Research Ethics: Why Bother?

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Outline

- Historical Background
- Problems of Calibration
- Problems of Trust
- Problems of Integrity
- Problems of Effectiveness
- Bare Essentials
- Issues of Research in Frailty

Historical context

1. **World War 2 Medical War Crimes**
2. **The Tuskegee Syphilis Study**
3. **The Jewish Chronic Disease Hospital Study**
4. **The Willowbrook Study**
5. **The San Antonio Contraceptive Study**
6. **For More see: http://www.ahrp.org/history/chronology.php**

Evolution of Codes

- Nuremberg Code
- Declaration of Helsinki
- CIOMS
- Belmont Report
- National Guidelines

Presidential Commission for
the Study of Bioethical Issues

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Moral Science: Protecting Participants in Human Subjects Research

Ethics Review

Problems of Calibration

Debate

Highly accessed Open Access

International variation in ethics committee requirements: comparisons across five Westernised nations

Felicity Goodyear-Smith [1], Brenda Lobb [2], Graham Davies [3], Israel Nachson [4] and Sheila M Seelau [5]

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BMC Medical Ethics 2002, **3**:2 doi:10.1186/1472-6939-3-2

The electronic version of this article is the complete one and can be found online at: http://www.biomedcentral.com/1472-6939/3/2

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QJM

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Oxford Journals › Medicine › QJM: An International Journal of Medicine › Volume 96, Number 4 › Pp. 305-307

Q J Med 2003; **96**: 305-307

Variations in experience in obtaining local ethical approval for participation in a multi-centre study

N.A. Maskell, E.L. Jones, R.J.O. Davies, and
on behalf of the BTS/MRC MIST steering committee

From the Oxford Centre for Respiratory Medicine, Churchill Hospital, John Radcliffe NHS Trust, Oxford, UK

Received 6 December 2002 Accepted for publication 16 December 2002.

Background: The Department of Health recently issued guidance on how Local Research Ethics Committees (LRECs) should handle an Multi-centre Research Ethics Committee (MREC)-approved application. This process is intended as a rapid standardized approval process, facilitating the execution of clinical trials.

QJM

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Q J Med 2003; **96**: 323-324

Editorial

The ethical bureaucracy

Christopher Martyn

Hands up those who think that research ethics committees are doing a good job. Do not expect to see Drs Maskell, Jones and Davies waving. Last month in the QJM, they reported what happened while they were setting up a multicentre study of intrapleural streptokinase.[1] They reckoned that the local investigators spent 62 hours photocopying to produce the 25 296 pieces of paper needed to satisfy the 51 local research ethics committees (LRECs) involved. Others have written about similar experiences.[2]

The present system of research ethics committees in the UK was established in

nature International weekly journal of science

News

Nature **438**, 136-137 (10 November 2005) | doi:10.1038/438136b

Researchers break the rules in frustration at review boards

Jim Giles

Experiments on human subjects go ahead without official approval, says survey.

Problems of Trust

External Influences on Science

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The NEW ENGLAND JOURNAL of MEDICINE

EDITORIAL

◂ Previous Volume 342:1516-1518 May 18, 2000 Number 20 Next ▸

Is Academic Medicine for Sale?

In 1984 the *Journal* became the first of the major medical journals to require authors of original research articles to disclose any financial ties with companies that make products discussed in papers submitted to us.[1] We were aware that such ties were

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Institutional Conflict of Interest

Financial conflicts of interest in a research setting can adversely affect patient care, teaching, and research. Discussions of these conflicts ordinarily focus on issues that arise when individual physicians and biomedical scientists conduct research in which they

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The NEW ENGLAND JOURNAL of MEDICINE

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Maintaining the Public Trust in Clinical Research

The Executive Council of the Association of American Medical Colleges (AAMC) recently approved a report entitled "Protecting Subjects, Preserving Trust, Promoting Progress — Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research."[1] The report provides guidelines to institutions for the oversight and management of individual (i.e., noninstitutional) conflicts of interest related to clinical research. I believe that the principles set forth in the report are crucial to maintaining the long-term health of the academic research enterprise. As a member of the task force that prepared the report and the dean of a medical school, I urge their rapid adoption.

Rationale for New Guidelines

Why was it necessary for the AAMC to establish these uniform standards? The simple answer is that public trust in the biomedical and clinical research enterprise in the United States has decreased in recent years, for two reasons. First, the recent explosion of research findings has not been translated into sufficient clinical advances to meet the high expectations of the public. This translation

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The NEW ENGLAND JOURNAL of MEDICINE

Volume 347:705-708 September 5, 2002 Number 10 Next ▸

Sounding Board: Nonfinancial Conflicts of Interest

"Appropriate management depends on the ethical standards and moral sensitivity of individual investigators, research mentors, IRBs, and institutional leaders."

