Nuffield Council on Bioethics Annual Report 2005 NUFFIELD COUNCIL™ BIOETHICS

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Foreword by the Chairman

The Nuffield Council on Bioethics remains the only body in the United Kingdom whose terms of reference cover the whole field of bioethics. These are to identify and examine ethical issues raised by new developments in biology and medicine. Our defining characteristic is that, unlike ethics councils in other countries, we are totally independent of Government. This is made possible by the generosity of our three funders, the Nuffield Foundation, the Medical Research Council and the Wellcome Trust. Although we have regular meetings with the funders and governmental bodies such as the Human Genetics Commission, they do not dictate or control what we do. We are always glad to have suggestions for work, but we do not respond to requests to give advice on short-term issues of relatively narrow scope. We choose our own topics and focus on in-depth studies of complex, longer-term issues that are usually still on the horizon. We are helped in doing so by regular Forward Look seminars. This year's meeting followed a stimulating public lecture by Professor Norman Daniels of the Harvard School of Public Health on 'Equity and Health: a Bioethics Agenda for the Next Decade'.

Despite our status as an independent private body we perform an important public function. For this reason, we embarked in 2005 on a new and more open method for selecting Council members who are each appointed for a three-year term renewable once. Unlike government commissions we do not seek to be a representative body, but we aim to draw the members from as wide a range of expertise, experience and background as possible. Our new

procedure involves an annual advertisement for expressions of interest in areas for which a vacancy exists. The Membership Panel has an independent Chair, Dame Elizabeth Butler-Sloss. The Panel makes recommendations to the Council. The first new members to be appointed under this process are Mr Anatole Kaletsky (Editor-at-Large of The Times), Dr Rhona Knight (a GP), and Professor Hugh Perry (a neuroscientist at Southampton University), who start their terms in January 2006. They replace Mr Nick Ross and Professor Martin Raff, who both made outstanding contributions to our work over a six year period.

The major public event of the year was the launch of our Report on The ethics of research involving animals. In her Foreword to the Report, the Chair of our Working Party, Baroness Perry of Southwark, pointed out that the issues have been the subject of public debate for the past four hundred years, and there are strongly held views on all sides, occasionally violently expressed. The remarkable achievement of Baroness Perry and her Working Party, whose members had many different and opposing views, was to avoid the polarisation which has so often stifled rational debate. They did this by setting out in some detail the many scientific uses of animals and the alternatives which are being developed, by a lucid analysis of the ethical basis on which different opinions are held, and by agreeing a short but ground-breaking consensus statement. There are important recommendations for regulation, information and education. The Report has been widely welcomed by those on all sides of the debate as a highly



valuable resource. The Council is deeply grateful to Baroness Perry (who also made a valuable contribution to the general work of the Council during her period of co-option), and to the members of the Working Party for their patient and painstaking work.

The many other activities during 2005 are described in this Annual Report. I draw special attention to the public consultation by our (renamed) Working Party on *Critical care decisions in fetal and neonatal medicine*, and the preparations for our new Working Party on *Public health*, which starts its work in January 2006. I should like to express the Council's appreciation for their hard work, imagination and commitment to the Secretariat, ably led by Professor Sandy Thomas.

bu key 4

Professor Sir Bob Hepple QC, FBA

Introduction

The Nuffield Council on Bioethics examines ethical issues raised by new developments in biology and medicine. Established by the Nuffield Foundation in 1991, the Council is an independent body, funded jointly by the Foundation, the Medical Research Council and the Wellcome Trust.

The Council has achieved an international reputation for addressing public concerns and providing independent advice to assist policy makers and stimulate debate on bioethics.

Terms of Reference

The Council's terms of reference require it:

- 1. to identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern;
- 2. to make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body;
- 3. in the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.

Further information about the Council's method of working and publications can be found on the Council's website: www.nuffieldbioethics.org



Membership of Council¹

a Professor Sir Bob Hepple QC, FBA (Chairman)

Emeritus Master, Clare College, and Emeritus Professor of Law, University of Cambridge; Barrister at Blackstone Chambers

b Professor Catherine Peckham CBE (Deputy Chairman)

Professor of Paediatric Epidemiology, Institute of Child Health, University College London

c Professor Tom Baldwin

Department of Philosophy, University of York

d Professor Margaret Brazier OBE

School of Law, University of Manchester (co-opted member of the Council for the period of chairing the Working Party on Critical care decisions in fetal and neonatal medicine: ethical issues)

e Professor Roger Brownsword Centre for Medical Law & Ethics, King's

College, London

f Professor Sir Kenneth Calman KCB FRSE Vice-Chancellor and Warden, University

Vice-Chancellor and Warden, University of Durham

g The Rt Reverend Richard Harries DD FKC FRSL

Bishop of Oxford

h Professor Peter Harper

Professor of Medical Genetics at University of Wales College of Medicine, Cardiff, and Consultant Physician and Medical Geneticist at University Hospital of Wales

i Professor Peter Lipton

Head of the Department of History and Philosophy of Science, University of Cambridge

j Lord Plant of Highfield

Centre for Medical Law & Ethics, King's College, London

k Baroness Perry of Southwark

(until May 2005) Member of the House of Lords and Pro-Chancellor of the University of Surrey (co-opted member of Council for the period of chairing the Working Party on *The ethics of research involving animals*)

l Professor Martin Raff FRS

(until May 2005) Professor of Biology (Emeritus), University College London

m Mr Nick Ross (until May 2005) Broadcaster

n Professor Herbert Sewell

Pro-Vice Chancellor and Professor of Immunology, University of Nottingham

o Professor Peter Smith CBE

Professor, Infectious Disease Epidemiology Unit, Department of Infectious Tropical Diseases, London School of Hygiene and Tropical Medicine

p Professor Dame Marilyn Strathern FBA

Mistress of Girton College, Cambridge and William Wyse Professor of Social Anthropology, University of Cambridge

q Dr Alan Williamson FRSE

Consultant on Biotechnology

Secretariat

Professor Sandy Thomas

Director

Dr Catherine Moody

Deputy Director

Mr Harald Schmidt

Assistant Director

Ms Julia Fox (until March 2005)

PA to the Director and Secretariat
Administrator

Ms Carol Perkins (from March 2005)

PA to the Director and Secretariat
Administrator

Ms Catherine Joynson

(from January 2005) Communications & Externals Affairs Manager

Ms Caroline Rogers

Research Officer

Ms Julia Trusler (from October 2005) Research Officer

Ms Elaine Talaat-Abdalla

(until June 2005)

Secretary

Ms Clare Stephens (from August 2005) Secretary

Mr Mun-Keat Looi (until September 2005)
Information Assistant

¹Positions correct as of 1 January 2006

Personnel

Professor Martin Raff, Emeritus Professor of Biology, University College London, and Mr Nick Ross, broadcaster, retired from Council in March 2005. Both had served two terms on Council and were members of the Working Party on *The ethics of research involving animals*. Baroness Perry of Southwark was co-opted onto Council for the period of chairing the Working Party on *The ethics of research involving animals*, which completed its work in May 2005.

