

R&D Bulletin

NIHR Cambridge Biomedical Research Centre
Research and Development Department

April 2011



GCP TUTOR LED TRAINING - HALF DAY AND REFRESHER COURSES

We now offer a two hour GCP refresher course. The course is aimed at those who are coming up to the **end of their two year** renewal period. Anyone who is over the two year period will be required to undertake the half day session or the online course.

Refresher dates: Monday 13 June09.00-11.00 Alice Fisher Lecture Theatre
Tuesday 14 June13.00-15.00 Alice Fisher Lecture Theatre
Monday 5 September09.00-11.00 Seminar Room 8 Clinical School
Monday 5 September14.00-16.00 Seminar Room 8 Clinical School
Monday 28 November13.00-15.00 Seminar Room 3 Clinical School

Half day dates: Tuesday 14 June08.30-12.30 Alice Fisher Lecture Theatre
Tuesday 6 September08.30-12.30 Seminar Room 3 Clinical School
Monday 28 November08.30-12.30 Seminar Room 3 Clinical School
Tuesday 29 November08.30-12.30 Seminar Room 2 Clinical School

**For further details on either course or to book a place
please contact Sylvie Robinson.**

BRC LECTURE SERIES

We have the following dates confirmed for the next lecture series:

8 June 2011 Women's Health
20 Sept 2011 Cardiovascular
29 Sept 2011 Musculoskeletal
13 Oct 2011 Imaging
16 Nov 2011 Transplant

The lectures will be held at the CRUK CRI Lecture Theatre at 5.00 pm, they are open to everyone and there is no need to pre-book a place.

Further details will be announced closer to these dates.

NEWS FROM THE R&D HR OFFICE

New enquiry mailbox

Researchers with enquiries relating to the **Research Passport system, Honorary Research Contracts and Letters of Access** can now contact a dedicated mailbox entitled research.passport@addenbrookes.nhs.uk

Changes in the administration of Honorary Research Contracts (HRCs)

1. Introduction of a signature page

An HRC will now be issued with a standard covering letter giving clear instructions for signing and distribution. The contract has a new front page setting out the duration of the Agreement and the signatures required. This page is separate from the terms of the contract and, once signed by all parties, two copies must be taken: the researcher keeps one and should return the other copy to the HR office for the signature of the R&D Manager. This is required for monitoring purposes.

2. Occupational Health clearance

Unless a researcher will be dealing with exposure prone procedures (EPPs) or will be handling tissues/organs in NHS laboratories, it is not necessary to have occupational health clearance.

3. Induction

All researchers should receive a local induction when they join a study/project team. If a researcher will be at Addenbrooke's for over three months it is essential that they attend a corporate induction which may be booked through the Learning & Development department on hrlarningcentral@addenbrookes.nhs.uk or ext. 4488.

Confirmation that the researcher has completed both local and corporate induction should be done via a P6 form. This should be sent directly to the Trust's Workforce Information department at Box 240.

Staffing of the HR office

Val Sparks, HR Manager

Monday, Tuesday and Thursday: 8.45 – 17.15

Friday: 8.45 – 15.00

Debbie Richards, HR Advisor

Monday: 8.30 – 12.30

Tuesday: 8.30 – 14.30

Wednesday: 8.30 – 17.30

Thursday and Friday: 8.30 – 14.30

Note: Researchers with research passports (RP) completed to section 6 may either post their RP and original documents to the R&D HR office or email/telephone to make an appointment to bring them in person.

CHANGE TO CAMBRIDGE RECs

The Research Ethics Committees in the Cambridge region have been renamed. Previously there were 4 committees in the local area however the new structure is now:

East of England – Cambridge Central (previously Cambridgeshire 2 REC)

East of England – Cambridge East (previously Cambridgeshire 1 REC)

East of England – Cambridge South (previously Cambridgeshire 4 REC)

Essex 1 and 2 RECs have merged and are now known as Essex REC. Cambridgeshire 3 REC no longer exists. Full details can be found at www.nres.npsa.nhs.uk/contacts/find-your-local-rec

STANDARD OPERATING PROCEDURES AND POLICIES AND PROCEDURES

Please ensure that you have read and are aware of the SOPs and P+Ps that have been written by the R&D Office that apply to all researchers.

We have recently updated a few of these documents so if you have them printed anywhere, please check back to our website to ensure you are using the most recent version.

www.cuh.org.uk/research/researchers/document_library.html

STUDY STATISTICS

For the Q4 period (December 10 – March 11), the department received **105** new applications, and **85** studies were issued with NHS permission.

CPFT R&D DEPARTMENT

The CPFT R&D Department is now based within the Addenbrooke's R&D office on S4.

Rachel Kyd (R&D Officer for portfolio studies) and Nicola Holloway (Administrator) work for both Addenbrooke's and CPFT.

Natercia Godinho has now left CPFT and the department is currently being restructured in order to cover her duties.

If you have a non-portfolio study that requires NHS permission from CPFT, please contact the department for guidance.

IMP Definition

In view of existing legal uncertainties relating to the definition of investigational medicinal products (IMPs), and products and non-IMPs which are nonetheless intended for research and development trials, the European Commission has made the following proposals:

- Narrow the definition of IMP to become: 'A medicinal product which falls within the definition of Article 3(3) of Directive 2001/83/EC, and which is being tested or used as reference in a clinical trial'.
- Introducing the notion of an 'auxilliary medicinal product' which covers all other medicinal products used in the context of a clinical trial and could be subjected to a proportionate regulatory regime separate from IMPs.

We will provide further details as and when they are known regarding the implications of this proposed change.

STAFF CHANGES

There have been further changes since our last bulletin.

- Nirvana Croft is now on maternity leave and Anna Jenkins is providing cover for her post.
- Rosemary Eichenberger started with us in November replacing Biren Patel.
- Clare Riddle left the Trust in December and as yet has not been replaced.

If you were liaising with Clare regarding your research study and are not sure who to contact, drop us a line on the R&Denquiries address and an R&D Officer will be in contact.

- Louise Stockley is now the Governance Manager for the department, overseeing governance procedures and the R&D Officers.

R&D OFFICE CONTACTS

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