The dramatic growth in associations between investigators and industry has raised appropriate concern about financial conflicts of interest. Investigators are also faced with potent nonfinancial conflicts of interest. Because career advancement in academic medicine depends on grant awards and research publications, investigators have strong personal interests in the successful completion of their research studies, which often involve human subjects. In this essay, the author explores how nonfinancial interests of investigators can be at odds with the interests of research subjects and outlines an approach to better management of nonfinancial conflicts of interest.

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Problems of Integrity

Science 1 December 2006:
Vol. 314. no. 5804, p. 1353
DOI: 10.1126/science.1137840

EDITORIAL

Responding to Fraud

Donald Kennedy*

Our journal--as well as science with a small "s"--went through a disappointing and troubling experience with the two stem cell papers from the South Korean research group led by Dr. Woo Suk Hwang. As a result of an investigation by a committee from Seoul National University, the first paper from this group, *Science* **303**, 1669 (2004), was found to be fraudulent and was subsequently retracted by *Science*. A second paper, *Science* **308**, 1777 (2005), published a year later, was retracted for the same reasons.

What *Science* did then entailed two steps. First, we compiled a chronological anthology of the editorial review process for both papers; it included all submissions; correspondence among editors, our Board of Reviewing Editors, peer reviewers, authors, and agencies responsible for regulatory oversight in South Korea; and notes on telephone conversations. This material was reviewed by an internal review committee of six in-house editors. This archive and their comments were then sent to an outside committee consisting of three members of our external Senior Editorial

J 2006;333:1088 (25 November), doi:10.1136/bmj.39041.511644.6C

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uide tells editors how to root out plagiarism and fraud

nn Eaton

ondon

itors from some of the leading international biomedical and scientific journals—including the editor of *BMJ*—have joined forces to produce a guide to rooting out poor and unethical practice in science olishing.

e Committee on Publication Ethics has published a practical, step by step guide for journal editors, h 14 flow charts that give straightforward advice on what to do when facing certain publishing emmas.

e flow charts include advice on what editors should do if they suspect plagiarism, fabricated ormation, or redundant or previously published data. They also cover how to deal with requests for anges in authorship, suspected undisclosed interests, and ethical issues.

The NEW ENGLAND JOURNAL of MEDICINE

PERSPECTIVE

Volume 355:2169-2171 November 23, 2006 Number 21

Next ►

Dangerous Deception — Hiding the Evidence of Adverse Drug Effects

Jerry Avorn, M.D.

otember 30 is becoming a day of infamy for drug safety. On that date in 2004, Merck announced that rofecoxib (Vioxx) ubled the risk of myocardial infarction and stroke, and the company withdrew the drug from the market after 5 years of use in re than 20 million patients. On September 30, 2006, a front-page article in the *New York Times* reported that the Food and g Administration (FDA) had issued a warning that the antifibrinolytic drug aprotinin, widely used to reduce perioperative eding in patients undergoing cardiac surgery, could cause renal failure, congestive heart failure, stroke, and death.

me experts had been concerned about aprotinin (Trasylol) ever since its approval in 1993.[1] As Hiatt explains in his Perspective cle in this issue of the *Journal* (pages 2171–2173), one of two epidemiologic studies reported early this year provided support this concern. In an observational study involving 4374 patients who underwent coronary revascularization,[2] Mangano et al. nd that patients who were given aprotinin had an incidence of postoperative renal failure requiring dialysis that was more than ce that among patients who received different agents. Among patients undergoing uncomplicated coronary-artery surgery, those

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EDICINE AND PUBLIC ISSUES

esearch Misconduct, Retraction, and Cleansing the Medical terature: Lessons from the Poehlman Case

larold C. Sox, MD, Editor, and Drummond Rennie, MD

April 2006 | Volume 144 Issue 8 | Pages 609-613

scientific literature is a record of the search for truth. Publication of faked data diverts this search. The scientific community has a y to warn people to ignore an article containing faked data and must try to prevent inadvertent citation of it. The scientific community omplishes these tasks by publishing a retraction and linking it to the fraudulent article's citation in electronic indexes of the medical rature, such as PubMed. This mechanism is far from perfect, as shown by a case history of scientific fraud perpetrated by Eric ehlman, PhD. His institution notified 3 journals that they had published tainted articles. Two journals failed to retract. The third journal acted immediately, but other authors continued to cite the retracted article.