A new process for appointing members to Council was implemented in 2005.
Vacancies in specific areas of expertise were advertised in one or more newspapers and on the Council's website.
A list of applications was reviewed by the

Membership Panel and a selection of suitable candidates was then put forward to the Council for consideration. This process led to the appointment of Dr Rhona Knight, a GP and lecturer, Anatole Kaletsky, Editor-at-Large of *The Times*, and Professor Hugh Perry, a neuroscientist from Southampton University, who will begin their terms on Council in January 2006.

Four new members of staff joined the Secretariat during 2005: Catherine Joynson, Carol Perkins, Clare Stephens and Julia Trusler. Julia Fox, PA to the Director and Secretariat Administrator, retired in March after almost eight years of service. Elaine Talaat-Abdalla, Secretary, and Mun-Keat Looi, Information Assistant, also left



the Secretariat in 2005. Anais Rameau joined the Council as an intern for eight weeks to help to prepare a background paper on the ethics of public health.

2005 Calendar

January

1st Council meeting

February

3rd meeting of Working Party on *Critical*Care Decisions in Fetal and Neonatal
Medicine: Ethical Issues²

Meeting with members of Comité Consultatif National d'Ethique

March

2nd Council meeting

Launch: The ethics of research related to healthcare in developing countries: a follow-up Discussion Paper

April

4th meeting of Working Party on *Critical Care Decisions in Fetal and Neonatal Medicine: Ethical Issues*

May

Lecture: Professor Norman Daniels, Harvard School of Public Health

Forward Look Seminar

Launch: The ethics of research involving animals

June

3rd Council meeting

July

5th meeting of Working Party on *Critical*Care Decisions in Fetal and Neonatal
Medicine: Ethical Issues (cancelled)

August

5th meeting of Working Party on *Critical*Care Decisions in Fetal and Neonatal
Medicine: Ethical Issues (re-arranged)

September

6th meeting of Working Party on Critical Care Decisions in Fetal and Neonatal Medicine: Ethical Issues

October

Public debate on *The ethics of research involving animals*, Dana Centre

Parliamentary briefing on *The ethics of research involving animals*, House of Lords

4th Council meeting

November

7th meeting of Working Party on Critical Care Decisions in Fetal and Neonatal Medicine: Ethical Issues

Meeting with members of the European Group on Ethics in Science and New Technologies

5

Sixth Forum of National Ethics Committees, London

²The title of this Working Party was changed from *The ethics of prolonging life in fetuses and the newborn* in October 2005.

Report by the Director

2005 was a productive and challenging year for the Council in which it produced two new publications. One, a Discussion Paper, The ethics of healthcare-related research in developing countries, followed up a 2002 Report on this topic. Based on a Workshop held in Cape Town, South Africa, funded by the UK Medical Research Council, the Wellcome Trust, the UK Department for International Development and the Rockefeller Foundation, it focused on research that is funded by wealthy countries but carried out in poor countries. The Paper, which has been widely disseminated in developing countries, concluded that applying recently revised and new international guidance is often fraught with difficulty. The second publication was a report published in May on The ethics of research involving animals. This topic was undoubtedly one of the most challenging that the Council has yet considered. An 18-strong Working Party, with a diverse range of views, together with the Secretariat worked unstintingly to produce a Report that provides an ethical framework for thinking through the complex and difficult issues that arise. I am greatly indebted to the Chair, Baroness Perry, and to Harald Schmidt, Secretary to the Working Party.

A new Working Party, chaired by Professor Margot Brazier, which started work in October 2004, is focusing on the ethical, social, legal and economic issues involved in critical care decisions in fetal and neonatal medicine. Prompted by our ability today to sustain the life of babies who in the past might not have survived a difficult birth and the knowledge that many very premature babies are at risk of disability, this study aims to produce

guidelines for doctors, nurses, and families in making decisions about whether to introduce, continue or withdraw lifesustaining treatment for babies who are critically ill. By the end of the 2005, the group had produced the first draft Report for the Council to review.

The Council regularly reviews its reports to ascertain whether follow up is needed. The Council's first Report on *Genetic Screening: Ethical issues* was published in 1993. In 2005, a small Working Group concluded that the commissioning of a new Report would be premature and that the ethical principles identified in the original Report were sufficient to guide current research and practice. However, the Council will publish in 2006 an account that describes developments in science and policy which updates the original Report.

2005 was also an important year for the Council as it prepared its funding bid for 2007-2011. In 2000, the Council's three sponsors, the Nuffield Foundation, the Medical Research Council and the Wellcome Trust, agreed that the Council should move to a five-year cycle of funding, with a new bid being prepared in the fourth year. The bid, submitted in September 2005, describes the Council's work over the previous five-year period and sets out its proposed work programme for the next period. Firm plans have been drawn up for the first two years. Thereafter, topics have yet to be agreed as the Council usually plans its work with a two-year lead time to allow some flexibility. The bid will be reviewed by eight international external experts and a decision made in 2006. As part of the bid, the Council prepared an analysis which



aimed to address the often difficult task of determining the impact of its work. An analysis of the take-up of over 170 recommendations made over 12 years proved to be an instructive exercise that will be incorporated in the Council standard procedures for monitoring its impact.

Finally, I should like to thank all the staff in the Secretariat who worked so hard in an exceptionally challenging year. In particular, I should also like to pay tribute to Julia Fox who retired in 2005 after giving outstanding service to the Council and its Working Parties. As PA and Administrator, she not only played a major role in expanding the capacity of the Secretariat but also set high standards for welcoming and supporting the many experts associated with the Council over her many years of service.



Professor Sandy Thomas

Forward Look seminar and lecture

The Council considers topics for future work and broader themes at its annual Forward Look Seminar. This year, a public lecture was arranged on the evening before the Seminar, Professor Norman Daniels of the Harvard School of Public Health, USA, gave his talk, Equity and Health: A Bioethics Agenda for the Next Decade, to approximately 110 people at the University of London on 11th May. A transcript of the lecture can be found on the Council's website at: www.nuffieldbioethics.org. Around 60 guests attended a reception at 28 Bedford Square afterwards. The Council plans to host another public lecture on a topic related to bioethics in 2007.

The following day, guests Professor Daniels and Dr Bettina Schöne-Seifert, a member of the German Nationale Ethikrat, joined Council members at the Forward Look Seminar. Participants reflected on the issues raised in Professor Daniels' lecture and discussed ethical issues raised by three separate topics: global health inequities, nanotechnology and neuroscience. The Council will hold a Workshop in May 2006 to explore further the ethical issues raised by neuroscience.





