

R&D Bulletin

October 2009

It has been another busy few months for the R&D Department, with the number of research applications, contracts, research passport applications and amendments steadily rising. Our GCP courses are also proving popular, and November is filling up fast. Please note that our next tutor led GCP course will be in April 2010.

MODEL SITE AGREEMENT

For multi-centred, Trust sponsored studies (either solely or jointly sponsored with the University) an agreement should be put in place with any participating sites.

For a copy of the current Trust template please contact Samantha Barker, Contracts Manager, who can assist with the completion of the agreement.

For any queries raised by a participating site please ensure that Sam is involved with any discussions.

All agreements must be reviewed by R&D and we will also arrange for them to be signed on behalf of the Trust.

HONORARY CONTRACTS

Please check that you are using the most recent version of the research passport application form in order to apply for an honorary contract.

We have a new policy and procedure to guide you through the process and the link for this can be found below.

For details of the November tutor led GCP course, or the online GCP course, please contact Sylvie Robinson – sylvie.robinson@addenbrookes.nhs.uk

Two new Policies and Procedures are available on our website:

Commercial Research Activity

www.cuh.org.uk/resources/pdf/research/researchers/policies/policy_externally_funded_research.pdf
and

Research Passport, Honorary Research Contracts and Letters of Access

www.cuh.org.uk/resources/pdf/research/researchers/policies/research_passport_honorary_research_contracts_and_letters_of_access.pdf

MHRA Training

We will be holding an MHRA training day on **Wednesday 18 November** which will be led by a member of the MHRA and held at the Clinical School.

Further details including the outline of the day will be communicated in early October.

In light of recent and future MHRA statutory inspections, **we strongly recommend that anyone involved in Clinical Trials attend this training.** Please contact Sylvie Robinson to book a place.

TRUST SPONSORED EU CLINICAL TRIALS

Over the last few months we have reviewed our processes for Trust sponsored EU Clinical Trials and have made new appointments in order to fulfil our sponsorship responsibilities.

Monitoring

This is a key sponsor responsibility and a requirement under ICH GCP. We now have one full time monitor, Helena Heanue-Travers, and one part time monitor, Mark Boysen, and they will be putting in place processes for monitoring of these trials.

Please be assured that in addition to fulfilling our sponsor legal obligations, the monitoring process will help researchers, by ensuring that compliance with ICH GCP has been followed.

Clinical Trials Administration

Mina Muthurajah is the Clinical Trials Officer for Trust sponsored EU Trials. She is responsible for the governance of these studies and also assists with the administration involved with monitoring and quality assurance.

Safety Reporting

The reporting of Adverse Events to the MHRA and Ethics is delegated to the Chief Investigator by the Trust. However we ask that the following research-related adverse events (AEs) are **notified** to us as **sponsor**:

Serious Adverse Event (SAE) – an untoward medical occurrence that results in 1) death or 2) initial or prolonged hospitalisation or 3) life threatening or 4) persistent incapacity or disability or 5) congenital anomaly or birth defect 6) in-patient hospitalisation.

This includes the following types of SAEs:

Serious Adverse Reaction (SAR) - where the adverse event(s) meets serious criteria and is causally related and expected

Serious Unexpected Suspected Adverse Reaction (SUSAR) - where the adverse event(s) meets serious criteria and is causally related and **Un**-expected

See the SOPs and Policies and Procedures on our website for further details.

New additions to the R&D Department

As well as Mina, Helena and Mark, we have made several other new appointments over the last few months:

Debbie Richards is the HR Advisor for the department and can assist with research passports, recruitment and general HR issues

John Carew has joined the Finance team and is working on Trust research accounts and CLRN funding.

Nirvana Croft and Biren Patel are our two new R&D Officers and will be responsible for the governance of non-commercial trials

TRUST APPROVAL FOR RESEARCH

We are working at trying to reduce the time it takes for issuing Trust approval, but we need your help! Please could you ensure the following documents are sent to us when applying for R&D approval:

- IRAS R&D Form (in a PDF and XML format)
- SSI Form
- Protocol
- Evidence of sponsorship (if applicable)
- Evidence of peer review

We will also require some additional documents in order for us to carry out the Site Specific Assessment (SSA), which has now transferred to us from the Ethics Committees, but we will advise on this once we are notified of your study.

Trust approval is required whenever Addenbrooke's patients, their tissue or data, facilities or staff are involved in research.

PEER REVIEW

All research requires an independent external scientific review. If your study has not been appropriately reviewed we can organise this for Trust sponsored studies.

We are unfortunately unable to confirm sponsorship until a suitable review has been done so please contact any R&D Officer for advice.

TISSUE BANK

Please see our updated web pages for the tissue bank which gives full details on how to obtain samples for research. If you are using control materials, please remember to list the requested tissue on the ethics application form.

www.cuh.org.uk/research/facilities/tissue_samples.html

MEDICAL DEVICE STUDIES

Whenever you are using a device which is deemed a 'medical device' the filter page on the IRAS form should be completed by selecting 'clinical investigation or other study of a medical device'

Please see the MHRA website or contact us for further details on the medical devices directive

<http://www.mhra.gov.uk/Howweregulate/Devices/index.htm>

Please also discuss your project with Clinical Engineering as they will need to ensure the device is safety tested, and can also assist with the completion of the medical device questions on the IRAS form.

SPONSOR DECLARATION PAGE

In addition to helping you to complete the IRAS form we will also need to sign the sponsor declaration page for those studies that the Trust will sponsor.

The earlier we can review your application, the quicker we can sign the page and not delay your submission to ethics, so please ensure that you contact us as soon as possible about your study.

R&D Website

We are currently updating our website, so please go to our site at http://www.cuh.org.uk/research/research_index.html

for information on how to get your study approved, relevant SOPs and Policies and Procedures, general guidance relating to R&D, and contact details of R&D staff.