



## Research Ethics Committees in the News

Issue 54, March 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 – 2008 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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NRES Policy and Information Specialist

### INTEGRATED RESEARCH APPLICATION SYSTEM (IRAS)

#### (IRAS 1) **IRAS now fully functional for IMP studies**

*Pharmatimes*, 18 March 2009

With the newly improved version of the Integrated Research Application System (IRAS), all of the information about an Investigation of a Medicinal Product (IMP) study can be entered in one place and researchers need only go to European Union Drug Regulating Authorities Clinical Trials (EudraCT) to obtain their EudraCT number. It is now also possible to generate the Medicines and Healthcare products

Regulatory Agency (MHRA) application form in the appropriate formats directly from IRAS.

<http://www.pharmatimes.com/ClinicalNews/article.aspx?id=15509>

## TRIAL REGISTRATION AND TRANSPARENCY

### (TR & T 1) **Reporting ethical matters in *The Journal of Physiology*: standards and advice**

Gordon B. Drummond, *J. Physiol.*, Feb 2009; 587: 713-719

This article addresses the structure of regulations, introduces the concept of research governance and UK law is summarised. Advice is given on the format and description of experiments, and common problems addressed. Aspects of human studies are addressed. Ethical considerations of publication such as authorship and originality, and problems such as plagiarism and fabrication are described.

<http://jp.physoc.org/cgi/reprint/587/4/713>

### (TR & T 2) **Industry attack on academics**

Jonathan Gornall, *BMJ*, 9 March 2009; 338:b736

An apparently uncontroversial study of potential industry influence on sponsored drug trials resulted in the researchers facing accusations of misconduct.

The researchers, of whom four worked for the Nordic Cochrane Centre in Denmark and two for the Centre for Statistics in Medicine in Oxford, had chosen to work with the Danish material because they were denied access to trial protocols in the UK. They found that in half of the trials they examined a sponsor had the ability to prevent publication and was in a position to have "recourse to practical or legal obstacles in most of the others."

Iain Chalmers, one of the founders of the Cochrane Collaboration, set up in 1993 to prepare systematic reviews of randomised controlled trials across all areas of health care, says the experience endured by the Nordic Cochrane researchers speaks volumes about the lack of progress made by the drug industry towards meaningful transparency, despite repeated assurances and various half hearted initiatives.

[http://www.bmj.com/cgi/content/extract/338/mar09\\_1/b736?paperoc](http://www.bmj.com/cgi/content/extract/338/mar09_1/b736?paperoc)

### (TR & T 3) **An Unbiased Scientific Record Should Be Everyone's Agenda**

The *PLoS Medicine* Editors, *PLoS Med* 2009; 6;2

This PLoS article proposes five ways in which authors and editors can improve the published scientific record and be free from bias when publishing; publication bias, reporting bias, declaring financial/competing interests and improve access to data etc. They hope that if authors and editors address these issues prior to publishing, science will be transparent which will lead to "a more rigorous and unbiased knowledge base".

<http://medicine.plosjournals.org/perlserv/>

## REGULATIONS AND GUIDANCE

(R & G 1)        **EMA Note for Guidance on Development Safety Update Report**  
*CRA*Advisor, 6 March 2009, 237, 2-4

Key elements of the European Medicines Agency (EMA) guidance on the Development Safety Update Report (DSUR), which is planned to become the common standard for annual clinical trial safety reporting in the ICH regions, are outlined. The executive summary section of the DSUR will be suitable to fulfill the ongoing safety information requirements for ethics committees and investigators.  
<http://www.canarybooks.com/index2.htm>

(R & G 2)        **Biomedical regulation workshop shapes long-term goals**  
MRC website 23 February 2009

The report of a workshop "Regulation and biomedical research" held jointly by the MRC and the Wellcome Trust 13-14 May 2008 has recently published. The workshop acknowledged that regulation is complex with potential for confusion, conflict and hindrance of the very processes that the regulations aim to assist. Keeping researchers informed and helping them understand regulations will go some way in establishing trust and reducing anxiety. There is reference that this is already happening with reference to the NRES Integrated Research Application System (IRAS) on page 2 of the summary.

