



Research Ethics Committees in the News

Issue 55, April 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).

General information: This publication can be accessed on the NRES website. <http://www.nres.npsa.nhs.uk/news-and-publications/publications/recs-in-the-news/> NHS Research Ethics Committee (REC) members can obtain free access to many journals electronically via a NHS Athens Account; REC coordinators have details for setting up a NHS Athens account. REC coordinators can also download articles so that lay members do not incur printing costs, or for members without internet access. NRES NPSA does not have the copyright or the resources to supply full text articles. Please contact your local healthcare library <http://www.hlisd.org/> for articles which can not be downloaded without a charge.

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.

Sandra Tapping
NRES Policy and Information Specialist

TRIAL REGISTRATION AND TRANSPARENCY

(TR & T 1) **Closer to Transparency**
Lisa Henderson, *Applied Clinical Trials*, March 2009

The chief architect of <http://www.clinicaltrials.gov/> offered some insights into the difficulties of ensuring transparency of clinical trials at the conference: *The Clinical Trials Registries and Results Databases*. This was the first held outside the United

States, and covered global and U.S. requirements.

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

Link to conference organiser's website

http://www.cbinet.com/includes/inthenews/articles/Update_From_London.cfm

(TR & T 2) **Towards agreement on best practice for publishing raw clinical trial data**

Iain Hrynaszkiewicz and Douglas G Altman, *Trials*, 18 March 2009, 10

The journal *Trials* aims to address inadequate reporting in randomised controlled trials, and in order to fulfil this objective, the journal is working with the scientific and publishing communities to try to establish best practice for publishing raw data from clinical trials in peer-reviewed biomedical journals. Potential next steps are outlined including that **Ethics Committees** encourage researchers to include plans to publish data in trial information sheets and discuss the safeguards in place to protect patient privacy.

<http://www.trialsjournal.com/content/10/1/17>

(TR & T 3) **GSK pledges to publicise clinical trial findings**

Andrew Jack, *Financial Times Companies and Markets*, 25 March 2009 p. 16

The UK-based pharmaceutical group GlaxoSmithKline, previously accused of concealing sensitive information about its medicines, has promised to make public the findings and details of all clinical trials within 18 months of their completion.

<http://www.ft.com/cms/s/0/1babb50e-18dc-11de-bec8-0000779fd2ac.html>

(TR & T 4a) **Patients and the public deserve big changes in evaluation of drugs**

Silvio Garattini and Iain Chalmers, *BMJ* 31 March 2009;338:b1025

The authors argue that patients and health services are getting a poor return on their investment into new drugs. They suggest four ways in which governments could alter the balance of their support in favour of patients and health services while also benefiting the industry. This includes making transparency in drug evaluation a legal requirement. Although industry has voluntarily taken some important steps towards greater transparency, mandatory, prospective publication of trial protocols should now be required by law.

<http://www.bmj.com/cgi/doi/10.1136/bmj.b1025>

(TR & T 4b) **Risks of doing as the Romans do**

Michael Tremblay, *BMJ* 31 March 2009;338:b1107

The author is critical of the above analysis, especially the recommendation to fund independent clinical trials.

<http://www.bmj.com/cgi/doi/10.1136/bmj.b1107>

(TR & T 5) **Research Integrity: A European perspective**

Andrew Smith, *CR Focus*, April 2009:20;4, 29-34

A commentary on selected presentations at the European Forum for Good Clinical Practice (EFGCP) conference of January 2009 aimed at providing a European perspective on integrity in the conduct and publication of clinical research. The role of RECs in maintaining integrity is also covered.

<http://www.icr-global.org/crfocus/>

(TR & T 6) **Conflict of Interest, Disclosure, and Trial Reports**

Bruce M. Psaty, *JAMA*, 8 April 2009:301;14, 1477-1479

The author writes that while transparency is a critical preventive measure, bias is not identifiable by the fact that funding may have been received from a source with special interests.

<http://jama.ama-assn.org/cgi/reprint/301/14/1477>

(TR & T 7) **Protocols, probity, and publication**

William Summerskill, David Collingridge, Helen Frabkish, *The Lancet*, 21 March 2009: 373;9668, 992

The role of ethics in research extends through the moral obligation to report that research and to do so in an honest, transparent, and timely manner. To help authors demonstrate that their findings are faithful to their research protocol, *The Lancet*, *The Lancet Oncology*, and *The Lancet Neurology* offer to publish links to the full study protocol.

