



## Research Ethics Committees in the News

Issue 59, August 2009

**Purpose of publication:** To alert everyone in the National Research Ethics Service (NRES) to articles and news items that may be of interest and provide useful background information.

**Disclaimer:** All entries are to inform readers of the different views and opinions in published in media as part of their ongoing training and development. Inclusion does not signify recommendation, or endorsement by NRES or the National Patient Safety Agency (NPSA).

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For a free text search from previous issues there are compilations of *RECs in the News* for the years 2004 – 2009 in the [Ethics Research Information Catalogue \(ERIC\)](#). ERIC was created and is managed by NRES Ethics Advisor, Dr Hugh Davies, and is a keyword-searchable resource of hundreds of articles relating to research ethics.

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### REGULATIONS AND GUIDANCE

(R & G 1)      **EU Looks Closer at Pharmacovigilance**  
Peter O'Donnell, *Applied Clinical Trials*, July 2009

New rules for pharmacovigilance are on the way in Europe. European Union health ministers took their first look at the proposals in June, and changes can be expected to be decided before the end of this year. The initiative comes from European industry commissioner who announced last December a "pharma package" of proposed new rules to tighten up EU monitoring of adverse effects.  
<http://appliedclinicaltrialsonline.findpharma.com/>

(R & G 2)            **Is paperwork suffocating British clinical research?**  
*Medical News Today*, 30 July 2009

This is a report of the paper by Adrian Burton (*The Lancet Oncology*, August 2009;10; 8,749 - 750, [http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(09\)70212-8/fulltext](http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(09)70212-8/fulltext)) of concerns being raised by British academics that bureaucratic overload is stifling their ability to undertake clinical research, compromising the future of this activity in the UK. The article includes quote from Janet Wisely that the use of one form, which can be sent to all appropriate regulatory bodies, has streamlined research administration.  
<http://www.medicalnewstoday.com/articles/159219.php>

*(n.b. Janet Wisely is attending the second meeting of the 'Sensible Guidelines for Clinical Trials Working Group' which is publicised in the paper)*

(R & G 3)            **The Rules Governing Medicinal Products in the European Union, Volume 10 - Guidance Documents Applying To Clinical Trials Questions & Answers, v4.0**  
EU website 28 July 2009

There has been an update to the European Question and Answers on Clinical Trials. This new document supersedes the previous version, adding two new questions ("Is an authorised medicinal product used as comparator in a clinical trial an investigational medicinal product?" and "What can be considered a "non-interventional trial?") and revising the answers to two others ("Can the sponsor delegate tasks or responsibilities?" and "Can the dates of the annual safety reports be aligned with other periodic reporting requirements?").  
<http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/>

(R & G 4)            **Delay to DSUR finalisation**  
*CR Advisor*, 247, 10 Aug 09

The International Conference on Harmonisation (ICH) E2F guideline – entitled '*Developmental Safety Update Reports*' (DSURs) – failed to reach Step 4 at the recent ICH Steering Committee meeting in Japan. The Steering Committee is hoping to finalise the document via teleconferences, and to achieve a sign-off by mail before the ICH meeting in October. The ICH guideline proposes the adoption of a consistent approach to providing annual safety reports from clinical trials.  
<http://www.canarybooks.com/index2.htm>

(R & G 5)            **Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial**  
*CR Advisor*, 247, 10 Aug 09, 2

This is a useful summary of the consultation document on proposed changes to EU guidance on clinical trials. The consultation draft can be accessed at:  
[http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2009/2009\\_06/2009\\_06\\_11-publicconsultation.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2009/2009_06/2009_06_11-publicconsultation.pdf).

The consultation ends 8 September.  
<http://www.canarybooks.com/index2.htm>

(R & G 6)            **EMA-FDA GCP Initiative**  
*EMA press release 31 July 2009*

The U.S. Food and Drug Administration and the European Medicines Agency (EMA) announced an agreement to launch a bilateral Good Clinical Practices (GCP) Initiative, designed to ensure that clinical trials submitted in drug marketing applications in the United States and Europe are conducted uniformly, appropriately and ethically. The initiative will begin with an 18-month pilot phase in September and will focus on collaborative efforts to inspect clinical trial sites and studies.  
<http://www.emea.europa.eu/pdfs/general/direct>

(R & G 6)            **Disharmony Stifling Research in Europe**  
*Peter O'Donnell, Applied Clinical Trial, 1 Aug 2009*