One speaker reported improvements in the regulatory processes. For example:

- NRES had a coordinating and supervising role
- There was now a unified (but still overlong) form with online submission
- NRES offered more training for ethics committee members, and there was more interaction with applicants at an early stage
- There was more control of process with targets and timelines.

<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC005613>

(R & G 3)        **A Healthy 2009 for the European Union**  
Peter O'Donnell, *Applied Clinical Trials*, 1 Feb 2009

In a brief review of the EU Clinical Trial Directive the author writes that contrary to the EU intention of attracting clinical trials, there appears to be a slight decline. Weaknesses identified by the Impact on Clinical Research of European Legislation (ICREL) report itself were similar. The key failings observed in EU clinical trial regulations were the lack of harmonization of procedures, the lack of transparency, unclear definitions, increased workloads (particularly for assessing annual safety reports), and the need to simplify reporting to ethics committees. Initial ICREL findings were that negative outcomes of clinical trial authorization applications had increased, as had protocol amendments. Meanwhile, the scientific and administrative workload rose, with a corresponding rise in costs.  
<http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/Regulatory+Articles/A-Healthy-2009-for-the-European-Union/ArticleStandard/Article/detail/579326>

(R & G 4)        **A practical guide to attaining research ethics approval in the UK**  
Angela M Tod, Peter Allmark and Althea Allison, *Nursing Standard*, 25 Feb 2009,  
23:25, 37-41

A comprehensive article which examines the permissions and approvals required to conduct research in the NHS. The authors conclude:

“For the nurse who is a novice researcher these processes can appear daunting. However, if a stepwise approach is taken, sufficient time allowed and help and advice sought it can be a straightforward process.”

<http://nursingstandard.rcnpublishing.co.uk/resources/archive/>

(R & G 5)        **EMA launches Committee for Advanced Therapies**  
EMA website, Feb 09

The European Medicines Agency (EMA) has announced that the first meeting of the new Committee for Advanced Therapies (CAT) took place on 15–16 January 2009. CAT is a multidisciplinary committee that brings together some of the best available experts in Europe to assess the quality, safety and efficacy of advanced therapy medicinal products (ATMPs), and to follow scientific developments in the field.

<http://www.ema.europa.eu/pdfs/human/cat/786609en.pdf>

(R & G 6)        **Number of global clinical trials done in UK fell by two thirds after EU directive**

Anne Gulland, *BMJ*, 13 March 2009;338:b1052

A leading clinician, Rory Collins, professor of epidemiology and medicine at Oxford University, told a briefing that the "hugely increased bureaucratic burden" imposed by the EU Clinical Trials Directive had made it much more difficult to investigate new treatments. The European Union Clinical Trials Directive came into effect in 2004 with the intention of harmonising clinical trials throughout Europe, lessening the bureaucratic burden, and improving the safety of patients. However, John Bell, president of the Academy of Medical Sciences said the opposite has happened. He said that the directive had been applied differently in different EU countries and that the bureaucratic burden has increased. "It is not clear what it has done to patient safety....Governance of clinical research in the NHS has added another layer of bureaucracy in the United Kingdom."

[http://www.bmj.com/cgi/content/extract/338/mar13\\_1/b1052?paperoc](http://www.bmj.com/cgi/content/extract/338/mar13_1/b1052?paperoc)

This same press release was covered by the BBC on 12 March as EU red tape 'blocks drug trials'

<http://news.bbc.co.uk/1/hi/health/7939606.stm>

## ADULTS LACKING CAPACITY

### (ALC 1) **Including Persons with Alzheimer Disease in Research on Co-morbid Conditions**

Anji Wall, *IRB: Ethics & Human Research*, January-February 2009:31;1

A paper advocating that research on persons with Alzheimer disease should be extended to include clinical trials involving common co-morbid medical conditions. Including persons with Alzheimer disease in some of these clinical trials can be justified when the trials offer the prospect of direct benefit, even if the research poses more than minimal risk.