The ethics of research involving animals



Membership of Working Party

Baroness Perry of Southwark (Chairman)

House of Lords Science and Technology Select Committee and Pro-Chancellor of the University of Surrey

Professor Kenneth Boyd

Professor of Medical Ethics, University of Edinburgh

Professor Allan Bradley FRS

Director, The Wellcome Trust Sanger Centre, Cambridge

Professor Steve Brown

Director, MRC Mammalian Genetics Unit, MRC Mouse Genome Centre, Medical Research Council, Harwell

Professor Grahame Bulfield

Vice-Principal and Head of College of Science and Engineering, University of Edinburgh

Professor Robert D Combes

Scientific Director, Fund for the Replacement of Animals in Medical Experiments (FRAME)

Dr Maggy Jennings

Head of Research Animals Department, Royal Society for the Prevention of Cruelty to Animals

Professor Barry Keverne

Director of sub-department of Animal Behaviour, Department of Zoology, University of Cambridge

Dr Mark Matfield

Executive Director, The Research Defence Society

Dr Judy MacArthur Clark

Chair, Farm Animal Welfare Council

Professor Ian McConnell

Professor of Veterinary Science, Centre for Veterinary Science, Department of Clinical Veterinary Medicine, University of Cambridge

Dr Timothy H Morris

Head of Comparative Medicine and Investigator Support, Laboratory Animal Science (LAS) UK, GlaxoSmithKline

Professor Martin Raff FRS

MRC Laboratory for Molecular Cell Biology, University College London and member of the Nuffield Council

Mr Nick Ross

Broadcaster and member of the Nuffield Council

Dr Lewis Smith

Syngenta CTL

Professor John Spencer

Professor of Law, Selwyn College, University of Cambridge

Ms Michelle Thew

Chief Executive Officer, Animal Protection Institute, Sacramento, USA

Professor Jonathan Wolff

Chief Executive Officer, Animal Protection Institute, Sacramento, USA

2003 to consider the issues surrounding research involving animals. It was comprised of academic and industry scientists, philosophers, members of animal protection groups, and a lawyer, to ensure that a wide range of perspectives were brought to the discussion. The

Working Party met twelve times between February 2003 and December 2004, and

Acknowledging that many people feel very

deeply about this topic, the Council

established a Working Party in February

held several fact-finding meetings with experts involved in the debate. Three evidence reviews were commissioned relating to the assessment of pain, suffering and distress in animals. A consultation with the public yielded 168 responses, many of which are available on the Council's website. The Report was peer reviewed by a panel of ten experts in July 2004, approved by Council in March 2005 and published in May 2005

In May 2005, the Council published the Report, *The ethics of research involving animals*, which seeks to clarify the debate and aims to help people think through the scientific and ethical issues that it raises. It

also makes practical recommendations for future policy and practice. A

Report³ and it was downloaded from the website more times in its first

year than any other publication produced by the Council. A short Guide

dissemination activities, including public meetings and a parliamentary

wide range of organisations involved in the debate welcomed the

to the Report was published in November 2005, and a number of

briefing, were carried out in the months after publication.



Terms of reference

- 1 To review recent, current and prospective developments in the scientific use of non-human animals, including genetic modification or cloning;
- **2** To assess the ethical implications of these developments, and, in doing so, to consider arguments about the differing status of various non-human animals and the implications of such arguments on their use in research;
- **3** To examine ways of assessing the costs and benefits of the scientific use of non-human animals;
- 4 To assess ways of regulating and enhancing good practice;
- 5 To assess the ethical implications of using alternatives to non-human animals in different fields of research;
- 6 To identify and review developments and differences internationally in the use of non-human animals in research and its regulation;
- 7 To explore ways of stimulating public debate and providing information and education about the issues involved.

³ See page 13 for some examples of comments in response to the Report.
⁴ www.nuffieldbioethics.org/go/ourwork/animalresearch/introduction

Report launch

The Report: findings

Too often the debate on research involving animals has been presented in a polarised manner, differentiating only between those 'for' or those 'against' all research involving animals. This is overly simplistic. There is in fact a continuum of views between these two ends of the spectrum. Improving the quality of the debate and promoting the Three Rs (Refinement, Reduction and Replacement) are crucial to reducing disagreement on animal research.

Ethical issues

A number of ethical viewpoints on research involving animals are described in the Report and the reader is invited to decide which they find to be the most acceptable. Despite the range of views that exist, the Report includes a 'Consensus Statement' that identifies agreement on several important issues.

The scientific validity of animal research

The Working Party concluded that, because of biological similarities between animals and humans, in principle animals can be useful models for studying aspects of human biology and disease and the likely effects of chemicals and medicines. However, the usefulness of animal models has to be judged on a case by case basis for each type of research or testing. The Working Party recommended that the Home Office, in liaison with major funders of research, animal protection groups and industry associations, should consider ways of funding and carrying out reviews on the scientific validity of animal research in specific areas.

Improving the quality of the debate

The Working Party sought to make unambiguous recommendations for policy and practice in order to reduce existing disagreement on research involving animals. It agreed that more can and must be done by all those involved to improve the quality of the debate about animal research. It recommended that:

- clearer information should be made available on how many animals of a particular species experience pain and suffering during experiments, to what degree and for how long;
- researchers at animal research facilities must find more ways to open themselves to two-way dialogue in order to improve and sustain public trust;
- animal protection groups and organisations representing those involved in animal research should produce fair and balanced information.



The role of the Three Rs

The importance of the Three Rs to reduce suffering as far as possible, and especially the need to find Replacement methods that avoid using animals, cannot be overstated. Current law says that animals should only be used for research if there is no other way of obtaining the results and if the benefits of the work outweigh the costs to the animals involved. A range of alternatives have been developed but there is a continued need to question why more alternatives are not available. The Working Party recommended that:

- a thorough analysis of the scientific barriers to Replacements should be undertaken:
- published papers should include more information on how the Three Rs have been applied in the work described;
- the ethical review process should play a more active role in promoting the Three Rs;
- the Government should consider which 'markers of reduction' can be set, for example, to reduce research that causes substantial suffering.

The Report was launched at a public meeting held at the British Library

Conference Centre on 25th May 2005.

Members of the Working Party presented the findings of the Report and a general discussion followed. Around 80 people participated in the meeting, including researchers, journalists, representatives from animal protection groups, organisations representing those involved in animal research and medical charities, MPs, Peers and members of the public.

Copies of the Report, together with letters highlighting specific recommendations, were sent to over 20 governmental and non-governmental organisations, as well as 850 other stakeholders. In the first week after publication the Report was downloaded 15,000 times from the website. Several organisations released

press statements describing their reactions to the Report, including The Royal Society, The British Union for the Abolition of Vivisection, The Association of the British Pharmaceutical Industry, the National Centre for the Three Rs, and Animal Aid.



Comments in response to the Report

"The National Centre will give close consideration to the recommendations in the report as part of our work to advance the ethical principles of the 3Rs which underlie the humane use of animals."