A report from a meeting calling for a unified clinical trial authorisation process in the EU. One of the speakers was Martyn Ward, Head of the Clinical Trials Unit at the Medicine and Healthcare Regulatory Agency, who conceded that despite the merits of the clinical trials directive, complications had crept into the implementation. A lack of EU guidance had led to local interpretation (and differential timing) when implementing the directive in national legislation, and this had been particularly aggravated by EU enlargement. The latter had subsequently brought 12 new member states into the picture, with varying experience, resources, and priorities in terms of clinical research.  
<http://appliedclinicaltrialsonline.findpharma.com/>

## PHASE 1

(Phase 1, 1)            **Perils of the professional lab rat**  
*Alison Motluk, New Scientist, 25 July 2009; 203, 40-43*

An article which explores the potential dangers of paying healthy volunteers to take part in clinical trials. The article is mainly about the US which elicited a response from a UK reader that many of the adverse comments do not apply to the UK.  
<http://www.newscientist.com/article/>

(Phase 1, 2)            **The Diploma and Certificate in Human Pharmacology (DHP and CHP)**  
FPM website

The Faculty of Pharmaceutical Medicine of the Royal College of Physicians has developed two integrated training programmes to address the specific training requirements of Principal Investigators (PIs) and all scientists and supporting staff involved in Phase 1 studies / Exploratory Development of Investigational Medicinal

Products (IMPs). The next course is scheduled for December 2009.  
[www.fpm.org.uk](http://www.fpm.org.uk).

## INFORMED CONSENT

(Inf Con 1) **A Consent Form Template for Phase I Oncology Trials**  
Shlomo A. Koyfman, Mary S. McCabe, Ezekiel J. Emanuel, and Christine Grady  
*IRB: Ethics and Human Research*, July - August 2009: 31; 4

Whilst this work was carried out in the US it will also be of interest to those interested in simplifying information for participants and improving the informed consent process. The researchers reviewed 272 phase 1 oncology trial consent forms and then created an improved informed consent template specific to phase 1 trials.  
<http://www.thehastingscenter.org/Publications/IRB/Detail.aspx?id=3744>

(Inf Con 2) **Tailoring consent to context: designing an appropriate consent process for a biomedical study in a low income setting**  
*PLoS Neglected Tropical Diseases*, 3 July 2009 e482

A research article considers the social, cultural, and economic factors which lay behind the procedures for gathering informed consent at the beginning of a genetic study in rural Ethiopia and discusses how these could be applied more widely.  
<http://www.plosntds.org/home.action>

## GENETICS/GENOMIC MEDICINE

(Gen 1) **The ethics and regulation of direct-to-consumer genetic testing**  
Paula Boddington *Genome Medicine* 20 July 2009, 1:71

A report of the workshop 'Direct-to-consumer genetic testing: ethical and regulatory issues', Oxford, UK, 21 May 2009. This was the first time a group of experts had gathered together in the UK to discuss the scientific, ethical and regulatory aspects of commercial genetic testing.  
<http://www.genomemedicine.com/content/pdf/gm71.pdf>

(Gen 2) **Musings on genome medicine: is there hope for ethical and safe stem cell therapeutics?**  
Mahendra Rao, and Maureen L Condic, *Genome Medicine* 14 July 2009, 1:70

The authors suggest that recent advances in the field have provided avenues to develop pluripotent cells that raise far fewer ethical concerns. Moreover, advances in cell sorting, gene modification and screening have allowed the development of safer therapeutic approaches. They argue that continued advances in this rapidly evolving field are likely to allow therapy to be delivered in a safe and effective manner without socially divisive ethical controversy in the not-so-distant future.  
<http://www.genomemedicine.com/content/1/7/70/abstract>

(Gen 3) **Genomic advances and their impact on clinical trial design**

Sumithra J Mandrekar and Daniel J Sargent, *Genome Medicine* 13 July 2009, 1:69

The authors highlight the impact of genomic advances on various aspects of clinical trial design. Specifically knowledge of the genetic make-up of the disease and the genotype of the patient can aid in patient stratification (risk assessment), treatment response identification (surrogate markers), and/or in differential diagnosis (identifying who is likely to respond to which drug(s)). Several critical issues, including scientific rationale, clinical trial design, marker assessment methods, cost and feasibility have to be carefully considered in the validation of biomarkers through clinical research before they can be routinely integrated into clinical practice.

<http://www.genomemedicine.com/content/1/7/69/abstract>

## HUMAN TISSUE

(HT 1) **Research FAQs**

Human Tissue Authority website

The Human Tissue Authority (HTA) website has a useful page of Frequently Asked Questions about research

<http://www.hta.gov.uk/licensingandinspections/>

(HT 2) **Stem cell projects pave the way for new therapies**

MRC website, 20 July 2009

The Medical Research Council has announced funding of £4.7 million for seven awards under its translational stem cell research scheme. This includes nearly £3 million for four early stage clinical trials involving adult stem cells.