<http://www.thehastingscenter.org/Publications/IRB/Detail.aspx?id=3134>

(free access with registration)

## HUMAN TISSUE

### (HT 1) **Interim UK regulatory route map for stem cell research and manufacture**

MHRA Website, March 2009

The MHRA participated in the production of a regulatory route map for stem cell research and manufacture which has been developed by the Department of Health with the support of regulatory bodies and the Gene Therapy Advisory Committee. This interim UK regulatory route map (dated 12 March 2009) is intended to be a reference tool for those who wish to develop a programme of stem cell research and manufacture ultimately leading to clinical application. A more detailed, web-based version of the map is currently being developed and will be available by the end of 2009.

<http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON041337>

## DATA PROTECTION

### (DP 1) **Charities call for "public-researcher partnership" in sharing electronic patient data**

Lizy Cooper, *BMJ* Published 27 February 2009,

UK charities involved in clinical research have called for greater public participation in the debate on the use of patients' data, in particular electronic records.

The British Heart Foundation, the Wellcome Trust, and Cancer Research UK warned that clinical trials are being delayed because of problems identifying patients suitable for research projects "The need for "consent for consent," where researchers have to apply to ethics committees to be allowed to contact patients to ask for their consent to participate in trials, is cutting into valuable research time."

[http://www.bmj.com/cgi/content/extract/338/feb27\\_2/b856?paperoc](http://www.bmj.com/cgi/content/extract/338/feb27_2/b856?paperoc)

(DP 2a) **Doctors' outcry over plan to sell patient records**

*Daily Telegraph*, 3 March 2009, pg 1

Leaders of the BMA, the Royal College of General Practitioners, the Royal College of Surgeons, and the Royal College of Nursing and medical defence organisations have expressed concern that government plans, contained in the Coroners and Justice Bill, would allow almost unlimited access to medical records of named individuals without their consent.

However, a spokesman for the Department of Health said: "We are currently in discussion with the Ministry of Justice about how the proposed legislation impacts on medical records. It is important to ensure that patient confidentiality is preserved and that patients consent to how their records are used."

<http://www.telegraph.co.uk/health/healthnews/4930666/Doctors-outcry-over-plan-to-sell-patient-records.html>

(DP 2b) **Amendments to the Coroners and Justice Bill**

Vivienne Nathanson, *BMJ*, 3 March 2009; 338 b895

An editorial expressing concerns about Clause 152 involving data sharing which may undermine doctors' and patients' confidence.

[http://www.bmj.com/cgi/content/full/338/mar03\\_1/b895](http://www.bmj.com/cgi/content/full/338/mar03_1/b895)

(DP 2c) **Government removes data sharing clause from coroners' bill**

Zosia Kmiotowicz *BMJ*, 11 March 2009; 338: b1009

Jack Straw, the UK justice secretary, is to abandon plans that could have allowed patients' medical records to be used by third parties without patients' consent.

A spokeswoman for the Ministry of Justice said that the government still believed strongly in data sharing but had accepted the concerns of many critics that clause 152 of the Coroners and Justice Bill was not the way forward.

[http://www.bmj.com/cgi/content/extract/338/mar11\\_1/b1009?paperoc](http://www.bmj.com/cgi/content/extract/338/mar11_1/b1009?paperoc)

(DP 3) **Balancing the use of patient information with public trust**

Nicola Perrin, *Clinical Discovery*, March 09

There is still considerable uncertainty about the processes that should be used when personal information is accessed for research. The author looks at what is needed to ensure public trust.