Dr Vicky Robinson, Chief Executive, National Centre for the Replacement, Refinement and Reduction of Animals in Research

"The report rightly counsels that there's no room for complacency about the validity of animal experiments."

Dr Gill Langley, Scientific Adviser, Dr Hadwen Trust for Humane Research

"The Nuffield Council on Bioethics is to be congratulated on having addressed a field which is vigorously debated but rarely illuminated. I have not previously encountered a document in which the arguments for and against the use of animals in science are presented in such a dispassionate and balanced way."

Bryan Howard, President, Laboratory Animals Science Association

"We have tried to analyse the ethical bases on which different opinions on research involving animals are held."

Baroness Perry of Southwark, Chair of the Working Party

Highlights of media coverage

A media briefing was held at the Science Media Centre on 23rd May in order to inform journalists about the main messages of the Report in advance of the launch. Media interest continued during the rest of the year.

Date	Media	Headline
25 May	Today Programme, BBC Radio 4	Feature on the findings of the Report
25 May	The Times	Call for review of animal testing
25 May	The Guardian	Scientists told: reduce animal experiments
25 May	BBC One O'clock and Six O'Clock News	Feature on the findings of the Report
26 May	Nature	UK panel urges animal researchers to go public
7 June	Cambridge Evening News	University welcomes new animal research report
7 July	Hospital Doctor	Honesty is the best policy for animal research
25 August	The Times	Use of animals still vital to progress, say top scientists
August	The Chemical Engineer	Animal research: unravelling the ethical debate
October	BBC Focus Magazine	What are the alternatives?
Winter issue	European Pharmaceutical Contractor	Research involving animals: the ethical issues (article by Lady Perry)
December	ATLA, Alternatives To Laboratory Animals	Comment. The ethics of research involving animals: The Report of the Nuffield Council on Bioethics, May 2005. Four reviews of the Report.

Post-publication activities

By the end of the year, the Report had been downloaded from the Council's website 53,000 times. Members of the Secretariat and the Working Party had presented the findings of the Report at a number of international conferences, and Report-related materials were sent to other events. A short eight-page *Guide to the Report* was produced and published in November 2005.⁵

Educational activities

The Council and the Nuffield Curriculum Centre (NCC) organised a focus group meeting in October where teachers and experts discussed educational resources on research involving animals. This topic is rarely covered in schools and, if it is, there is little guidance on where it should fit within the curriculum or how to structure a lesson. Resources to help teachers plan and conduct debates on the topic will be developed in 2006.





Parliamentary activities

MPs, peers and civil servants attended a Parliamentary Briefing organised by the Council in the House of Lords on 18th October. Baroness Perry of Southwark chaired the event and Dr Timothy Morris, Professor Jonathan Wolff, Professor Bob Combes and Ms Michelle Thew presented the findings of the Report and took questions from the audience. Members of the Working Party also met with a number of MPs on an individual basis to discuss the Report's conclusions in relation to the new EU chemicals legislation (REACH). In November 2005, Dr Ian Gibson MP tabled a parliamentary Early Day Motion (EDM) welcoming the Report and supporting the Council's concerns about the potential impact of REACH to greatly increase animal testing. By the end of 2005 it had received 52 signatures of support.

Public debate

The Council collaborated with the Dana Centre (a centre where adults can take part in debates about contemporary science, technology and culture) to organise a free public discussion on the ethics of research involving animals on 12th October 2005. Professor Albert Weale, a former member of the Council chaired the event and the speakers were Professor Jonathan Wolff, Professor Steve Brown and Mr David Thomas (British Union for the Abolition of Vivisection). The event was fully booked and around 80 people attended.



work in progress





Critical care decisions in fetal and neonatal medicine: ethical issues

Membership of Working Party

Professor Margaret Brazier OBE (Chair)

Professor of Law, University of Manchester

Professor David Archard

Professor of Philosophy and Public Policy, Institute of Environment, Philosophy & Public Policy, Furness College, University of Lancaster

Professor Alastair Campbell

Emeritus Professor of Ethics in Medicine, Centre for Ethics in Medicine, University of Bristol

Professor Linda Franck

Professor and Chair, Children's Nursing Research Centre for Nursing and Allied Health Professions Research, Great Ormond Street Hospital and Institute of Child Health

Ms Bonnie Green

Head of Professional and Public Affairs. BLISS – the premature baby charity

Professor Erica Haimes

Executive Director, Policy, Ethics & Life Sciences Research Institute Bioscience Centre, Newcastle upon Tyne

Dr Monica Konrad

Rausing Fellow in Collaborative Anthropology, Department of Social Anthropology, University of Cambridge

Professor Neil Marlow

Professor of Neonatal Medicine, School of Human Development, Queen's Medical Centre, Nottingham

Professor Catherine Peckham (Deputy Chair of the Council)

Professor of Paediatric Epidemiology, Institute of Child Health, University College London

Dr Stavros Petrou

Health Economist. National Perinatal Epidemiology Unit (NPEU), University of Oxford

Professor Charles Rodeck

Head of Department, Department of Obstetrics and Gynaecology, University

Dr Philippa Russell CBE

Disability Rights Commissioner; Policy Adviser for Disability, National Children's Bureau, London

Partner, Leigh, Day & Company, Solicitors, London

Professor Andrew Whitelaw

Professor of Neonatal Medicine, University of Bristol Medical School, Bristol

Terms of reference

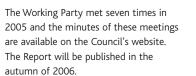
- 1 To identify and consider ethical, social, economic and legal issues arising from recent developments in fetal and neonatal medicine relating to prolonging life.
- 2 To examine scientific and medical research in these fields, considering in particular:
 - a. diagnostics;

 - c. neonatal care (including resuscitation);
 - d. recent evidence on the capacity of fetuses and the newborn to experience pain and suffering.
- 3 To examine current medical practices in these fields and their outcomes in the UK and more widely. In particular to review:
 - a. implications arising from the possibility of survival of premature babies of increasing frailty and at lower ages;
 - b. the relationship between changing survival rates and longer term outcomes.
- 4 To consider issues raised by advances in research and practice, particularly:
 - a. arguments about the moral and legal status of fetuses beyond the first trimester and the newborn;
 - b. the ethical and legal basis for providing, withdrawing or withholding life-prolonging treatment;
 - c. the process of decision-making, including the relative roles of families and healthcare professionals;
 - d. the availability of support for families in the short and the long term;
 - e. resource implications for providers of healthcare, education and social care.
- 5 In light of the above, to make recommendations.