<http://www.mrc.ac.uk/Newspublications/News/MRC006229>

(HT 3) **Review of Human Tissue Authority**

HTA press release, 23 July 2009

The Hampton Implementation review, carried out in November 2008, praised the Human Tissue Authority (HTA) for using the principles of Better Regulation to ensure the HTA's regulations are risk-based, proportionate and transparent. The review team rated the HTA highly on provision of advice and guidance and minimisation of inspections and data collection burdens.

The review recommended that in the future the HTA should:

- continue to monitor the effectiveness of our regulatory activity by commissioning surveys of public perception about handling human tissue, at regular intervals
- work with the Department of Health to update/amend the Human Tissue Act, using the feedback and experience gained from the first years of its implementation

<http://www.hta.gov.uk/newsandevents/htanews.cfm/646-Hampton-Implementation-Review.html>

## CHILDREN IN RESEARCH

(Child 1)        **Support for UK Pediatric Studies**  
Andrew C. Rose, Rosalind L. Smyth,

A description of the UK's Medicines for Children Research Network (MCRN) and its work to improve medicines for the young.

<http://appliedclinicaltrialsonline.findpharma.com>

(Child 2)        **EMA adopts guideline on neonate investigations**  
EMA website, 22 July 2009

The European Medicines Agency has formally adopted a guideline on the investigation on medicinal products in term and preterm neonates (up to 27 days). Special aspects of clinical trial design are covered on pages 15 onwards.

<http://www.emea.europa.eu/pdfs/human/paediatrics/53681008enfin.pdf>

## MISCELLANEOUS

(Misc 1)        **A Ten Step Trial Crisis Plan**  
John F Kouten, *Applied Clinical Trials*, July 2009

This paper is written for an American audience, but the importance of having a crisis communications plan for when drug trials go wrong are universally applicable. This article provides a summary overview of the changes that have occurred in the legal and research environment, what caused them, and how researchers and institutions can prepare and manage their strategic communication plans to avert or manage these new potential crises.

<http://appliedclinicaltrialsonline.findpharma.com/>

(Misc 2)        **Bridging the divide between pharma and academia**  
Katrina Megget, *Clinical Discovery*, July/Aug 2009

The UK Drug Discovery Consortium was officially launched in March to encourage pharmaceutical grade research in academia. The reporter looks at whether this will translate into clinical trials.

<http://www.clinicaldiscovery.com/readArticle.aspx?articleId=125>

(Misc 3)        **Safety first**  
Peter Schüler, *Clinical Discovery*, July/Aug 2009

A looks at pharma industry's response to the latest drug safety regulations and a discussion of potential improvements for safety monitoring in clinical trials.

<http://www.clinicaldiscovery.com/readArticle.aspx?articleId=122>

(Misc 4) **Get a load of me: the biobank boom takes shape**

Mark Gould, *Health Services Journal*, 30 July 2009, 119 p.20-22

A feature article profiles a volunteer who has signed up to participate in UK Biobank - a study of 500,000 people to determine the genetic and environmental causes of common diseases. While participants appear to be taking part for truly altruistic reasons, some commentators continue to express concern that large pharmaceutical companies will be able to access data.

<http://www.hsj.co.uk/resource-centre/best-practice/>

(Misc 5) **Can the Relationship between Doctors and Drug Companies Ever Be a Healthy One?**

Emma D'Arcy and Ray Moynihan, *PLoS Med*, 21 July 2009;6; 7, e1000075

A debate on the financial ties between doctors and drug companies. Emma D'Arcy, co-founder of a social networking site that facilitates interactions between doctors and drug companies, argues that it would be valuable to the public if we could establish "authentic alliances" between these professionals. But journalist Ray Moynihan argues that such alliances are prone to the corrupting influence of pharmaceutical industry money, and that disentanglement is a healthier alternative.

<http://clinicaltrials.ploshubs.org/article/info:doi/10.1371/journal.pmed.1000075>

(Misc 6) **Ethical and policy issues in cluster randomized trials: rationale and design of a mixed methods research study**

Monica Taljaard, Charles Weijer, Jeremy M Grimshaw, Judith Belle Brown, Ariella Binik, Robert Boruch, Jamie C Brehaut, Shazia H Chaudhry, Martin P Eccles, Andrew McRae, Raphael Saginur, Merrick Zwarenstein and Allan Donner. *Trials*, 28 July 2009;19;61

The researchers plan to conduct a mail survey of RECs in the UK, US and Canada to determine whether they have any experience in reviewing cluster randomised trials, whether they have any training and/or recommendations in place for reviewing cluster trial protocols, whether any ethical challenges with respect to cluster randomised trials have been addressed, and solicit their views and experiences regarding ethical issues in cluster randomised trials.