<http://www.clinicaldiscovery.com/readArticle.aspx?contents=Balancing%20the%20use%20of%20patient%20information%20with%20public%20trust&articleID=116>

(DP 4) **The use of personal information in medical research**

Wellcome website

A series of links provided by the Wellcome Trust on:

[Coroners and Justice Bill](#) The Trust's position on the Bill.

[Access to GP records](#) Developing best practice for the use of patient records for research in general practice.

[E-health](#) Realising the research potential of electronic patient records.

[Data Sharing Review](#) Recommendations relating to the use of data in research.

[Public engagement](#) Exploring public attitudes to research involving personal information.

[Policies and positions](#) The Trust's policies and consultation responses relating to the use of personal information.

[Policy reports from other organisations](#) Recent studies on the use of personal information in research.

<http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Personal-information/index.htm>

## INFORMED CONSENT

(Inf Con 1) **When one signed consent form is not enough**  
*CRA* *Advisor*, 6 March 2009, 237

The regulatory requirement to obtain written and dated informed consent from a potential trial subject prior to the commencement of any clinical trial procedure is a clear and fundamental element of Good Clinical Practice (GCP). However, the situation becomes more complex when a protocol incorporates a sub-study.

<http://www.canarybooks.com/index2.htm>

(Inf Con 2) **Written informed consent and selection bias in observational studies using medical records: systematic review**

Michelle E Kho, Mark Duffett, , Donald J Willison, , Deborah J Cook, Melissa C Brouwers, *BMJ*, 12 March 2009;338:b866

A systematic review to determine whether informed consent introduces selection bias in prospective observational studies using data from medical records, and consent rates for such studies.

The researchers conclude that significant differences between participants and non-participants may threaten the validity of results from observational studies that require consent for use of data from medical records. To ensure that legislation on privacy does not unduly bias observational studies using medical records, thoughtful decision making by research ethics boards on the need for mandatory consent is necessary.

[http://www.bmj.com/cgi/content/abstract/338/mar12\\_2/b866?paperoc](http://www.bmj.com/cgi/content/abstract/338/mar12_2/b866?paperoc)

MISCELLANEOUS

(Misc 1) **Legumes, lemons and streptomycin: A short history of the clinical trial**

Roger Collier, *Canadian Medical Association Journal*, 6 Jan 2009, 180: 23-24

The author writes that the first documented experiment resembling a clinical trial was not conducted by a scientist or doctor, but by King Nebuchadnezzar, and he ruled Babylon for almost 60 years, his reign ending in 562 BC.

<http://www.cmaj.ca/cgi/content/full/180/1/23?etoc>

(Misc 2) **From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns**

Hastings Center website, March 09

This is a free online book written for American journalists, policy makers and campaigns, but some of the chapters might be of interest to UK REC members. It contains 36 overviews of issues in bioethics including a chapter on:

Clinical trials

Biobanks: DNA and Research

Conflict of Interest in Biomedical Research

Genetic Testing and Screening

Multinational Research

Personalized Medicine and Genomics

Stem Cells

<http://www.thehastingscenter.org/Publications/BriefingBook/Default.aspx>

(Misc 3) **The high incidence and bioethics of findings on magnetic resonance brain imaging of normal volunteers for neuroscience research**

N Hoggard, G Darwent, D Capener, I D Wilkinson, and P D Griffiths, *J Med Ethics* 2009; 35: 194-199

The researchers were finding normal volunteers for functional magnetic resonance imaging studies with abnormalities requiring referral surprisingly frequently. They discuss that the bioethics surrounding the incidental findings are not straightforward and whether all participants have review of their imaging by an expert and who should be informed?

<http://jme.bmj.com/cgi/content/abstract/35/3/194>

(Misc 4) **The Shock of the Human: how the media can change the way we think about ethical dilemmas in medicine**

Sarah Barclay, *Clin Ethics*, Mar 2009; 4: 26 – 30

The relationship between the media and the medical profession is often one of mutual mistrust. However, the media, and especially television, is a powerful tool for telling individual stories and for providing a medium for medico-ethical dilemmas to be portrayed to a wide audience.

