

**Clinical Research Update - Issue 2  
May 2005**

Dear Colleague

**WELCOME** to issue 2. If you have any useful information which you feel our subscribers would benefit from please contact us at [info@logic2.co.uk](mailto:info@logic2.co.uk). Also please let us know what you think of this newsletter, using the same address. All feedback and suggestions will be gratefully received.

**UK Ethics Committees**

COREC and the R&D Forum have produced a joint approval form, which replaces part D of the COREC form. The idea behind this is to have one standard form that can be used for both REC approval and R&D approval, in order to standardise and eliminate some of the issues around R&D approvals. More information can be found on the COREC site and the R&D Forum site.

<http://www.corec.org.uk/applicants/index.htm>  
<http://www.rdform.org.uk/Default.aspx?browser=NS6>

As of 1<sup>st</sup> April 2005 COREC has moved into the National Patient Safety Agency and Professor Terry Stacey has resigned as head of COREC. My understanding is that Dr Janet Wisely has taken over from him. More information on the NPSA can be found at [www.npsa.nhs.uk](http://www.npsa.nhs.uk)

**MHRA**

The MHRA has published its new corporate plan for the next 5 years. Further information is available from <http://www.mhra.gov.uk/publications/corpPlan/foreword.htm>

**UK Clinical Research Collaboration (UKCRC)**

This initiative was set up last year to bring together all the stakeholders in clinical research in the UK to maximise the potential of the NHS for research. There are various workstreams looking at different aspects. Latest news from this initiative is the establishment of International Clinical Research Day, which aims to raise awareness of the importance of clinical research. This year it took place on 20 May. Also there has been an announcement of £74 million worth of funding for experimental research on new treatments in the UK. There is also a new report which sets out a training pathway to encourage more healthcare professionals to take up a career in academic medical research. For more information visit the website: [www.ukcrc.org](http://www.ukcrc.org)

**GCP Directive**

This has now been issued and you can access a copy at [http://pharmacos.eudra.org/F2/eudralex/vol-1/DIR\\_2005\\_28/DIR\\_2005\\_28\\_EN.pdf](http://pharmacos.eudra.org/F2/eudralex/vol-1/DIR_2005_28/DIR_2005_28_EN.pdf)

The directive refers generally to the need to take into account the consensus on Good Clinical Practice reached by ICH in 1995, and also the scientific guidelines regarding safety, quality and efficacy published by the EU. There are brief chapters on Good Clinical practice, Ethics Committees, Sponsors, the Investigators Brochure and Trial Master File and Archiving. There is more detail on Manufacturing and Import Authorisation, Inspectors and Inspection Procedures.

The Directive came into force (I think!) 29 April 2005 and Member States have until 29 January 2006 to implement national laws.

**That's all** for this time. Just an extra reminder that the Institute of Clinical Research issue a monthly update bulletin which is available on the website [www.instituteofclinicalresearch.org](http://www.instituteofclinicalresearch.org) and includes lots more information on all aspects of medical research. We will continue to send you this bulletin if you wish, which will contain more of a distillation of clinical research legislation and guideline updates.

Best wishes

Jo Burmester