Purpose of publication: To alert everyone in the National Research Ethics Service (NRES) to information that may be of interest.

Disclaimer: All entries are to inform readers about different views and opinions as part of their ongoing training and development. Inclusion does not signify recommendation, nor endorsement by NRES.

General information: This publication can be accessed on the NRES website. NHS 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 Head Office does not have the copyright nor the resources to supply full text articles. Please contact your local healthcare library 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.

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INTEGRATED RESEARCH APPLICATION SYSTEM (IRAS)

(A 1) A united front
Peter Charlish, Scrip World Pharmaceutical New, 6 June 2008, 13-15

A description of the work of the UK Clinical Research Collaboration (UKCRC), including reference to the Integrated Research Application System (IRAS).
http://www.pjbpubs.com/scrip/index.htm
A Quick Guide to IRAS
Jon Bell, Clinical Discovery, May/June 08:3;3, 19-21

A readable guide to the Integrated Research Application System (IRAS). The author writes that taking the time to learn how to use IRAS now should save considerable time in the future.

REGULATIONS AND GUIDANCE

(R & G 1) Leaflet on NIHR CSP
UKCRN website May 08

UK Clinical Research Network (UKCRN) have published a leaflet (v.1 April 2008) which gives details about the development and implementation of the National Institute for Health Research Coordinated System for gaining NHS Permission (NIHR CSP) to undertake clinical research.

(R & G 2) Impact on Clinical Research of European Legislation
European Organisation for Research and Treatment of Cancer website

ICREL (Impact on Clinical Research of European Legislation) is a one-year EU FP7 project that aims at analyse the impact of the Clinical Trials Directive 2001/20/EC on clinical research in Europe. The outcomes of the ICREL project will be discussed at a workshop on 8 December 2008 and are likely to contribute to suggestions for possible changes to the current EU legislative framework.

ICREL has just launched a survey giving stakeholders (commercial and non-commercial sponsors, ethics committees and competent authorities) the opportunity to contribute to this project. The deadline for responses is 20 July 2008. The survey and more information can be found at www.eortc.be/icrel

(R & G 3) WMA proposes revision to Declaration of Helsinki for children
CRAadvisor 213, 13 June 2008, pg 11

The World Medical Association’s (WMA) Declaration of Helsinki is currently undergoing revision for the first time in 7 years. Among the proposed changes are those providing extra protection for participants in medical research. The new version highlights the need for populations that have previously been under-represented in medical research (e.g. Children and pregnant women) to be provided with equitable access to participation in studies.
http://www.canarybooks.com/index2.htm
Update from MHRA: Statutory Instruments and Regulatory Changes
Jo Bowler, CR Focus, June 2008:19;6, 62-64

A report of the presentation by Dr Martyn Ward, Head of the Clinical Trials Unit, Medicines and Healthcare products Regulatory Agency (MHRA). The presentation included an update on changes to the legislation and other developments including IRAS, first-in-human studies and performance assessment.
http://www.icr-global.org/crfocus

EU Imbalances in Risks and Benefits
Peter O'Donnell, Applied Clinical Trials, June 2008

A criticism of the EU Regulators who are consulting on regulations relating to medical devices, and the biotechnology industry.
http://appliedclinicaltrialsonline.

GOVERNMENT POLICY

Changes to PIAG
DH website May 08

The Patient Information Advisory Group (PIAG) in England and Wales has announced a number of developments. The following link explains important changes that are happening in relation to PIAG and approvals for use of data including the implications of these changes, such as where, when and how applications for access to data need to be made.