<http://ce.rsmjournals.com/cgi/>

(Misc 5) **When is deception in research ethical?**

Nafsika Athanassoulis and James Wilson, *Clin Ethics*, Marc 2009; 4;1, 44-49;

This article examines when deceptive withholding of information is ethically acceptable in research. The authors argue that some important features of research make it more difficult to justify withholding information in the context of research than elsewhere.

<http://ce.rsmjournals.com/cgi/content/abstract/4/1/44>

(Misc 6) **Bringing clinical research into the classroom**

Mark Hallsworth, *Clinical Discovery*, March/April 2009:4;2, 20-21

The author, who is the Head of Communications to the UK Clinical Research Two new initiatives are now underway that are designed to bring the subject of biomedical research directly into the classroom: one is Centre of the Cell, a science education centre, online resource and an outreach project aimed at schools, young people and families; the other is Starfish, a new play for schools by Y-Touring, Central YMCA's theatre company.

<http://www.clinicaldiscovery.com/readArticle.aspx?contents=Bringing%20clinical%20research%20into%20the%20classroom&articleID=115>

(Misc 7a) **New report examines obstacles to non-commercial clinical trials**

MHRA Press Release, 12 March 09

MHRA welcomed the publication of the European Science Foundation's (ESF) report *Forward Look: Investigator Driven Clinical Trials* (IDCT). The report highlights and analyses the main obstacles that hinder achieving an increased number of non-commercial and academic clinical trials in Europe. It also identified the need to increase levels of funding for IDCT and adopt a 'risk-based' approach to regulation. Some interesting statistics included in the 'notes to editors' section of the Press Release:

- The total numbers of clinical trials approved in the UK have remained stable since the implementation of the EU Clinical Trials Directive in May 2004.

2005 – 1085

2006 – 1206

2007 – 1218

2008 – 1252

The press release also advises that: as from 9 March 2009 all the data required to make an application to the MHRA for authorisation of a clinical trial of an Investigational Medicinal Product (IMP) can be completed within the Integrated Research Application System (IRAS); Through IRAS all the information about a study can be entered in one place and researchers only need to go to EudraCT to obtain their EudraCT number and IRAS contains extensive guidance to support researchers in completing their application form. Additionally, it is now possible to generate the application form to the MHRA in the appropriate formats directly from IRAS.

<http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON041316>

The full report is 60 pages. [http://www.esf.org/fileadmin/links/EMRC/FL\\_IDCT.pdf](http://www.esf.org/fileadmin/links/EMRC/FL_IDCT.pdf).

Of particular interest to research ethics committees is that the UK is already way ahead of some of the recommendations concerning accreditation of RECs and of categorising low risk studies.

(Misc 7b) **Strengthen clinical trials driven by investigators, Europe research councils say**

Jacqui Wise, *BMJ*, 17 March 2009, 338:b1111

The European Medical Research Councils, part of the European Science Foundation, held a series of five workshops to examine the problems that are facing researchers who are conducting clinical trials. The resulting report, *Forward Look: Investigator Driven Clinical Trials*, lists 26 recommendations to strengthen such research in Europe. Investigator driven clinical trials tend to have a much broader scope and potential impact than clinical trials driven by industry. Typical topics include proof of concept studies, comparison of diagnostic or therapeutic interventions, surgical therapies, or new indications for registered drugs. In the Executive Summary the top five recommendations on strengthening Investigator Driven Clinical Trials (IDCT) are listed as:

1. To improve the education, training and career structure, and opportunities for scientists involved in patient-oriented clinical research.
2. To increase levels of funding for IDCT.
3. To adopt a 'risk-based' approach to the regulation of IDCT.
4. To streamline procedures for obtaining authorisation for IDCT.
5. To ensure that IDCT are carried out with an appropriate number of patients to produce statistically reliable results so that the trials are 'correctly powered'.  
[http://www.bmj.com/cgi/content/extract/338/mar17\\_1/b1111?paperoc](http://www.bmj.com/cgi/content/extract/338/mar17_1/b1111?paperoc)