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(09\)60590-0/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(09)60590-0/fulltext)

REGULATIONS AND GUIDANCE

(R & G 1) **Horizon scanning' for regulatory and governance developments**

UKCRC website

The UK Clinical Research Collaboration (UKCRC) Partners and stakeholders are committed to facilitating early and effective involvement with regulatory change by:

- Promoting consultation and debates on UK regulatory and governance issues
- Engaging early with European regulatory developments.

As a large proportion of new regulation in the UK now comes from Europe, the regulatory horizon-scanning activities have included the formation of a group called the European Bioscience Intelligence Coalition (EBIC). EBIC provides a forum for the sharing of information on legislation emerging from Europe and discussing the likely impact on research. Where appropriate, it also facilitates the coordination of efforts to inform the development of new regulations.

<http://www.ukcrc.org/regulationgovernance/horizonscanning.aspx>

(R & G 2) Impact of the EU Clinical Trials Directive on medical research

Hansard, 31 March 09, Column 1096W

Mark Todd MP asked whether there had been an assessment of the impact of the EU Clinical Trials Directive on medical research activity in England. Dawn Primarolo gave a written answer. She included that:

“A UK-wide regulatory and governance advice service now gives researchers free access to expert advice regulation. **Research ethics committees** are now organised in a national research ethics service which facilitates and promotes ethical research by maintain a consistent UK-wide system of ethical review. An integrated research application system now offers a single point from which to apply for permissions and approvals for health and care research in the UK, enabling researchers to enter the information about their project once instead of duplicating information in separate application forms. The National Institute for Health Research coordinated system for gaining National Health Service permission will standardise and streamline the process for gaining NHS permission in England. These measures are reducing approval times and bureaucracy.”

<http://www.publications.parliament.uk/pa/>

(R & G 3) Hampton Review concludes regulator is confident, transparent and risk-aware

MHRA press release 8 April 2009

The findings of the Hampton Implementation Review (HIR) were supportive of the MHRA and its ongoing effort to be a proportionate, transparent and risk-aware regulator. Key findings included:

- The MHRA has a good range of contact channels, which it supplements with external engagement events.
- The MHRA is developing systems to facilitate better sharing of information across the Agency.
- The potential of the MHRA website is currently not being maximised as a communications tool in terms of layout and usability.
- MHRA guidance is, on the whole, extensive and issued in good time although it could be ‘road tested’ better in some cases.
- The perception and credibility of the MHRA’s approach towards better regulation can be hampered by occasional miscommunication.

<http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON043915>

<http://www.berr.gov.uk/files/file50890.pdf> full report 40 pages

(R & G 4) What is a Directive?

Europa website

The European Commission website provides useful information to answer questions such as:

- What is a Directive?
- What is a Regulation?
- What is a guideline in the pharmaceutical legislative framework?
- What is the legal status of guidelines?

http://ec.europa.eu/enterprise/pharmaceuticals/pharmleg/pharmleg_en.htm

Paper to describe and define the different guidelines that support the European pharmaceutical legislative framework and to describe a harmonised procedure for their development.

<http://www.emea.europa.eu/pdfs/human/regaffair/2414304en.pdf>

HUMAN TISSUE

(HT 1) **Ethical row over blood made from fetuses**

Beezy Marsh, *Daily Mail*, 24 March 2009 p. 6

Scientists are to produce synthetic blood from discarded IVF embryos and aborted fetuses. The Health Service and medical research charity the Wellcome Trust are funding research that could see synthetic blood transfusions from discarded embryos within three years. The research could save thousands of lives by revolutionising blood transplant services in the UK - and reduce the dependence on donors. But critics say it is unethical to use embryos and fetuses in this way, no matter how many lives they could save.

<http://www.dailymail.co.uk/news/article-1164284>

INFORMED CONSENT

(Inf Cons 1) **Feasibility and cost of obtaining informed consent for essential review of medical records in large-scale health services research**

Sian Noble, Jenny Donovan, Emma Turner, Chris Metcalfe, Athene Lane, Mari-Anne Rowlands, David Neal, Freddie Hamdy, Yoav Ben-Shlomo, and Richard Martin
J Health Serv Res Policy, Apr 2009; 14: 77 - 81

The researchers evaluate the effectiveness and cost of obtaining consent for review of medical records. They conclude that a high consent rate for review of medical notes is achievable but at a cost. They recommend renewed debate about the automatic need for consent to review medical records where the chance of personal harm is negligible.

