Quality Assurance Manager - Samantha Wileman

Samantha joined the Unit in October 1997 as a research fellow working on the Seasonal Affective Disorder study. In 1999, Samantha joined the Health Care Assessment programme as the trial co-ordinator on the REFLUX trial before accepting the position of Quality Assurance manager in January 2007. Since starting in this new position, Samantha has been busy developing links with other Quality Assurance Managers from the oil & gas industry, the Rowett Institute and the Clinical Trials Unit in Leeds amongst others. She has also been liaising with the IAHS Research Governance & Quality Assurance Committee and the Grampian NHS R&D Department.

Samantha is currently working with others on the development of a staff training manual, a new version of the HSRU staff handbook and a new set of SOPs.

Contact details: Samantha is in the office on Thursdays and Fridays.
Health Services Research Unit, University of Aberdeen, Health Sciences Building, Foresterhill, Aberdeen AB25 2ZD;
Telephone: 01224 554196; Email: hsruqa@abdn.ac.uk; Web address to be confirmed.

Message from the Director

During the past five years, there has been a striking change in the environment in which research is conducted. In light of this, the role of Quality Assurance Manager was created within HSRU (including CHaRT) to meet the wide range of legal, ethical, regulatory and governance requirements that are now required. In addition, I see this role as an important one for developing robust HSRU specific quality assurance systems and integrating them into our current best working practices. We look forward, as a unit, to improving on the already high-standard and quality of work delivered by all of HSRU’s activities.

Marion

What is Quality Assurance?

Quality Assurance (QA) is defined as all those planned and systematic actions that are established to ensure that the work we perform and the data generated, documented (recorded), and reported is in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

What is the HRSU Quality Assurance Policy?

“To find, promote and integrate the best working practices into HSRU to assure quality in the delivery of all our research.”

What are the HSRU QA objectives?

- Ensure quality is demonstrated throughout the delivery of all HSRU activities.
- Implement in-house quality assurance systems.
- Develop, implement and manage a new HSRU specific Standard Operating Procedures (SOP) system.
- Provide advice and reporting upon compliance within the Research Governance Framework.

In addition, we are required to adhere to the IAHS research governance and QA policy and ALL staff are expected/required to have read the relevant policy document which can be found at the following website:

http://www.abdn.ac.uk/iahs/docs/research-governance-and-quality-assurance-policy.doc
**Quality Assurance update**

**HSRU specific**

**Staff handbook**
The staff handbook is currently being revised and a new user-friendly version will be accessible online within the next 6 months. We will keep you updated as to its progress.

**Staff development manual**
As a way of easily demonstrating the training experience we all have, it is important to maintain a record of our staff development for the annual staff appraisal system and future HSRU accreditations/monitoring visits. A draft manual will shortly be piloted within the Unit before being rolled out to everyone.

**SOP (Standard Operating Procedures)**
A new set of SOPs are being prepared and drafted by various members of HSRU and it may be that you will be asked to assist or comment on them. Your help with these is of great importance as it is fundamental that we have a detailed set of up-to-date instructions that uniformly reflect the work that we perform within HSRU.

**UKCRC (UK Clinical Research Collaboration) Accreditation of CHaRT**
CHaRT is applying for accreditation by the UKCRC this year. The application is currently being drafted and will be submitted for 1 June 2007. This is of critical importance for the continued ability of CHaRT to deliver high quality trials of important health care issues and questions.

**MAGI (Monitoring & Audit Group, IAHS) visit**
MAGI have scheduled an audit visit to HSRU on 12 June 2007. Besides looking at generic HSRU procedures (training, staff handbook etc), they will also monitor two HSRU projects (these are yet to be selected).

**Other**

**Research Governance Framework Sponsorship:** Please note that as of April 2007 the procedures for confirmation of Sponsorship of projects have been amended. The relevant forms are available from Research & Innovation at: [http://www.abdn.ac.uk/r&i/support/sponsorship.shtml](http://www.abdn.ac.uk/r&i/support/sponsorship.shtml).

**Research Ethics:** On 1 April 2007 the National Research Ethics Service (NRES) incorporated the Central Office for Research Ethics Committees (COREC) and NHS Research Ethics Committees (RECs) in England. Please see [http://www.nres.npsa.nhs.uk/recs/index.htm](http://www.nres.npsa.nhs.uk/recs/index.htm) for further details.

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**Useful information and links**

**IAHS research governance and quality assurance**

**Clinical Trials Tool Kit**
[www.ct-toolkit.ac.uk](http://www.ct-toolkit.ac.uk)

It is planned that future newsletters will be accessed on the S: drive with live links to the above websites.

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**Quality Assurance Message board**

Samantha has recently acquired copies of pocket guides to:

**EU directive**

**ICH Guidelines**

**SOP checklist**

**Archiving**

**Monitoring**

……should you want to find out more about these topics.

If you have any questions, news or other information that you would like included in future editions of this newsletter, please contact either Samantha Wileman or Janice Cruden.

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**TAKE SOME QUALITY TIME!!**

Your response will be monitored for quality assurance!

Quality Assurance

IAHS

Inspection

Regulatory

Governance

Training

GCP

SOP

(Monitoring (Raising!)) Standards

Documentation

Please return to Janice for your chance of winning a ‘quality’ prize!