(Misc 8) **Paying clinicians to join clinical trials: a review of guidelines and interview study of trialists**

James Raftery, Christine Kerr, Sheila Hawker, John Powell, *Trials* 10 March 2009, 10:15

The motivations of clinicians to participate in clinical trials have been little studied. This project explored the potential role of payment for participation in publicly funded clinical trials in the UK. The aims were to review relevant guidelines and to collate and analyse views of clinical trialists on the role of payments and other factors that motivated clinicians to join clinical trials. Of particular interests was the finding that the requirement that full details of trial funding be made available to ethics committees not only increased transparency but made departures from recommended practice more difficult.

<http://www.trialsjournal.com/content/10/1/15/abstract>

(Misc 9) **The clinically-integrated randomized trial: proposed novel method for conducting large trials at low cost**

Andrew J Vickers, Peter T Scardino, *Trials* 5 March 2009, 10:14

Randomised controlled trials provide the best method of determining which of two comparable treatments is preferable. Contemporary randomised trials have become increasingly expensive, complex and burdened by regulation, so much so that many trials are of doubtful feasibility. Here the authors present a proposal for a novel, streamlined approach to randomised trials: the "clinically-integrated randomised trial".  
<http://www.trialsjournal.com/content/10/1/14/abstract>

OVERSEAS

(Overseas 1a) **Ethical and Scientific Implications of the Globalization of Clinical Research**

Seth W. Glickman, John G. McHutchison, Eric D. Peterson, Charles B. Cairns, Robert A. Harrington, Robert M. Califf and Kevin A. Schulman, *N Engl J Med*, 19 February 2009, 360;8

This is a very comprehensive paper with 62 references. The authors found that clinical trials increasingly occur on a global scale as industry and government sponsors in wealthy countries move trials to less wealthy countries. They write that "a major concern is the ethical oversight of research involving human subjects in developing countries. Wide disparities in education, economic and social standing, and health care systems may jeopardize the rights of research participants. There may be a relative lack of understanding of both the investigational nature of therapeutic products and the use of placebo groups. In some places, financial compensation for research participation may exceed participants' annual wages, and participation in a clinical trial may provide the only access to care for persons with the condition under study."

<http://content.nejm.org/cgi/content/full/360/8/816>

(Overseas 1b) **Outsourcing of Drug Trials Is Faulted**

Natasha Singer, *New York Times*, 18 February 2009

A summary of the above paper published in the *New England Journal of Medicine*.

[http://www.nytimes.com/2009/02/19/business/19clinic.htm?\\_r=1](http://www.nytimes.com/2009/02/19/business/19clinic.htm?_r=1)

(Overseas 1c) **The Call for Ethical Clinical Trials in Developing Countries**

Call for Ethical Clinical Trials in Developing Countries website

The Call for Ethical Clinical Trials in Developing Countries has been formulated out of concern about the shift in many clinical drug trials away from the richer nations and towards developing countries, and the associated ethical violations. It represents a call to action for policy makers, regulators and pharmaceutical companies to protect vulnerable trial subjects and it has been signed by leading figures in the field of medicine and ethics, and other concerned parties.

<http://www.fairdrugs.org/>

**(Overseas 2) Subjects' views of obligations to ensure post-trial access to drugs, care and information: qualitative results from the Experiences of Participants in Clinical Trials (EPIC) study**

N Sofaer, C Thiessen, S D Goold, J Ballou, K A Getz, G Koski, R A Krueger, and J S Weissman, *J Med Ethics* 2009; 35: 183-188

An American study to report the attitudes and opinions of subjects in US clinical trials about whether or not, and why, they should receive post-trial access (PTA) to the trial drug, care and information. Many participants in US trials for chronic conditions thought there are obligations to facilitate PTA to the trial drug at a "fair" price; these views were less demanding than those of non-US subjects in other studies. However, our participants' views about informational obligations were broader than those of other subjects and many bioethicists. Our results suggest that the PTA debate should expand beyond the trial drug and aggregate results.