<http://www.trialsjournal.com/content/10/1/61>

(Misc 7) **Research - getting started**

R Egan and J Coulston, *British Medical Journal*, 08 Aug 2009, p359

Two trainee doctors write of the delay in getting their research started which they attribute to unfamiliarity with the application system, misinterpretation of certain key stages in the process and some misguidance from governing authorities. They provide a list of key points to assist other researchers.

<http://www.bmj.com/>

(Misc 8) **For Patients: Questions to Ask About a Clinical Trial**  
*New York Times*, 2 August 2009

A list of questions that patients could ask their doctor if they are invited to participate in a clinical trial.

<http://www.nytimes.com/2009/08/03/health/research/03trialside.html?ref=research>

(Misc 9) **Discouraging participation**  
*New York Times*, 3 August 2009

A recent Phase 3 clinical trial was analysed to find how much time is involved when a clinician recruits patients into a clinical trial.

<http://www.nytimes.com/imagepages/2009/08/03/health/research/03trialsgrx.html>

(Misc 10) **Remedy for a malady**  
Andrew Jack, *Financial Times*, 14 August 2009

The report of a meeting convened by the Association of the British Pharmaceutical Industry which included discussions to improve clinical research. One delegate argued for greater use of sophisticated statistical techniques, such as Bayesian analysis, to scrutinise the data generated in drug tests and adapt as necessary the clinical trials that are already under way. Another suggestion was “conditional approvals” of new drugs, in recognition that it is impossible to identify extremely rare side effects during even large trials. Compounds would instead be authorised for use after smaller trials provided they are then closely watched for signs of danger once in broader use

<http://www.ft.com/cms/s/0/4447244e-88f3-11de-b50f-00144feabdc0.html>

## OVERSEAS

(Overseas 1) **DART trial participants tell their stories**  
MRC website, 21 July 2009

The experiences of some of the 3,316 participants who took part in the Development of Anti-retroviral therapy (DART) trial in Africa are reported. A documentary about the DART trial featuring the experiences of trial participants is also available.

<http://www.mrc.ac.uk/Newspublications/News/MRC006231>

(Overseas 2) **Clinical Research Safety and Ethical Standards in Developing World Up to U.S. Levels**  
ACRO press release 21 July 2009

A report by the Association of Clinical Research Organizations (ACRO) has concluded that clinical trials in the developing world meet the same safety, ethical and quality standards as those conducted in the developed world. Two factors are fuelling the growth in developing world trials: because fewer Americans are enrolling in trials, and because global trials enable pharmaceutical companies to bring drugs to market more quickly and cost-effectively. The report found that disparities in

education, economic and social status and healthcare systems may jeopardize the rights of research participants

<http://www.acrohealth.org/press-release-detail.php?serial=58>

(Overseas 3) **Australian team to transplant pig islet cells into patients with unstable diabetes**

Susan Mayor, *BMJ*, 31 July 2009; 339:b3089

Australian researchers have been given permission to do a clinical trial in which pig islet cells are transplanted into adult patients with unstable type 1 diabetes in an attempt to cure their disease. A research group from the company Living Cell Technologies has been granted approval to conduct the trial in New Zealand because there is a moratorium on xenotransplantation (the transplantation of living animal cells or tissues into humans) in Australia. The New Zealand Bioethics Council said that the xenotransplantation technique had met the requirement of equipoise, in which treatment is expected to be neither better nor worse than the best alternative, for a clinical trial to proceed. The council had also considered that trial participants were in a position to give free and informed consent.

[http://www.bmj.com/cgi/content/extract/339/jul31\\_1/b3089?paperoc](http://www.bmj.com/cgi/content/extract/339/jul31_1/b3089?paperoc)

(Overseas 4) **Pfizer pays out for child deaths**

*The Daily Telegraph*, 31 July 2009, p. 12

Pfizer has signed a settlement worth up to \$75mn with Nigeria's Kano state related to a 1996 meningitis drug trial. The northern state of Kano sued the world's largest drug maker in May 2007 for \$2bn in damages over the testing of the meningitis drug Trovan, saying the drug killed 11 children and left dozens disabled. Under the deal, Pfizer agreed to underwrite several healthcare initiatives chosen by the Kano state government totalling \$30mn over a period of two years.