College London

Ms Anne Winyard



The Council established a Working Party in October 2004 to consider

the ethical, social, legal and economic issues involved in critical care

sustain the life of extremely premature or critically ill babies who in

the past would not have survived birth. Many such babies do well but

those of their families will develop. This uncertainty raises difficulties

for parents and doctors when making decisions about treatment.

it is difficult to predict which babies will thrive and how their lives and

decisions in fetuses and the newborn. Modern medicine can now

Public consultation

A consultation with the public was held between March and June 2005. The Consultation Paper provided background information and posed a number of questions to respondents, such as:

- How should decisions be made about whether or not to intervene to prolong the life of a fetus or newborn baby?
- Who is best placed to judge the quality of life for a child?
- How much weight (if any) should be given to economic considerations in determining whether to prolong the life of fetuses or the newborn?
- Would drawing up more directive professional guidance be helpful to parents and professionals?

Copies of the Consultation Paper were distributed to approximately 1,200 individuals and organisations, and it was downloaded from the Council's website 3,800 times. Over 100 responses were received from a range of individuals and organisations and these are being considered carefully by the Working Party. The Council is grateful to everyone who contributed to the consultation.



"By listening to what people have to say, the Working Party will gain a better insight into these highly sensitive issues."

Professor Margaret Brazier, Chair of the Working Party

Fact-finding meetings

The group held a number of fact-finding meetings with the following experts and organisations during 2005:

- BLISS, the premature baby charity
- Department of Neonatal Medicine, Homerton Hospital, Hackney, London
- Department of Neonatal Medicine, St Mary's Hospital, Manchester
- University of Nottingham, Academic Division of Child Health, Queen's Medical Centre
- Ms Jane Fisher, Director, Antenatal Results and Choices

Further fact-finding meetings are planned for 2006, including meetings with experts in France and the Netherlands.

Inter-faith Workshop

An Inter-faith Workshop was held in September 2005 to enhance the Working Party's understanding of the diversity of approaches to critical care decision making in fetal and neonatal medicine. The twelve participants included representatives from the Christian, Jewish, Hindu, Buddhist and Muslim faiths.

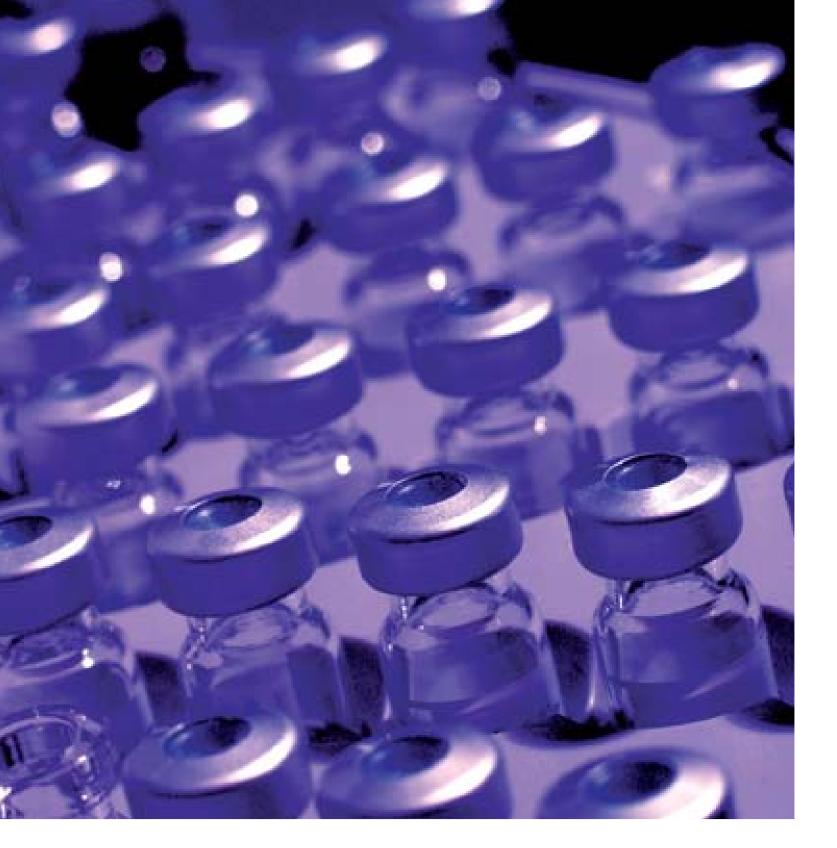


Highlights of media coverage

Views on critical care decisions in the newborn received regular media attention in 2005. The Councils' public consultation, the court case involving Charlotte Wyatt, and debate about setting a minimum age for resuscitation all contributed to the continuing interest of journalists in the topic. Members of the Working Party gave a number of interviews to raise awareness of the issues involved.

Date	Media	Item headline/description
6 January	The Guardian	Study reveals hazards facing premature babies (comments from Professor Neil Marlow).
25 January	BBC Radio 4	Case notes – Premature babies (participation by Professor Neil Marlow)
10 March	BBC News Online, BBC Radio 5 Live and BBC Radio Wales	Coverage of the Council's public consultation
24 March	Operating Theatre Journal	Nuffield Council on Bioethics seeks views on prolonging life in fetuses and the newborn
6 June	The Daily Mail	Let premature babies die, says ethics expert
21 June	BBC Radio 4, Woman's Hour	Feature on treating premature babies (participation by Ms Bonnie Green)
30 July	BBC News Online	Premature babies 'need advocates' (comments from Professor Andrew Whitelaw)
31 July	BBC Radio 5 Live	Too Young to Live (participation by Professor Neil Marlow, Ms Bonnie Green, Dr Philippa Russell and Professor Andrew Whitelaw)
September	Journal of Neonatal Nursing	Decisions at the beginning of life (article by Dr Catherine Moody and Professor Margot Brazier)





Public health: ethical issues

Membership of Working Party

Professor Sir John Krebs (Chair)

Principal, Jesus College, Oxford.

Dr Raghib Ali

Clinical Lecturer, Department of Clinical Pharmacology, Green College, University of Oxford

Professor Tom Baldwin

Department of Philosophy, University of York, Member of Council

Professor Roger Brownsword

Professor of Law, King's College London, Member of Council

Professor Sir Kenneth Calman KCB FRSE

Vice-Chancellor and Warden, University of Durham, Member of Council

Professor Christine Godfrey

Professor of Health Economics, Centre for Health Economics and Department of Health Sciences and Clinical Evaluation, University of York

Professor Trisha Greenhalgh OBE

Professor of Primary Health Care and Programme Director, Unit for Evidence-Based Practice and Policy, Department of Primary Care and Population Sciences (PCPS), University College London

Professor Sally McIntyre

Director, Medical Research Council Social and Public Health Sciences Unit, University of Glasgow

Professor Jonathan Montgomery

Professor of Health Care Law, University of Southampton School of Law

Julia Unwin

Senior Associate, Kings Fund and Deputy Chair, Food Standards Agency

A new Working Party on *Public health: ethical issues* will meet for the first time in January 2006. Making use of case studies, the group will consider ethical issues in relation to the balance between individual choice and community benefit.