[abstract](#)

(Inf Cons 2) **Reformed Consent: Adapting to New Media and Research Participant Preferences**

James Henry, Barton W. Palmer, Lawrence Palinkas, Danielle Kukene Glorioso, Michael P. Caligiuri, and Dilip V. Jeste, *Hastings Center Report*, March-April 2009

Individuals contemplating enrolling in a hypothetical randomized drug trial expressed interest in a consent process that involved accessing the Internet or contacting prior study participants to obtain further study-relevant information, rather than relying solely on the printed consent forms.

Although current regulations generally require printed consent documents, multimedia consent procedures and Internet tools matched to an individual's preferences can be valuable aids in a participant's comprehension of the informed consent process.

<http://www.thehastingscenter.org/Publications/IRB/Detail.aspx?id=3288>

GENETICS/GENOMIC RESEARCH

(Genetic 1) **Is it ethical to deny genetic research participants individualised results?**

Paul Affleck, *Journal of Medical Ethics*, April 2009; 35:209-213

This article examines a key ethical concern that has arisen in the work of the international research consortium GenoMEL (<http://www.genomel.org>) and that has relevance to all genetic research in humans. The question is whether it is ethical to deny research participants the opportunity to receive individualised genetic results obtained from the biological samples they provide. Where those results are of clinical importance, a "respect for persons" requirement would make the offering of those results imperative. However, where those results are of uncertain clinical value, the picture is less clear. This paper argues that researchers may not be ethically obliged to offer such results to their participants, because of competing ethical demands. <http://jme.bmj.com/cgi/content/abstract/35/4/209?etoc>

(Genetic 2) **Researchers' preferences and attitudes on ethical aspects of genomics research: a comparative study between the USA and Spain**

M Ruiz-Canela, J I Valle-Mansilla, and D P Sulmasy, *Journal of Medical Ethics* April 2009;35:251-257

The use of human samples in genomic research has increased ethical debate about informed consent requirements and the information that subjects should receive regarding the results of the research. However, there are no quantitative data regarding researchers' attitudes about these issues. This study provides evidence of a wide range of views among scientists regarding some controversial ethical issues related to genomic research, suggesting the need for more study, debate and education.

<http://jme.bmj.com/cgi/content/abstract/35/4/251?etoc>

(Genetic 3) **Medical profiling and online medicine: The ethics of 'personalised' health care in a consumer age**

Nuffield Council on Bioethics press release 21 April 2009

The Nuffield Council on Bioethics is holding a public consultation on the ethical issues raised by online healthcare, telemedicine and commercial medical profiling technologies such as DNA testing and body imaging.

The Council would like to hear the views of a wide range of people, including those using or contemplating using these services, those involved in providing them in the public and private context, researchers, academics, regulators, policy makers and others. Responses to the consultation will be carefully considered, and a report setting out the Council's findings will be published in spring 2010.

There is no direct reference to research ethics. The 35 page consultation document has 15 questions and including electronic health records, and DNA profiling. Deadline for responses 21 July 2009.

http://www.nuffieldbioethics.org/go/ourwork/personalisedhealthcare/page_968.html

Covered by *The Times* as **Ethics inquiry to judge challenges of genetic testing**

<http://www.timesonline.co.uk/tol/news/uk/health/article6135597.ece>

MISCELLANEOUS

(Misc 1) **ABPI Guidance Notes on Joint Working Between Pharmaceutical Companies and the NHS and Others For the Benefit Of Patients**

ABPI website March 2009

The NHS is changing rapidly and there is a desire on the part of Government and the NHS for the NHS to engage with the pharmaceutical industry on a broader agenda. The ABPI has introduced guidance to provide a framework and greater clarity about various aspects of joint working between the pharmaceutical industry and the NHS.

There is reference to ethics committee approval on page 6.