The victims' families said that they did not consent to the drug being administered, although Pfizer said the tests were undertaken with the consent of the Nigerian government, and the parents were fully informed.

<http://www.telegraph.co.uk/news/worldnews/>

(Overseas 5) **Clinical Trials, Wrapped in Red Tape**

Sally Satel, *New York Times*, 7 Aug 2009,

An article criticising the US system of ethical approval.

[http://www.nytimes.com/2009/08/08/opinion/08satel.html?\\_r=2&em](http://www.nytimes.com/2009/08/08/opinion/08satel.html?_r=2&em)

(Overseas 6a) **Research and ethics in China**

*The Lancet*, 15 August 2009; 374; 9689, 502

An editorial discusses the China-UK Research Ethics Committee (CURE) report published by the UK Medical Research Council, which identifies areas of strength, weakness and inconsistency in Chinese ethical practice.

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(09\)61465-3/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(09)61465-3/fulltext)

(Overseas 6b) **China-UK Research Ethics Committee (CURE) Report**  
MRC website, 14 August 2009

The authors of this report met with various UK bodies, including NRES to compare ethical practice. They report that there are important differences between the UK and China in terms of the institutional structures that conduct ethical reviews. China has followed the US model of institutional review boards (IRBs) and has no equivalent to the UK's NRES to administer these committees and ensure consistency of procedure.

<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC006303>

(Overseas 6c) **Survey on the function, structure and operation of hospital ethics committees in Shanghai**

P Zhou, D Xue, T Wang, Z L Tang, S K Zhang, J P Wang, P P Mao, Y Q Xi, R Wu, and R Shi, *Journal of Medical Ethics* 2009;35:512-516

Shanghai hospitals established Hospital Ethics Committees (HEC) as from 1998. Most HECs function as clinical ethics committees, as well as research ethics committees. A survey found that the functions of the HECs need to be further developed and formal training on bioethics should be provided to HEC members. In addition the standard operating procedures and bioethical review should be improved to assure the independence and good performance of HECs.

<http://jme.bmj.com/cgi/content/abstract/35/8/512>

(Overseas 7) **Protecting subjects: the IRBs role today**  
*Applied Clinical Trials*, July 2009

This 20 page supplement describes the role of the Institutional Review Boards (IRBs) which operate in the US. Many of the chapters are of interest to a UK audience since the recommendations of the various authors reflect much of the good practice already operating in UK.

**Safeguards applied to research**

The *Protecting subjects: the IRBs role today* supplement was compiled to clarify the role of IRBs following a 'sting' operation which uncovered poor practice in a 'for-profit' IRB in the US in Spring 2009.

**What should sponsors ask their IRBs?**

A recommendation that sponsors chose IRBs to review their studies based on information about IRB accreditation, previous audits, capacity and research community support.

**Common sense and the rules**

The author recognises that IRBs operate in a constrained regulatory world, but recommends that they should consider 'shades of grey' in the rules by applying common sense and flexibility in their ethical reviews.

**Compliance through partnership**

A recommendation that the IRBs educate their applicants to improve the approval rate of the submitted studies.

### **US moves are ethically unclear**

A Canadian view of the plans to improve the system of ethical review in the US.

### **Lessons learned for IRBs**

The author advises that IRBs should prepare for increased scrutiny of their work by focusing on training of IRB members and updating their Standard Operating Procedures. The author also recommends that IRBs apply for accreditation to provide confidence that they meet or exceed federal standards for protecting human subjects.

### **Ethical Integrity of independent IRBs**

A response from an independent IRB that they maintain high standards of quality, integrity and regard for human safety, whilst being responsive to customer demands for a 24-48 hour turnaround.

### **How to choose a central IRB**

The criteria for the selection of an IRB to review a study are provided. The new era will view the IRB as a trusted consultant that can prevent costly errors, and works with the sponsor/Contact Research Organisation to support decisions made if they are ever questioned.

### **Transparency and Cooperation**

The author writes of the need to increase transparency in research.

[http://digital.findpharma.com/nxtbooks/advanstar/act\\_200907/#/18](http://digital.findpharma.com/nxtbooks/advanstar/act_200907/#/18)

### **(Overseas 8) Lack of Study Volunteers Hobbles Cancer Fight**

Gina Kolata, *New York Times*, 3 Aug 2009

A major hurdle in the fight against cancer involves finding cancer patients willing to participate in clinical trials, and doctors willing to recruit them into the studies.

[http://www.nytimes.com/2009/08/03/health/research/03trials.html?\\_r=3&hp](http://www.nytimes.com/2009/08/03/health/research/03trials.html?_r=3&hp)