Public health has been described as 'the science and art of preventing disease, prolonging life and promoting health through organised efforts of society' 6. Over the centuries, public health has been significantly improved by measures such as vaccination programmes. However, these types of interventions also raise a number of complex ethical issues.

The Working Party, to be chaired by Professor Sir John Krebs, Principal, Jesus College, Oxford, will examine the issues that are raised by reconciling individual choice of lifestyles and claims to entitlement to healthcare with ensuring benefits to the wider population. It will draw on case studies to consider questions such as: what is the role of government in influencing health-related behaviour? How should limited health resources be

efficiently and fairly distributed? Should systems of public healthcare, like the NHS, provide treatment to individuals who have behaved in ways that harm their health? How should the circumstances in which people make choices be taken into consideration? And what are the obligations of governments in controlling the spread of infectious diseases?

A number of controversial policy developments have shown how public health measures are being increasingly questioned. For example, three Suffolk primary care trusts recently announced plans to deny obese people hip and knee replacements, which has drawn criticism from patient groups.⁷ The government's strategy to increase taxes on cigarettes and introduce a smoking ban in most enclosed public and work places has also

been widely debated. Other concerns have ranged from criticism about the preparedness of authorities in the case of an avian flu epidemic, to dissatisfaction with policies aimed at motivating people to behave in a way that promotes the health of the population.

The Working Party includes members with expertise in health economics, law, philosophy, public health policy, health promotion and social science. The group will meet throughout 2006 and 2007, and their discussions will be informed by a number of fact-finding meetings. Members of the public, professionals and organisations will be invited to contribute to a consultation exercise in the summer of 2006. A Report is expected to be published in autumn 2007.

⁶ Faculty of Public Health at the Royal College of Physicians of the United Kingdom. See http://www.fphm.org.uk/about_faculty/what_public_health/default.asp

⁷ BBC News Online (23 Nov 2005) *Obese patients denied operations*, available at: http://news.bbc.co.uk/1/hi/england/suffolk/4462310.stm

Accessed on: 21 March 2006



The Council instigates a programme of follow-up activities after each Report is published. Initially, external relations activities, such as media coverage, presentations at conferences and communication with a wide range of stakeholders ensure effective dissemination of the Report.8 In the next phase, uptake of the Council's recommendations by the appropriate organisations is monitored and encouraged. At a later stage, steps may be taken to consider new developments in the form of a follow-up workshop or short publication. Follow-up activities continued to be prominent in the Council's work during 2005.

⁸ See External Relations section for more information.



The ethics of research related to healthcare in developing countries: a follow-up Discussion Paper

Membership of Steering Committee

Professor Zulfiqar Bhutta

Professor of Paediatrics, Aga Khan University, Pakistan

Professor Sir Kenneth Calman KCB FRSE

Vice-Chancellor and Warden, University of Durham, member of the Nuffield Council on Bioethics, and former Chairman of the Working Party on the ethics of research related to healthcare in developing countries

Dr Soledad Diaz

Consultorio De Plantification Familiar, Institute Chileno de Medicina Reproductiva, Santiago, Chile

Dr Imogen Evans

Research Strategy Manager, Medical Research Council, London

Dr Richard Lane

Former Head of International Programmes, The Wellcome Trust, London

Dr Alwyn Mwinga

Project Co-ordinator, UNZA-UCLMS Project, University Teaching Hospital Lusaka

Professor Catherine Peckham CBE

Professor of Paediatric Epidemiology, Institute of Child Health, University College London, Deputy Chairman of the Nuffield Council on Bioethics, and former member of the Working Party on the ethics of research related to healthcare in developing countries

Professor Prescilla Reddy

Director of Health Promotion Research and Development, South African MRC

Professor Peter Smith CBE

Department of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine, and former member of the Working Party on the ethics of research related to healthcare in developing countries

Dr Bella Starling

Programme Officer, Biomedical Ethics, The Wellcome Trust, London

In March 2005, the Council published a Discussion Paper on *The ethics of research related to healthcare in developing countries* as a follow-up to its 2002 Report on the same topic. It concluded that applying new or updated international guidance on healthcare-related research in developing countries in practice is often fraught with difficulty, and that existing guidelines are often inconsistent and inappropriate for the developing country setting.

Research in developing countries is crucial for improving healthcare by providing appropriate treatments and preventing disease. However, lack of resources and weak infrastructure mean that researchers in developing countries are often unable to conduct their own clinical research. As they increasingly establish partnerships with groups from developed countries, a sound ethical framework is a crucial safeguard to

avoid possible exploitation of research participants in these circumstances.

The Council published a report on the ethics of research related to healthcare in developing countries in 2002.⁹ Since then, a number of international organisations have revised existing guidelines or prepared new ones. As a follow-up to its 2002 report, the Council held a Workshop, co-hosted with

the Medical Research Council of South Africa, in February 2004 to give researchers from around the world the opportunity to exchange experiences and consider how the new guidance is implemented in practice. The discussions that took place at the Workshop are summarised in the follow-up Discussion Paper.

⁹ Nuffield Council on Bioethics (2002) *The ethics of research related to healthcare in developing countries* (London: NCOB). Available at: http://www.nuffieldbioethics.org/go/ourwork/developingcountries/publication_309.html

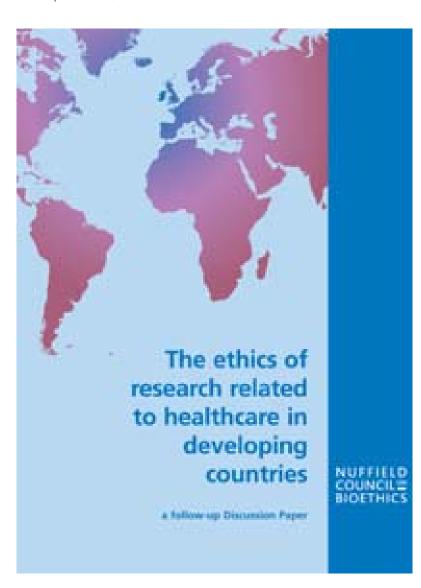
The ethics of research related to healthcare in developing countries: a follow-up Discussion Paper

The Discussion Paper

The Workshop delegates emphasised that when the different guidelines are compared, they are inconsistent in some areas. For example, the guidelines disagree about:

- the kind of information that should be provided to participants when seeking their consent;
- whether new medicines should be compared with the universal standard of care (best available alternative) in trials in developing countries as they are in developed countries;
- whether a placebo should be used in research, as a comparison for the medicine being tested, when an effective treatment is available;
- the extent to which research participants are owed access to medicines after the research is complete; and
- the degree of involvement of the developing country in the ethical review process.

In addition, some of the guidelines set standards that are inappropriate for the developing country setting. Delegates at the Workshop provided a number of case studies that demonstrate the difficulties of adhering to the new guidance. These include obtaining consent in emergency situations, providing the universal standard of care for control groups in vaccine trials, and securing guarantees from sponsors or physicians that access to medicines will be provided to participants once a trial is over.



