Quality Assurance in HSRU

HSRU

Staff Handbook: The handbook, which had a thorough revamp last year is currently being reviewed and updated. A new version will be available Summer 2013.

The handbook is a reference document which outlines policies and procedures relevant to working practices within HSRU and, as such, should be consulted accordingly.

Security: Can all staff please remember that it is good practice to lock your computer when you are away from your desk by pressing Ctrl/Alt/Del and selecting ‘lock this computer’.

Staff training: The recent appraisals should have provided an opportunity for all staff to review their ‘Staff Development Manual’ (or equivalent) and ensure that their training logs, training certificates, CVs etc. are filed and up-to-date.

CHaRT specific

Trial paperwork: CHaRT have continued to develop their centralised resource repository of standardised trial paperwork templates (e.g. consent forms, trial master file checklists, case report forms etc.), all of which can be easily customised to each new study.

These templates are managed and version-controlled through Q-Pulse (QA specific software), ensuring an auditable approach to template upgrading.

Trial e-folders: The template for the electronic folder structure for CHaRT’s trials has recently been revised and updated to align with the Trial Master File (TMF) checklist. In addition the QA Manager, together with DIT, have recently reviewed and updated the permissions and access to the individual trial folders. These reviews ensure we maintain a secure and systematic approach to managing the day-to-day trial documentation and has proved to be highly advantageous during monitoring visits.

Monitoring

R&D initiation & monitoring visits: Within the last 6 months, five CHaRT trials have had either a (pre)study initiation or monitoring visit. The aim of these visits is to ensure we are complying with the approved protocol, and relevant regulatory requirements.

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If you have any questions, or are interested in finding out more about the topics above, please contact the QA manager.

Samantha’s Jargon Buster

CERB (College Ethics Review Board) … The remit of the CERB is to provide a review of ethical aspects of any research proposal for projects on human volunteers or human tissue samples carried out by University staff and students within the college which are not covered by another committee e.g. the National Research Ethics Service or the Psychology Ethics Committee. For further information, see their website:

http://www.abdn.ac.uk/clsm/services/cerb.php
General regulatory and QA update

The Research Governance team, who are all now based in the Research Governance Office in Foresterhill House Annexe

have a new generic email address, researchgovernance@abdn.ac.uk

All protocols, amendments and general research governance queries should now be directed to this new address which is checked during office hours.

NEW Health Research Authority (HRA) decision tool

The HRA has, with the help of the MRC Regulatory Support Centre, developed two new tools ‘Is it research?’ & ‘Do I need NHS REC review?’ to help researchers decide whether their project would be managed as research within the NHS and whether it needs ethical approval by an NHS Research Ethics Committee.

These web-based decision tools are valid for health and social care projects being conducted in the UK:
• www.hra-decisiontools.org.uk/research/
• www.hra-decisiontools.org.uk/ethics/

The Declaration of Helsinki Revision was first adopted in 1964 and next year will celebrate its 50th anniversary. During this time it has been amended six times, and the most recent revision, which was approved by the World Medical Association (WMA) is currently open for public consultation:
http://www.wma.net/en/40news/2013/2013_08/

A decision as to whether the revised Declaration will be adopted & published will be made by the WMA’s ethics committee and Council in October 2013 (publication likely 2014)

Take some QUALITY time out!

The following paragraphs have been taken from three different QA related documents. Firstly find the words to fill in the blanks, and then find the missing words in the word search. There are 13 words to find in all...Good luck!

UoA-NHSG-SOP (Sponsorship):

Before the UoA or NHSG will agree to act as .......... or co-sponsor the .... (or delegate) will undertake an initial .... of the study, including assessing and confirming the ............ arrangements (see Section 6.2), for the study.

HSRU Staff Handbook:

There are ............ for all Unit outputs and a list, and links to them, are given at the end of this section. A good example of a previous .......... is the 2011 Chief Scientist Review (split into 3 volumes). The documents are available in the ‘.........’ drive. If you cannot access the folder, please contact the Unit ................. who will arrange this for you.

IAHS Res Gov & QA Policy

The Institute strives to maintain the highest .......... research and financial standards in all its activities

...... practice can be built into any work activity no matter how .........., by subdividing the activity into .......... portions and by ensuring that, at each stage, the correct work practices are used at all times.

Please pass your answers to either Samantha or Janice by the end of June to have a chance of winning a quality prize.