More involvement and choice for patients
DH website 24 June 08

Plans to give as many patients as possible the opportunity to be part of health research have been announced by the Department of Health. Under the plans, patients from every part of the country, with any illness or disease, would be made aware of research of relevance to them and would be able to take part in clinical trials if they met the criteria. The announcement coincides with the launch of a report 60 years of research in the NHS benefiting patients. www.nihr.ac.uk

The Financial Times also covered this announcement on 24 June with a comment "But the right to be informed may depend on the deployment of the NHS's electronic patient record, running four years late." http://us.ft.com/ftgateway/superpage.ft?news_id=fto062320082219124507&page=2
Big drugs companies shift trials overseas
FINANCIAL TIMES, 26 June 08, Pg 3

Leading pharmaceutical companies are cutting back on clinical research in the UK, claiming insufficient commitment by the government and the National Health Service to support new drug development. Pfizer, Roche and Merck-Serono are among the companies which have told the Financial Times that they have reduced, or will reduce, the number of British patients enrolled in trials to test experimental medicines for life-threatening diseases such as cancer. There is criticism of the National Institute of Clinical Excellence (NICE), but no mention of ethics review being a burden. http://www.ft.com/

Joint parliamentary bioethics committee
Parliament website 26 June 2008

There has been an Early Day Motion to support the establishment of a joint parliamentary bioethics committee to consider both human and animal bioethical issues. http://edm.parliament.uk/EDM/EDMDetails.aspx?EDMID=36220%09%09%09%09%09%09%09%09%09&SESSION=891

PHASE 1

Elephant Man' drug trial victims challenge hospital for test results
Robert Mendick, EVENING STANDARD, Tues 3 June (West End final edition pg 17)

The victims of the TGN 1412 drugs trial have initiated legislation against Northwick Park Hospital for withholding data related to the effects of the drug on their physiology and long term health. The Northwick Park data is critical in securing them payouts worth several hundred thousand pounds each from the American company Parexel, which administered the drug at its private clinic on the hospital site. http://www.thisislondon.co.uk

Virtual man’ will revolutionise R&D, says PwC
Pharmatimes 20 June 08

By 2020, R&D times may be shortened by two-thirds, success rates could dramatically increase and clinical trial costs could be slashed with the help of computer-based technologies, according to a new report.

The study, from PricewaterhouseCoopers and entitled Pharma 2020: Virtual R&D, which path will you take?, argues that new technologies will create “a greater understanding of the biology of disease”. It adds that the evolution of ‘virtual man’ will enable researchers to predict the effects of new compounds before they enter humans. http://www.pharmatimes.com/WorldNews/article.aspx?id=13742&src=EWorldNews
Link to the original report http://www.pwc.com/extweb/pwcpublications.nsf/docid/9367E5486347EA278025746A006029B1
RESEARCH IN CHILDREN

**Child 1**  **Parental authority, research interests and children’s right to decide in medical research – an uneasy tension?**
Ulrica Swartling, Gert Helgesson, Mats G Hansson, and Johnny Ludvigsson, *Clin Ethics*, June 2008: 3;2, 69-74

The report of a questionnaire study of 2,500 families in Sweden (with and without research experience) to explore parents’ views on issues relating to information, consent and research data.
http://ce.rsmjournals.com/cgi/content/abstract/3/2/69

ADULTS LACKING CAPACITY

**ALC 1**  **What to tell and how to tell: a qualitative study of information sharing in research for adults with intellectual disability**

The authors explore opinions and attitudes regarding the current information-giving practices in research involving adults with intellectual disabilities.
http://jme.bmj.com/cgi/content/abstract/34/6/501?etoc

INFORMED CONSENT

**Inf Con 1**  **Consent: Patients and Doctors Making Decisions Together**
GMC website


As the law relating to decision-making and consent, particularly for patients who lack capacity, varies across the UK, doctors need to understand the law as it applies where they work (*see paragraphs 62-63*). This guidance takes account of, and is consistent with, current law across the UK. The *legal annex* gives more detail about relevant common law and legislation, and links to further information.