Launch

The Discussion Paper was launched on 17th March 2005 at an afternoon seminar held at 28 Bedford Square, London. Around 40 participants gathered to discuss the findings with Steering Committee members Professor Peter Smith and Professor Catherine Peckham. The Wellcome Trust's new guidelines on conducting research in developing countries were launched at the same event.



Printed copies of the Discussion Paper were sent to around 900 relevant organisations and interested individuals. It was downloaded from the Council's website 11,400 times in the first week of publication.

Highlights of media coverage

Date	Media	Item headline/description
17 March	Medical News Today	Discussion Paper on ethics of research in developing countries finds problems in practice
19 March	British Medical Journal	Nuffield Council calls for ethical framework for developing world research
30 March	Financial Times	US under fire over clinical trials in developing world

Post-publication activities

In the months after publication, members of the Steering Committee and Secretariat undertook a number of initiatives to raise awareness of the Discussion Paper. Several presentations on the Paper were given at

international meetings and Professor Sandy Thomas, Director, discussed the findings with local organisations and researchers in Malawi, Tanzania and India. Requests for the Discussion Paper were received from Africa, Asia, North and South America, and it had been downloaded over 17,000 times from the Council's website by the end of the year.

Highlights of presentations

Date	Meeting	Title	Speaker
18 March	Global Forum on Bioethics in Research VI, Blantyre, Malawi, Africa	The ethics of research related to healthcare in developing countries	Professor Sandy Thomas
13 June	Commission on Intellectual Property Rights, Innovation and Public Health, World Health Organization, Geneva, Switzerland	The ethics of clinical research in developing countries – is there a Roadmap?	Professor Sandy Thomas
1 August	African Malaria Network Trust Workshop, Dar es Salaam, Tanzania	The ethics of research related to healthcare in developing countries	Professor Sandy Thomas
29 September – 2 October	3rd Pugwash Workshop on Science, Ethics and Society, Corsica, France,	Ethical Dimensions of HIV/AIDS	Professor Catherine Peckham



genetic screening

Membership of Steering Group

Professor Elizabeth Anionwu

Professor of Nursing, Head of Mary Seacole Centre for Nursing Practice, Thames Valley University; Member of the original Working Party on Genetic Screening (1993)

Professor Martin Bobrow

Head of Department of Medical Genetics, Cambridge Institute for Medical Research; Deputy Chairman of the Nuffield Council on Bioethics until January 2003

Professor Neva Haites

Professor in Medical Genetics and Associate Dean (Clinical), University of Aberdeen

Professor Peter Harper

University Research Professor in Human Genetics, Cardiff University; Member of Nuffield Council on Bioethics and Member of the original Working Party on Genetic Screening (1993)

David Shapiro

Former Executive Secretary of the Nuffield Council on Bioethics and Secretary to the original Working Party on Genetic Screening (1993)

Genetic Screening: ethical issues (1993) was the Council's first Report and remains one of its most cited and influential publications. It is still frequently accessed and was downloaded from the Council's website nearly 23,000 times during 2005. A Steering Group was convened in 2003 to consider whether scientific and policy developments in the area over the past decade were such that a new Working Party should be established.

Genetic screening involves testing members of a population (or subpopulation) for a defect or condition, usually where there is no previous evidence of its presence in the individual or their family. In 1993, most genetic screening programmes were at the pilot stage, although there were some exceptions. For example, programmes had been established to screen all newborn children for phenylketonuria, and to screen certain sub-populations for diseases such as sickle cell disease and thalassaemia. Since then, advances in scientific

understanding and developments in testing technologies have led to new diagnostic tests and treatments. However, few completely new screening programmes have been implemented over the past 13 years, although a number of pilot studies have been undertaken.

There have been several changes in the UK regulatory and advisory framework since 1993, such as the formation of the Human Genetics Commission and the National Screening Committee. More recently, the White Paper, *Our Inheritance, Our Future*

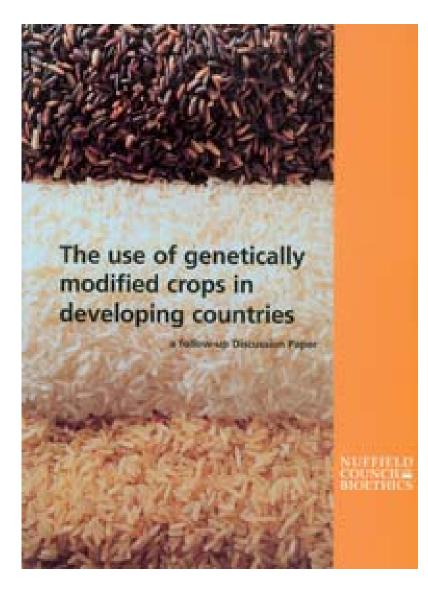
set out the UK Government's plans for investment in genetic services within the National Health Service.¹⁰

The Steering Group did not attempt a detailed analysis of ethical developments since 1993. Instead, it aimed to bring the original Report up to date by reviewing scientific and policy developments and identifying areas for future work. The Council plans to publish the update as a supplement to the original Report on its website in 2006.

¹⁰ Department of Health (2003) *Our Inheritance, Our Future* (Norwich: TSO)

Other follow-up activities

The follow-up Discussion Paper, *The use of genetically modified crops in developing countries*, was published in December 2003 and the topic has continued to receive attention. A reunion dinner was held in February 2005 for members of the Working Group to discuss the impact of the Report and consider whether there was a need for further work in the area. The participants recommended that developments in China, India, South Africa and South America should be monitored.





The Council has placed increasing emphasis on external relations activities in order to promote discussion on bioethics issues, and to encourage uptake of the recommendations in the Council's publications. The Council's audiences are diverse and include policy-makers, health professionals, scientists, professional bodies, regulators, the media and others.

The website

The Council's website is a core element of its strategy for dissemination and education. More than 70,000 different people visited the site during 2005, with many of those returning to the site more than once. All of the Reports, minutes of the meetings of the Council and its Working Parties, and responses to the Council's public consultations are placed on the website.

www.nuffieldbioethics.org



Number of downloads of publications for 2005

Publication	Number of downloads
The ethics of research involving animals	53,746
The ethics of research related to healthcare in developing countries	39,659
Genetically modified crops: the ethical and social issues	26,897
Genetic screening: ethical issues	23,364
The ethics of research related to healthcare in developing countries: a follow-up discussion paper	17,149
Genetics and human behaviour: the ethical issues	12,812
Human tissue: ethical and legal issues	11,980
Mental disorders and genetics: the ethical context	11,120
Animal-to-human transplants: the ethics of xenotransplantation	8,648
The ethics of patenting DNA: a discussion paper	8,284
The ethics of clinical research in developing countries: a discussion paper	6,945
Pharmacogenetics: ethical issues	3,656
The use of genetically modified crops in developing countries: a follow-up discussion paper	2,841
Stem cell therapy: the ethical issues	1,696

Short Guides to Reports

To increase accessibility, the Council now produces short 'Guides' to every new Report. The guides provide an eight-page summary of the findings and recommendations. In addition to producing short versions of new Reports, in 2005 the Council began to produce summaries of several previous Reports: Genes and human behaviour: the ethical context (2002), The ethics of research related to healthcare in developing countries (2002) and The ethics of patenting DNA (2002). The Guides will be available on the Council's website in 2006.