other duty of the scientific community is to verify the integrity of other articles published by the author of a fraudulent article. This task s to the author's institution and requires coauthors to vouch for their article's integrity by convincing institutional investigators that the spect author could not have altered the raw scientific data from their study. Two universities are currently investigating Poehlman's lished research.

ntaining the integrity of the scientific literature requires governmental institutions that have the authority to investigate and punish ty scientists and requires that research institutions investigate alleged fraud. It requires journal editors to issue a retraction when they rn that their journal has published a tainted article. It requires research institutions to accept their responsibility to investigate every

Vol. 291 No. 20, May 26, 2004 TABLE OF CONTENTS >
Original Contribution

Empirical Evidence for Selective Reporting of Outcomes in Randomized Trials

Comparison of Protocols to Published Articles

An-Wen Chan, MD, DPhil; Asbjørn Hróbjartsson, MD, PhD; Mette T. Haahr, BSc; Peter C. Gøtzsche, MD, DrMedSci; Douglas G. Altman, DSc

JAMA. 2004;291:2457-2465.

ABSTRACT

Context Selective reporting of outcomes within published studies based on the nature or direction of their results has been widely suspected, but direct evidence of such bias is currently limited to case reports.

Objective To study empirically the extent and nature of outcome reporting bias in a cohort of randomized trials.

Design Cohort study using protocols and published reports of randomized trials approved by the Scientific-Ethical Committees for Copenhagen and Frederiksberg, Denmark, in 1994-1995. The number and characteristics of reported and unreported trial outcomes were recorded from protocols, journal articles, and a survey of trialists. An outcome was considered incompletely reported if insufficient data were presented in the published articles for meta-analysis. Odds ratios relating the completeness of outcome reporting to statistical significance were calculated for each trial and then pooled to

Scientists behaving badly

Brian C. Martinson, Melissa S. Anderson and Raymond de Vries

Nature **435**, 737-738 (9 June 2005)

Table 1 | Percentage of scientists who say that they engaged in the behaviour listed within the previous three years ($n = 3,247$)

Top ten behaviours	All	Mid-career	Early-career
1. Falsifying or 'cooking' research data	0.3	0.2	0.5
2. Ignoring major aspects of human-subject requirements	0.3	0.3	0.4
3. Not properly disclosing involvement in firms whose products are based on one's own research	0.3	0.4	0.3
4. Relationships with students, research subjects or clients that may be interpreted as questionable	1.4	1.3	1.4
5. Using another's ideas without obtaining permission or giving due credit	1.4	1.7	1.0
6. Unauthorized use of confidential information in connection with one's own research	1.7	2.4	0.8 ***
7. Failing to present data that contradict one's own previous research	6.0	6.5	5.3
8. Circumventing certain minor aspects of human-subject requirements	7.6	9.0	6.0 **
9. Overlooking others' use of flawed data or questionable interpretation of data	12.5	12.2	12.8
10. Changing the design, methodology or results of a study in response to pressure from a funding source	15.5	20.6	9.5 ***
Other behaviours			
11. Publishing the same data or results in two or more publications	4.7	5.9	3.4 **
12. Inappropriately assigning authorship credit	10.0	12.3	7.4 ***
13. Withholding details of methodology or results in papers or proposals	10.8	12.4	8.9 **
14. Using inadequate or inappropriate research designs	13.5	14.6	12.2
15. Dropping observations or data points from analyses based on a gut feeling that they were inaccurate	15.3	14.3	16.5
16. Inadequate record keeping related to research projects	27.5	27.7	27.3

Note: significance of χ^2 tests of differences between mid- and early-career scientists are noted by ** ($P < 0.01$) and *** ($P < 0.001$).

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The Haunting of Medical Journals: How Ghostwriting Sold "HRT"

Adriane J. Fugh-Berman

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Citation: Fugh-Berman AJ (2010) The Haunting of Medical Journals: How Ghostwriting Sold "HRT". PLoS Med 7(9): e1000335. doi:10.1371/journal.pmed.1000335

Published: September 7, 2010

Funding: The author received no specific funding for this article.

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‘Is science bulls—t?’ John Oliver attacks the media’s tendency to turn all scientific studies into ‘gossip’

Matt Bobkin | May 9, 2016 4:31 PM ET
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Problems of Effectivness

Viewpoint:
A method to estimate the cost in lives of ethics board review of biomedical research

S. N. Whitney[1] & C. E. Schneider[2]

From the [1]Department of Family and Community Medicine, Baylor College of Medicine, Houston, TX; and [2]University of Michigan Law School and University of Michigan School of Medicine, Ann Arbor, MI, USA

Keywords: biomedical research/ethics, ethical review, ethics committees, research, government regulation, public policy, research/legislation &jurisprudence.