**Inf Con 2**  **Southall faces accusations of ethically flawed research**

Doctors, who conducted research in the early 1990s at North Staffordshire Hospital into the ventilation technique known as continuous negative extrathoracic pressure, are accused of submitting an inaccurate application to the hospital’s research ethics committee. They are also are accused of failing to ensure that appropriate procedures were in place to obtain informed parental consent and of producing a misleading patient information leaflet, which claimed that the technique had been proved safe.
http://www.bmj.com

The authors assessed the effects of providing audio-visual information alone, or in conjunction with standard forms of information provision, to potential clinical trial participants in the informed consent process. They found mixed evidence as to whether audio-visual interventions enhance people's knowledge of the trial they are considering entering, and/or the health condition the trial is designed to address. http://www.cochrane.org/reviews/en/ab003717.html

HUMAN TISSUE

Licensing of procurement organisations

The Human Tissue Authority (HTA) has announced that all establishments procuring tissues and cells for human application must apply for an HTA licence or have a third party agreement in place with an HTA licensed establishment by 5 July 2008. http://www.hta.gov.uk/about_hта/eutcd_information/licensing_of_procurement_organisations.cfm

SOCIAL CARE

Government announces a National School for Social Care Research

The Government's commitment to improve social care services will be given a boost with a new National Institute for Health Research School for Social Care Research. The new School will be part of the National Institute for Health Research (NIHR) and will receive £3 million funding a year, for five years in the first instance. http://nds.coi.gov.uk/environment/fullDetail.asp?ReleaseID=369014&NewsAreaID=2&NavigatedFromDepartment=False

MISCELLANEOUS

The experiences of ethics committee members: contradictions between individuals and committees

A small study of members of university ethics committees to look at the occurrence and frequency of variations between the opinions of the members. http://jme.bmj.com/cgi/content/abstract/34/6/489?etoc
(Misc 2)  **An update from the National Research Ethics Service**  
Harpreet Seehra, *CR Focus*, June 2008;19;6, 28-30

A very positive report of the presentation by Dr Janet Wisely at the Institute of Clinical Research in April. The reporter concluded that:

"The potential of IRAS is huge, exciting and positive, and the update given in this session instilled further confidence that the UK is an attractive place in which to perform high quality ethical research."

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

(Misc 3)  **Phase IV research: innovation in need of ethics**  

Author abstract: Worries about safety of approved drugs have pushed post registration research (phase IV) to become the fastest growing drug research phase. Until recently, phase IV studies were mainly conducted for marketing purposes and run much like a phase III trial — at institutions with experienced investigators and a list of inclusion and exclusion criteria. Innovative phase IV studies involve ordinary physicians in research naive communities. This brings ethical issues familiar to medical research into clinical practice. As a consequence, individual physicians are challenged to protect scientific integrity and to secure the ethical conduct of research. Several ethical issues need to be addressed in the process of developing a scientifically sound and ethically high principled practice of phase IV research.

http://jme.bmj.com/cgi/content/extract/34/6/415?etoc

(Misc 4)  **Genes, race and research ethics: who's minding the store?**  

A study to gain insight into how a group of genetic scientists conceptualise and use racial/ethnic variables in their work and their strategies for managing the ethical issues and consequences of this practice.

http://jme.bmj.com/cgi/content/abstract/34/6/495?etoc

(Misc 5)  **Scientific responsibility for the dissemination and interpretation of genetic research: lessons from the "warrior gene" controversy**  
D Wensley and M King, *J Med Ethics* June 2008;34 507-509

The authors examine what went wrong in the dissemination of their research which fueled misleading and/or potentially discriminatory attitudes in society.

http://jme.bmj.com/cgi/content/abstract/34/6/507?etoc
(Misc 6)  **Drugs don't work... but thinking you've taken them does**

*THE TIMES*, 18 June 2008, 24

An Australian study has found that athletes who take growth hormones to improve their performance perform worse than those who take a placebo instead. Over eight weeks at the Garvan Institute in Sydney, athletes were given either growth hormones, which are banned by the World Anti-Doping Association, or inactive placebos - without knowing which substance they were taking. At the end of the study, volunteers who took placebos could sprint faster, jump higher and lift heavier weights.

