The UKCRC Registered CTUs via their Quality Assurance Working Group wish to comment on the consultation initiated by the HRA regarding research sponsor responsibilities.

We understand that concerns have been raised by organisations which host and regulate research about the extent and variability of sponsor oversight within sponsoring organisations in the UK. The HRA are considering a number of approaches to ensure that researchers and regulators have greater assurance that sponsoring organisations have the necessary systems and processes in place in order to support and promote high quality research, including:

* Publishing a set of expectations around sponsor responsibilities
* Requiring sponsoring organisations to make public a Declaration for Sponsors to demonstrate how those responsibilities are met within their organisation

Whilst we are broadly supportive of this work, we are mindful that the consultation does not make reference to the existence of UKCRC Registered Clinical Trials Units (CTU) and the benefits to researchers and regulators when research is managed by a Registered CTU on behalf of the sponsor and/or investigator. The UKCRC Registered CTUs are academic trials units based in Universities or NHS Organisations within the UK.

CTUs which have been awarded UKCRC Registration are able to provide specialist expertise in the coordination of clinical trials and other high quality research studies and have established robust systems to ensure conduct and delivery is to the highest quality standards. Many sponsors require that Chief Investigators collaborate with a Registered CTU (within their host institution or externally) on higher risk or multi-centre clinical trials. It is our opinion that some of the issues described in the consultation in terms of management of research could have been avoided with the involvement of a Registered CTU.

The HRA requires appropriate levels of assurance regarding the suitability of sponsorship arrangements for studies it reviews. We therefore propose that a specific question is included on the REC form to indicate how the research will be managed on behalf of the sponsor. We also propose that the Declaration for Sponsors enables sponsors to indicate where they may require that management of trials is via a Registered CTU.

We understand that the involvement of a Registered CTU may not be appropriate in all research scenarios but would like to promote the benefits of engagement, where relevant. We would be happy to further engage with the HRA on this or other scoping and consultation exercises to ensure that the role of trials units within the UK is fully considered and understood.