<http://www.abpi.org.uk/Details.asp?ProductID=343>

(Misc 2) **Clinical trial participation poses ethical, practical issues**

Ann Silversides, *Can. Med. Assoc. J.*, Mar 2009; 180: 500 – 502

A view on paying doctors for their participation as researchers in clinical trials

<http://www.cmaj.ca/cgi/content/full>

(Misc 3) **Providing ethics committees with meaningful safety data**

*CRA*ditor, April 2009:239;1-3

Sponsors and investigators in Europe and the USA are required to make safety reports to ethics committees (IECs) and institutional review boards (IRBs). This is a short summary of the information to be provided.

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

(Misc 4) **Is ICH E9 still fit for purpose?**

*CRA*ditor, April 2009:239;6-7

Experts believe that an updated International Conference on Harmonisation (ICH) guideline on the design and analysis of clinical trials is now due.

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

(Misc 5) **Patient and Public Engagement Strategy April 2009 - March 2011**

MHRA website 31 March 2009

The MHRA has embarked on a new programme of activity to engage patients and the public in its work and the decisions it makes. The Agency's first Patient and Public Engagement strategy, covering the period until March 2011, sets out the vision and strategic priorities in this area, and identifies a range of activities that will help build the Agency's capacity and capability to successfully engage with patients and the public.

<http://www.mhra.gov.uk/NewsCentre/CON041520>

(Misc 6) **Public Health Research Ethics: A Research Agenda**

Marcel Verweij and Angus Dawson, *Public Health Ethics* 2009 2: 1-6

An editorial that the dominant approach to research ethics has focused on producing numerous regulations. This is potentially problematic for a number of reasons. They write that research ethics is dominated by a very particular paradigm of research, namely the clinical drug trial. This results in limitations in the range of ethical issues discussed and problems in applying this model to other perfectly legitimate types of research.

The authors also argue that some guidelines are regarded as rules and this can encourage ethics committees in turn to apply such rules in a rather absolutist way, rather than making their own judgement about whether or not a particular research project is justified based upon all elements of the protocol.

<http://phe.oxfordjournals.org/cqi/content/extract/2/1/1>

(Misc 7) **Tools and updates for CTAs**

Judi Eaton, *CR Focus*, April 2009:20;4, 35-39

A summary from a Clinical Trial Administrators' workshop held in November 2008 featuring updates on ethics, regulatory and governance changes including presentations by NRES.

<http://www.icr-global.org/crfocus/>

(Misc 8) **Porton Down 'not death sentence'**

BBC news 25 March 2009

A study commissioned by the Ministry of Defence, has concluded that Porton Down veterans used as guinea-pigs to test chemical weapons face no greater risk of dying from cancer but health worries remain.

<http://news.bbc.co.uk/1/hi/health/7961034.stm>

(Misc 9) **CTD to be new centre of national excellence for drug discovery**

Pharmatimes, 07 April 2009

A new centre dedicated to the discovery of novel drugs, involving academics and industry, is being set up in the UK.

The MRCT Centre for Therapeutics Discovery, which will be based in London, is being created by the Medical Research Council and MRC Technology. The founders say that it will build on the existing work of the MRCT Drug Discovery Group, and its aim is to expand "current capability and capacity to provide the UK with a national drug discovery resource with the critical mass to progress high quality projects towards clinical benefit".

<http://www.pharmatimes.com/UKNews/article.aspx?id=15638&src=EUKNews>

(Misc 10) **Reporting of ethics-related methods in epidemiological research**
K H Jacobsen, *Journal of Medical Ethics*, April 2009, 35:262-267

This paper describes the variety of ways that information about ethics-related methods are included or not included in public health research articles. The author concludes that more complete reporting would facilitate the design, evaluation and comparison of future research studies.

<http://jme.bmj.com/cgi/content/abstract/35/4/262?etoc>

(Misc 11) **Clinical Research by GPs in their own practices**
Nigel Mathers, Amanda Howe and Steve Field, *British Journal of General Practice*, 1 April 2009

The authors are advocating that GPs work in an network, rather than doing individual research projects. They note "There have been moves in recent months by the National Research Ethics Service to streamline the process further, and these have been supported by the Royal College of General Practitioners".

<http://www.rcgp.org.uk/publications/bjgp/login.aspx>

(Misc 12) **An afternoon at UK Biobank**
The Lancet, 4 April 2009: 373, p.1146

An article highlights the progress of the UK Biobank - a £62 million project seeking to understand more about the causes of disease - and discusses why the 500,000 volunteers might choose to take part.

