Quality Assurance (QA) Operational Group

Supplementary Terms of Reference and Priorities

General:

1. Through the QA representatives of each UKCRC Registered Unit, identify key challenges in the regulation, governance and conduct of CT research in the UK specifically relating to quality assurance issues and identify annual priorities and actions as a result (* key priorities below).
2. Through horizon scanning by the Core QA Group and all QA representatives identify key changes to and challenges in legislation and regulations impacting CT research in the UK and facilitate an appropriate response or other actions required through the QA representatives of each UKCRC Registered Unit. Specifically to respond to consultations on legislative and regulatory changes impacting CT research in the UK on behalf of the UKCRC Registered CTU Network, ensuring that all units have an opportunity to contribute.
3. Identify and develop relationships with other relevant organisations / groups in order to improve access to timely information regarding QA / regulatory and governance issues and sharing of best practice. Specifically: MHRA GCP Consultative Committee, CRUK Funded CTUs Governance Group, HRA. Following attendance at any meetings with these groups provide timely dissemination of information to all QA representatives.
4. Facilitate a process by which any CTU may request a key issue highlighted during inspection (such as spurious recommendations) in order to facilitate a consensus response from the UKCRC network of CTUs.
5. Continue to facilitate discussion and offering peer to peer support through the JISCMail list specifically to support general sharing of best practice.
6. Organise an annual face to face meeting of all QA representatives including setting an agenda and organising speakers, using the annual budget for the Sub-Committee. Key themes will be ‘sharing current practical methods of risk adaptation’ and ‘practical implementation of new CT Regulations’.
7. Develop links with the other Subcommittees to ensure that priorities are communicated and to minimise duplication of work.

* **Key priorities**

Likely task and finish groups:

- Identification of basic QC and QA standards for all Units (will include CTUs following Sponsor / 3rd party SOPs)
- Identification of QA standards for central laboratories
- Working with E-Records (eCRFs, RDC, eMedical notes, electronic archiving)

Likely theme at annual QA Representatives face to face meeting

- Practical implementation of new CT Regulations
- Sharing current practical methods of risk adaptation

Likely consultation and response collation via email

- On-going responses to known consultations on new CT Regulations and DPA Regulations.