- When biomedical research produces ***life-saving*** interventions like new drugs and devices, new uses for old drugs and new systems of care, ***time is critical*** – cardiologists want to learn of breakthroughs in treating heart attacks immediately, and intensivists want to reduce central line infections now. ***Medical journals***, through rapid online publication***, labour to save weeks***, days and even hours ***to speed life-saving research to physicians***. Regulatory delay is as harmful as any other delay. Further, biomedical research does not just save lives, it promotes other important social goods, like soothing suffering and diminishing disability. Regulatory delay presumably diminishes these benefits as well in ways that also need to be assessed.

Hyman

- "The available evidence indicates that there are substantial direct and indirect costs associated with IRB oversight of research. IRBs also operate inconsistently and inefficiently, and focus their attention on paperwork and bureaucratic compliance. **Despite their prevalence, there is no empirical evidence that IRB oversight has any benefit whatsoever**—let alone benefit that exceeds the cost."

Research Ecology

- Modern Research is a complex human undertaking
- Highly trained professionals, institutions, funders and research subjects
- Multiple interacting parts
- Most linear view: idea-grant proposal-approvals-study execution-publication-dissemination-action

Richard Smith

- Prepublication peer review is faith based not evidence based, and Sudlow's story shows how it failed badly at *Science*. Her anecdote joins a mountain of evidence of the failures of peer review: ***it is slow, expensive, largely a lottery, poor at detecting errors and fraud, anti-innovatory, biased, and prone to abuse.*** As two Cochrane reviews have shown, the upside is hard to demonstrate. Yet people like Sudlow who are devotees of evidence persist in belief in peer review. Why?


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Peer review for improving the quality of grant applications
Vittorio Demicheli[1], Carlo Di Pietrantonj[2]
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Conclusions

- ***There is little empirical evidence on the effects of grant giving peer review.*** No studies assessing the impact of peer review on the quality of funded research are presently available. Experimental studies assessing the effects of grant giving peer review on importance, relevance, usefulness, soundness of methods, soundness of ethics, completeness and accuracy of funded research are urgently needed. Practices aimed to control and evaluate the potentially negative effects of peer review should be implemented meanwhile.

Time to publication for results of clinical trials (Review)

Hopewell S, Clarke MJ, Stewart L, Tierney J

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Conclusion

- Two studies with a total of 196 trials met the inclusion criteria. In both studies ***just over half of all trials had been published in full.***
- Trials with positive results (i.e. statistically significant in favour of the experimental arm) ***were published in approximately 4 to 5 years.***
- ***Trials with null or negative results*** (i.e. not statistically significant or statistically significant in favour of the control arm) ***were published after about 6 to 8 years***.

Grants

NIH Report Average age of independent investigator award:

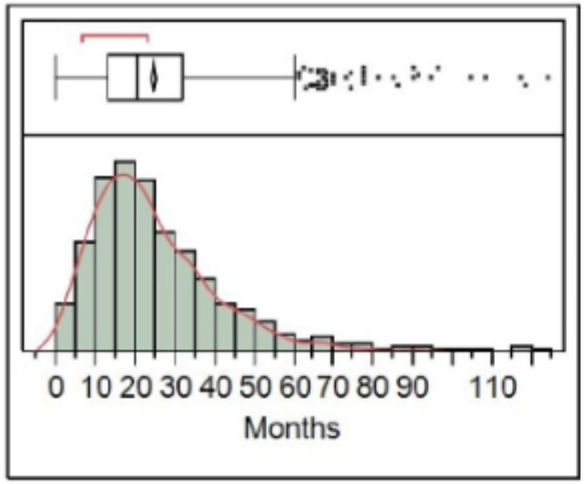
- 42 for PhD
- 43 for MD-PhD

Average NIH funding cycle ***27 months***

Success Rates low

Time to Publication (Ross et al. JAMA 2013)

eFigure: Time to publication after completion among clinical trials registered in ClinicalTrials.gov and published in the biomedical literature (cited in MEDLINE).