[http://www.timesonline.co.uk/tol/sport/article4160494.ece](http://www.timesonline.co.uk/tol/sport/article4160494.ece)

(Misc 7)  **Ethics and research governance: the views of researchers, healthcare professionals and other stakeholders**

Nina Hallowell, Sarah Cooke, Gill Crawford, Michael Parker, and Anneke Lucassen  
*Clin Ethics* June 2008:3;2, 85-90

This report is based on a survey carried out between Jan 2006 and March 2007. It is recognised that IRAS may solve some of the problems, and some of the criticism is directed at R&D. The authors report "It was noticeable that our interviewees commonly failed to distinguish between research governance procedures from ethical review."

[http://ce.rsmjournals.com/cgi/content/abstract/3/2/85](http://ce.rsmjournals.com/cgi/content/abstract/3/2/85)

(Misc 8)  **The Last Piece of the Jigsaw**

Magnus Jaderberg, *Clinical Discovery*, May/June 08:3;3, 16-18

The author is from the pharma industry. He reviews how the UK has become more attractive as a venue and calls on the NHS to deliver the final changes. He writes very positively of the UK ethics system. For example: the "National Research Ethics Service, has provided the UK with one of the most efficient ethics review systems." and "the UK is competitive, if not class-leading, when it comes to regulatory and ethical reviews."

[http://www.clinicaldiscovery.com/readArticle.aspx?contents=The%20last%20piece%20of%20the%20jigsaw?&articleID=85](http://www.clinicaldiscovery.com/readArticle.aspx?contents=The%20last%20piece%20of%20the%20jigsaw?&articleID=85)

(Misc 9)  **Setting up non-commercial clinical trials takes too long in the UK: findings from a prospective study**


This study is from a multi-centre cancer study which was approved in July 2006. The authors are aware of IRAS but still have concerns that each R&D centre (without imposed deadlines) have to approve the application. They suggest that for multi centre trials it should not be necessary to have local review by RECs or R&D. They suggest some solutions.[http://jrsm.rsmjournals.com/](http://jrsm.rsmjournals.com/)
(Misc 10)  **The social functions of Research Ethics Committee letters**  
Mary Dixon-Woods, Emma Angell, Richard E. Ashcroft and Alan Bryman  
*Social Science & Medicine*, August 2007:65;4, 792-802  

The authors report a traditional content analysis and an ethnographic content analysis of 141 letters to researchers, together with an analysis of the organisational and institutional arrangements for RECs in the UK.  
[http://www.sciencedirect.com](http://www.sciencedirect.com)  

(Misc 11)  **Un-ethical review? Why it is wrong to apply the medical model of research governance to human geography**  
Sarah Dyer and David Demeritt  
*Progress in Human Geography*, May 2008  

The Economic and Social Research Council, the body which funds much social science in the UK, recently imposed on UK social science a system of research ethics governance already well established in other areas of research and in much of the rest of the developed world. The paper draws on empirical research investigating National Health Service (NHS) research ethics committees to propose three salutary lessons geographers would do well to consider from experience elsewhere with ethical review. They argue that in review by committee deliberations extend beyond the ethical to include the methodological, that the system is a self-perpetuating and increasingly rule-bound mechanism, and that despite a rhetoric of accountability it is a system as obscure to outsiders as professional ethics.  
[http://phg.sagepub.com/](http://phg.sagepub.com/)  

(Misc 12)  **Guide, guide thyself: law and order in clinical research**  

A short report on legal powers, RECs, and the Royal College of Physicians Guidelines.  

(Misc 13)  **North research firm collapses**  
*PRESS & JOURNAL (ABERDEEN.) 28 JUNE 2008, PG 2*  

The news report about a research company, Ness Foundation, which has gone into liquidation. The reporter writes of the North of Scotland REC not approving a study involving collection of saliva samples.  
[http://www.pressandjournal.co.uk/Article.aspx/712602?UserKey=0](http://www.pressandjournal.co.uk/Article.aspx/712602?UserKey=0)  

OVERSEAS  

(Overseas 1)  **Age of Consent for Clinical Research**  

This short article includes an interesting table showing how the age of consent in the US varies from state to state.  