written information currently provided to patients in interventional health and social care research;
- Recruitment strategies and developing / strengthening existing networks to facilitate cost effective patient recruiting into research;
- Continued development of a standardised approach for contracts with research sites;
- Guidance on carrying out research with vulnerable patients such as children and pregnant women;
- Appropriate independent oversight for all research types, not just clinical trials.

We feel the following comments, although referring to the situation for academic clinical trials units are applicable to many types of research and would recommend revisions of the principles.

Principles that apply to individuals and organisations

In practice the design, conduct and reporting of clinical trials is by a multidisciplinary team; a non-exhaustive list may include a Chief Investigator, academics, statisticians, trial and data managers and other research staff who can often be employed by different organisations. This document does not accurately reflect or describe the complexity that exists in practice for the design, conduct and reporting of many clinical trials and the key role of the clinical trials unit (CTU) in particular in

the academic community. In the non-commercial setting the sponsor, for example, may reasonably be an organisation such as the higher education institution of the CTU which carries substantial responsibility for the design, conduct and reporting of the trial.

There is a lack of detail in regard to the important role of independent oversight of research, where appropriate, for example the role of Trial Steering Committees and Data Monitoring and Ethics Committees in clinical trials. The role of the Sponsor (Section 8) should include a responsibility to ensure that the level of independent oversight is relevant to the type of project and risks it involves.

Principles that apply to all health and social care research

- The wording of Principle 7.8 suggests that all research anticipates some benefit for an individual research participant. This contradicts the equipoise required of randomised clinical trials and can never be said to be the case in certain trials such as those in the early phase setting and emergency care. Although benefits may result for an individual research participant a re-wording of this section is advised; we recommend a definition which takes into account the 'Ethical principles for medical research involving human subjects', as defined by the Declaration of Helsinki.
- The principles defined in Section 7 do not include principles for refusal to participate or withdrawal of consent and these should be added. We recommend in line with the Declaration of Helsinki.
- We support Principle 7.16e to provide findings from the research to those who took part, however this is not possible or appropriate in all cases e.g. individually to those who are deceased and their families or for very large trials where the costs for individual feedback may be prohibitively expensive; we suggest 'where appropriate' be added to this principle to cover such cases.
- We consider it a benefit to include care users and patient representatives in the reporting of research (Principle 7.4) and we would be supportive of any financial initiative to facilitate this.
- The researcher and sponsor must consider relevant laws, professional standards and other principles such as the Declaration of Helsinki.
- We would consider that 'provides greater confidence' describes one of the benefits of research rather than as currently described in Section 1.2 'removes uncertainties'.

In summary we are supportive of the policy framework, in particular in the introduction of standards that will apply across the UK and moves to reduce duplication in terms of research approvals. We would welcome recognition within the policy of the important role CTUs play in leading and facilitating research and

oversight from independent committees in ensuring the quality and integrity of the research. We appreciate that this is a high level policy document and that more detailed guidance will be provided through operational frameworks developed by the HRA and devolved nations. The UKCRC CTU Network would welcome the opportunity to contribute to the development of the operational frameworks as appropriate.