Time to approval

Schnitzbauer et al. BMJ 2009

Time taken to get ethics committee approval (time with committee)

Country	No of committees	Median (range) No of days
Austria	2	35 (26 to 44)
Belgium	3	119 (119 to 181)
Finland	1	47
France	1	123
Germany	14	43 (29 to 93)
Italy	7	61 (35 to 107)
Netherlands	2	91 (61 to 120)
Spain	2	75 (72 to 77)
Sweden	2	30
UK:		
National	1	168
Local	3	78 (24 to 98)
Total	4	246 (192 to 266)

Bare Essentials

Canadian guidelines

Tri-Council Policy Statement

Living document, reflecting evolving field of scholarship

HOWEVER

- **It mandates minimum and universal standards**

Ethics review

Research requiring review

REBs are responsible for ethics review of research involving humans as subjects of research

Research Ethics Boards (REBs)

The REB has the authority to approve, disapprove, propose modifications to, or terminate any proposed or ongoing research involving human subjects

Review process

REBs adopt a proportionate approach to ethics review, based on the principle that the more potentially invasive or harmful the research, the more care should be taken in its review.

FOCUS IS ON HUMAN SUBJECT PROTECTION

Fundamental principles

- **The moral imperative of respect for human dignity translates into other correlative ethical principles:**

1. **Respect for free and informed consent**
2. **Respect for vulnerable persons**
3. **Respect for privacy and confidentiality**
4. **Respect for justice and inclusiveness**
5. **Balancing harms and benefits**

Emanuel's 7 Requirements

Table 2. Seven Requirements for Determining Whether a Research Trial Is Ethical*

Requirement	Explanation	Justifying Ethical Values	Expertise for Evaluation
Social or scientific value	Evaluation of a treatment, intervention, or theory that will improve health and well-being or increase knowledge	Scarce resources and nonexploitation	Scientific knowledge; citizen's understanding of social priorities
Scientific validity	Use of accepted scientific principles and methods, including statistical techniques, to produce reliable and valid data	Scarce resources and nonexploitation	Scientific and statistical knowledge; knowledge of condition and population to assess feasibility
Fair subject selection	Selection of subjects so that stigmatized and vulnerable individuals are not targeted for risky research and the rich and socially powerful not favored for potentially beneficial research	Justice	Scientific knowledge; ethical and legal knowledge
Favorable risk-benefit ratio	Minimization of risks; enhancement of potential benefits; risks to the subject are proportionate to the benefits to the subject and society	Nonmaleficence, beneficence, and nonexploitation	Scientific knowledge; citizen's understanding of social values
Independent review	Review of the design of the research trial, its proposed subject population, and risk-benefit ratio by individuals unaffiliated with the research	Public accountability; minimizing influence of potential conflicts of interest	Intellectual, financial, and otherwise independent researchers; scientific and ethical knowledge
Informed consent	Provision of information to subjects about purpose of the research, its procedures, potential risks, benefits, and alternatives, so that the individual understands this information and can make a voluntary decision whether to enroll and continue to participate	Respect for subject autonomy	Scientific knowledge; ethical and legal knowledge
Respect for potential and enrolled subjects	Respect for subjects by (1) permitting withdrawal from the research; (2) protecting privacy through confidentiality; (3) informing subjects of newly discovered risks or benefits; (4) informing subjects of results of clinical research; (5) maintaining welfare of subjects	Respect for subject autonomy and welfare	Scientific knowledge; ethical and legal knowledge; knowledge of particular subject population

*Ethical requirements are listed in chronological order from conception of research to its formulation and implementation.

CFP CANADIAN FAMILY PHYSICIAN

Ask not what your REB can do for you; ask what you can do for your REB

Ross E.G. Upshur, MD MSc CCFP FRCPC

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Research ethics boards (REBs) are perhaps the most unloved component of the

Special Considerations in Frailty Research

Consent

Anticipate and plan for accommodating and responding to cognitive impairment

- Consent shall be given voluntarily.
- Consent can be withdrawn at any time.
- Consent must be informed

Participants in Vulnerable Circumstances

In considering the need for an alteration to consent requirements, researchers and REBs should also consider whether the prospective participants (as individuals, groups, or populations) are in vulnerable circumstances (see Article 4.7). The existence of vulnerable circumstances may require greater effort to minimize risks to participants and/or maximize potential benefits (see Chapter 2, Section B).

- In keeping with the principle of Justice, those who lack the capacity to decide on their own behalf must neither be unfairly excluded from the potential benefits of research participation, nor may their lack of decision-making capacity be used to inappropriately include them in research.
- **Article 4.5** Elderly people shall not be inappropriately excluded from research solely on the basis of their age.

Tips for success

- Do the TCPS tutorial
- Get to know your REB chair
- Take responsibility for research ethics submissions (do not delegate until such time as you are competent and you know the person to whom you have delegated is competent
- Be a good academic citizen: Serve on an REB!

TCPS 2

- Pdf: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/
- Tutorial: http://www.pre.ethics.gc.ca/english/tutorial/