<http://www.thelancet.com>

(Misc 13) **EMEA Reflects on Global Data in Pivotal Studies**
Europa website

The EMEA has published a reflection paper on the extrapolation of results from clinical studies conducted outside Europe to the EU-population. The consultation ends on 31 May 2009.

<http://www.emea.europa.eu/pdfs/human/ewp/69270208en.pdf>

(Misc 14) **Public Health Research Ethics: A Research Agenda**
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An editorial that the dominant approach to research ethics has focused on producing numerous regulations. This is potentially problematic for a number of reasons. They write that research ethics is dominated by a very particular paradigm of research, namely the clinical drug trial. This results in limitations in the range of ethical issues discussed and problems in applying this model to other perfectly legitimate types of research.

The authors also argue that some guidelines are regarded as rules and this can encourage ethics committees in turn to apply such rules in a rather absolutist way, rather than making their own judgement about whether or not a particular research project is justified based upon all elements of the protocol.

<http://phe.oxfordjournals.org/cgi/content/extract/2/1/1>

(Misc 15) **Is the UK falling behind in clinical trials?**

Pharmafocus, Tuesday , April 21, 2009

New initiatives to bolster collaboration between the NHS, academia and industry have come amid claims that the UK is losing its standing in clinical trials. A Royal College of Physicians (RCP) report found that during 2005-6, the average time from notification of a clinical trial to the first patient visit was 101 days, but that time has now increased to 173 days.

One of the key contributors to a RCP report, David Gillen, says the UK's deterioration is unfortunate, since new initiatives set up between industry and government are now showing promise

<http://www.pharmafocus.com/cda/>

(N.B. NRES are attending a National Institute of Health Research workshop at the end of April on issues in conducting trials in the UK).

OVERSEAS

(Overseas 1) **Research ethics review: Do it once and do it well**

Paul Hébert and Raphael Saginur, *Can. Med. Assoc. J.*, Mar 2009; 180: 597.

An editorial recommending that in Canada there needs to be a new national system to replace totally independent multiple reviews with support of an interactive open review model at the local level.

<http://www.cmaj.ca/cgi/reprint/180/6/597>

(Overseas 2) **Clinical trials: the balance between protecting participants and promoting drug and product development**

Miriam Shuchman, *Can. Med. Assoc. J.*, Mar 2009; 180: 603 - 606.

A criticism of the need for multiple reviews in the Canadian research ethics review system but recognition that "the British system offers standardized forms, a central approval site and, since last year, online capability for submissions and reviews."

<http://www.cmaj.ca/cgi/reprint/180/6/603>

(Overseas 3a) **Testing Firm finds itself being tested**

Barry Meier, *New York Times*, 12 March 2009

Report of a US investigation to determine whether companies that are paid to oversee the safety of patients in clinical studies of drugs and medical devices do their job.

http://www.nytimes.com/2009/03/13/business/13sting.html?_r=1

(Overseas 3b) **Clinical Trial Fraud Detected by Independent Review Board, part of a congressional “sting” operation**

Coast IRB website, March 2009

Press release from the relevant IRB

<http://www.coastirb.com/press-releases>

(Overseas 3c) **IRB system flaws exposed at US Congressional hearing**

Pharmatimes, 30 March 09

Legislation to tighten up the oversight of institutional review boards (IRBs) could be in the pipeline after a US Congressional hearing was told of serious flaws in the national system for ethical review and monitoring of clinical trials.

Concerns about rubber-stamping by a fast-proliferating independent IRB network – there are currently more than 6,000 institutional review boards registered with the US Department of Health and Human Services’ (HHS) Office for Human Research Protections (OHRP) – were lent weight by the success of a ‘sting’ operation conducted by the US Government Accountability Office (GAO).

<http://www.pharmatimes.com/clinicalnews/article.aspx?id=15584&src=EUKNews>

(Overseas 3d) **US clinical trial system urgently in need of reform**

Pharmatimes 12 April 2009

A US Government Accountability Project (GAP), has found that the current US system for conducting and regulating clinical studies is “rife with conflicts of interest that put trial subjects at risk and produce suspect data on drug safety and efficacy”. The Project’s ‘white paper’ on *The ABCs of Drug Safety: Accountability, Balance, and Citizen Empowerment* comes hard on the heels of a Congressional hearing that exposed serious flaws in the ethical review system for clinical research in the US.