<http://jme.bmj.com/cgi/content/abstract/35/3/183>

**(Overseas 3a) Clinical trials: the muddled Canadian landscape**

Ann Silversides, *Canadian Medical Association Journal*, Jan 6, 2009: 180, 20-22

This overview of the landscape of Canadian clinical trials is the first in a series of articles the *Canadian Medical Association Journal* will present this year on the state of clinical trials in Canada and abroad. Many believe the system is in disarray because of spiraling costs and conflicting requirements. Among the issues that will be explored in upcoming articles are costs, recruitment, registration, ethical oversight, patient safety, reporting and the push for reforms.

<http://www.cmaj.ca/cgi/content/full/180/1/20?etoc>

**(Overseas 3b) Canadian doctors admit earning thousands in trial recruitment fees**

David Spurgeon, *BMJ*, 6 March 2009; 338:b951

Several Canadian doctors have admitted, on condition of anonymity, that they earn tens of thousands of dollars each year by recruiting patients for clinical trials. The doctors made the revelation in the *Canadian Medical Association Journal (CMAJ)* (doi:10.1503/cmaj.090131). The news article, part of a series on clinical trials that *CMAJ* will run throughout 2009, says that many doctors are increasingly concerned about the pressure to commercialise research, raising potential conflicts of interest and, for some, ethical quandaries about receiving such money.

[http://www.bmj.com/cgi/content/extract/338/mar06\\_2/b951?papetoc](http://www.bmj.com/cgi/content/extract/338/mar06_2/b951?papetoc)

**(Overseas 4) Composition, training needs and independence of ethics review committees across Africa: are the gate-keepers rising to the emerging challenges?**

A Nyika, W Kilama, R Chilengi, G Tangwa, P Tindana, P Ndebele, and J Ikingura, *J Med Ethics* 2009; 35: 189-193.

The African Malaria Network Trust (AMANET) undertook a survey of 31 ethics review committees (ERCs) across sub-Saharan Africa as an initial step to a comprehensive capacity-strengthening programme. The number of members per committee ranged from 3 to 21, with an average of 11. Members of 10 institutional committees were all

from the institution where the committees were based, raising prima facie questions as to whether independence and objectivity could be guaranteed in the review work of such committees.

<http://jme.bmj.com/cgi/content/abstract/35/3/189>

(Overseas 5) **Assurance of Protection of Human Subjects' Safety and Privacy**  
Jeffrey P. Callen and June K. Robinson, *Arch Dermatol.* 2009;145;2, 193-194

A summary of the protection of the welfare, rights, and privacy of human subjects requires review and approval of the research plan by an institutional review board (IRB) or a human subjects committee (HSC).

<http://archderm.ama-assn.org/>

(Overseas 6) **Prominent celecoxib researcher admits fabricating data in 21 articles**

Jeanne Lenzer, *BMJ*, 9 March 2009;338:b966

Scott S Reuben, chief of the acute pain service at Baystate Medical Center in Springfield, Massachusetts, has admitted the fraud, says a notice issued by the centre in late January. A well known researcher who promoted the use of the non-steroidal anti-inflammatory drug celecoxib has admitted fabricating data in 21 of his 72 articles indexed by PubMed. The case is "among the biggest which has come to light," said Harvey Marcovitch, chairman of the Committee on Publication Ethics, an international forum for publishers and editors of peer reviewed journals.

[http://www.bmj.com/cgi/content/extract/338/mar09\\_2/b966?papetoc](http://www.bmj.com/cgi/content/extract/338/mar09_2/b966?papetoc)