The report’s recommendations include:

- Extending federal regulation of clinical trials beyond those overseen by the FDA or the Department of Health and Human Services. According to the GAP report, many pre-Phase I, Phase IV and investigator-initiated trials are exempt from these controls, “leaving an estimated 40% of studies and over five million research participants uncovered each year”.
- Legislative reforms to ensure that IRBs “operate at arm’s length from drug sponsors and that IRB members are, themselves, free of compromising industry conflicts”.
- Launching pilot projects to determine whether the current IRB system provides genuine informed consent. The system in place “focuses almost exclusively on the review of consent forms” the report says. The law “does not require IRBs to regularly observe consent interviews or the conduct of study protocols.

<http://www.pharmatimes.com/clinicalnews/article.aspx?id=15664&src=EUKNews>

(Overseas 3e) **Policies regarding IRB members' industry relationships often lacking**

Eureka alert, 25 March 2009

In the April issue of *Academic Medicine*, researchers from the Massachusetts General Hospital (MGH) Institute for Health Policy report that many IRBs do not require members to disclose industrial relationships and that procedures for defining, reporting and handling conflicts vary widely among institutions.

http://www.eurekalert.org/pub_releases/2009-03/mgh-pri032309.php

(Overseas 4) **The State of Medical Research Ethics Is an “Enron-Type” Collapse Possible?**

Darren McDaniel, Coast IRB website

A commentary on how the press and the American public view the pharmaceutical industry, with particular reference to ethical review. The writer concludes: Do not use an Independent Review Board (IRB) that questions nothing. Many IRBs are known to have a “rubber stamp” approval/process approach to research review..... I am advocating that if your IRB does not ask good questions or make good suggestions, then I would strongly suggest you seek out a new IRB. View your IRB relationship as a partnership that

exists to make conducting medical research a win-win scenario for all stakeholders.

<http://www.coastirb.com/library/documents/pdf/articles/>

(Overseas 5a) **India probe raises concern about drug tests on humans**

Geeta Anand & Shirley Wang, *Karmayog*, 24 March 2009

The Drugs Controller General of India, Dr. Surinder Singh, has found that supervisory shortcomings, rather than problems with a vaccine itself, led to the death of a baby girl in India last autumn during a Wyeth clinical trial. Pfizer, which recently bought Wyeth, has said that it only conducts trials in countries where it plans to market the new drug and doesn't pay patients to enrol in trials.

http://www.karmayog.org/newspaperarticles/newspaperarticles_23049.htm

(Overseas 5b) **Inquiry into vaccine trial in India suggests ineffective oversight**

Ganapati Mudur *BMJ* 2009;338:b1418

An inquiry by the Indian government into the death of an infant during a clinical trial of an investigational vaccine has indicated deficiencies in the supervision of the trial, rekindling concerns about standards of scrutiny of clinical trials in India.

http://www.bmj.com/cgi/content/extract/338/apr08_1/b1418?papetoc

(Overseas 6) **IDF's anthrax vaccine trial "violated Helsinki Convention"**

Judy Siegel-Itzkovich, *BMJ* 30 March 2009;338:b1325

After an 18 month investigation of a clinical trial in which, from 1999 to 2006, an Israeli developed anthrax vaccine was injected into more than 700 soldiers in the Israel Defense Forces (IDF), a committee appointed by the Israel Medical Association has released a critical report. The 90 page document concluded that the ministry, the IDF, and the IDF's Helsinki committee for human medical experimentation handled the experiment badly and with no civilian supervision, the committee said, violating the Helsinki Convention and with apparent conflicts of interest.

http://www.bmj.com/cgi/content/extract/338/mar30_2/b1325?paperoc

(Overseas 7) **Pfizer Reaches Settlement in Nigerian Drug-Trial Case**

Joe Stephens, *Washington Post*, 4 April 2009, pg A03

Pfizer has reached a broad agreement to pay millions of dollars to Nigeria's Kano state to settle a criminal case alleging that the drug company illegally tested an experimental drug on gravely ill children during a 1996 meningitis epidemic.

<http://www.washingtonpost.com/wp-dyn/content/>