Media activities

Discussion of the Council's work by the media helps to increase its impact and promote public debate. The Council actively engages with the media on the issues addressed in its Reports, particularly around the time of publication. All of the Council's current projects attracted

significant media attention in 2005.
Topics previously covered by the Council also regularly appeared in the media. Members of the Secretariat and Council gave a number of interviews to raise awareness of the work carried out by the Council.

Highlights of media coverage relating to previous reports and general bioethics¹¹

Date	Media	Item headline/description
8 February	BBC News	Genes and behaviour: cosmetic neurology (interview with Professor Sandy Thomas)
25 February	News Radio 93.8FM, Singapore	Reproductive and therapeutic cloning (interview with Professor Sandy Thomas)
3 March	Material World, BBC Radio 4	Gene patenting (interview with Professor Sandy Thomas)
27 August	BBC News 24	Death on television, Edinburgh Television Festival (interview with Professor Sandy Thomas)
December	Res Medica (Journal of the Royal Medical Society of Edinburgh)	Pharmacogenetics: ethical issues (article by Professor Peter Lipton)

¹¹ See previous sections for highlights of media coverage and presentations relating to current work and Reports published in 2005.

external relations

Nuffield Council on Bioethics 2005

Presentations

A number of presentations made at conferences and meetings allowed members of the Council and Secretariat to discuss the findings of Reports with a range of specific audiences.

Highlights of presentations relating to previous reports and general bioethics

Date	Meeting	Title	Speaker
9 February	MHRA Conference on Pharmacogenetics, London	Pharmacogenetics: the ethical issues	Professor Peter Lipton
25 February	UNESCO French Commission Conference 'Bioethics and International Law', Paris	Information and the public debate	Mr Nick Ross
7 March	"Pharmacogenomics: <i>Primum non nocere</i> " symposium Guadalajara, Jalisco, Mexico	Ethics in pharmacogenomics	Professor Sandy Thomas
31 May	2nd Meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, Montreal, Canada	The use of GM crops in developing countries – ethical and regulatory issues	Mr Harald Schmidt
26 May	King's College, Cambridge	Ethics in pharmacogenomics	Professor Peter Lipton
13 July	2nd Annual Pharmacogenomics and Clinical R&D Conference, London	Ethics in pharmacogenomics	Professor Peter Lipton
11 October	Cambridge University Horizon Conference on Personalized Medicine, Cambridge	Ethics in pharmacogenomics	Professor Peter Lipton
29 October	34th ESCP Symposium on Clinical Pharmacy, Amsterdam	Pharmacogenetics: ethical issues	Professor Sandy Thomas
22 November	Foresight Brain Science, Addiction and Drugs Project – Beckley Foundation Meeting, London	Ethical dilemmas	Mr Harald Schmidt

Educational activities

Discussion about the impact of science on society is becoming an essential part of the education of young people and the Council is aware of the need to engage young people in debate about bioethical issues. An Advisory Group on Reaching Out to Young People, which includes members of Council and external experts, met for the second time in October 2005. The Group advocated the production of dedicated educational resources for school groups or teachers. The Council and the Nuffield Curriculum Centre plan to produce material on the topic of *The ethics* of research involving animals. This work will continue into 2006.

The Advisory Group previously recommended that young people should have the opportunity to participate in the Council's public consultations. In 2005, the Council worked with Ecsite-UK, the UK

Network of Science Centres and Museums, to develop and run workshops for young people on the issues surrounding decision making about the care of premature babies. The outputs from the workshops were made available to the Working Party for consideration. With the help of the Council, Ecsite-UK plans to continue these workshops in 2006 and initiate workshops on the ethical issues surrounding public health.

The Council has previously advised Y Touring, the Central YMCA's national touring theatre company, on its productions for students, teachers, governors and members of the public. Drawing on the Report on *The ethics of research involving animals*, the Council provided advice on the content of a new play on this topic, entitled *Every Breath*, which began development in autumn 2005.

The Advisory Group on Reaching Out to Young People plans to meet regularly in future to monitor progress and developments and to suggest further initiatives.



Engagement with policy makers

In order to encourage implementation of the Council's recommendations, an important part of the Council's external relations strategy involves engagement with policy makers (such as, parliamentarians, government departments, research councils and regulatory bodies). For example, the Council hosted a meeting in the House of Lords to brief policy makers on the Report *The ethics of research involving animals*.

Members of the Council and Secretariat regularly attend meetings and conferences to discuss the issues raised in the Council's Reports with organisations and individuals that share an interest. The Council also meets annually with the UK Department of Health and the Human Genetics Commission to exchange information about current and future work.

In 2005, the Council submitted written responses to the following public consultations held by other organisations:

- Department of Health:
 Recommendations of the House of
 Commons Science and Technology Select
 Committee report on Human
- Reproductive Technologies and the Law
 National Institute for Health and Clinical
 Excellence: Social Value Judgements:
 Guidelines for the Institute and its
 Advisory Bodies
- Council for Science and Technology: Rigour, respect and responsibility: a universal ethical code for scientists
- Department of Health: Review of the Human Fertilisation and Embryology Act



Uptake of recommendations

As one way of assessing the impact of the Council's strategy for engaging with policy makers, an analysis of the uptake of recommendations in selected Reports from 1993 to 2005 was conducted.¹²

Publication	Number of recommendations	Number taken up
Genetic screening: ethical issues (1993)	11	9
Human tissue: ethical and legal issues (1995)	23	10
Animal-to-human transplants: the ethics of xenotransplantation (1996)	25	21
Mental disorders and genetics: the ethical context (1998)	26	7
Genetically modified crops: the ethical and social issues (1999)	36	12
Stem cell therapy: the ethical issues (2000)	5	2
The ethics of research related to healthcare in developing countries (2002)	16	14
Genetics and human behaviour: the ethical context (2002)	13	7
The use of genetically modified crops in developing countries: a follow-up discussion paper (2003)	16	5

International activities

Much of the Council's work is relevant to global issues and members of the Council and Secretariat participated in a range of international activities in 2005.

Sixth Forum of National Ethics Committees

The European Commission's Directorate General for Research established a Forum of National Ethics Committees (NEC) in 2002. The NEC, which has a complementary role to that of the European Group on Ethics in Science and New Technologies (EGE) (see



page 39), aims to facilitate networking and discussion of topics of mutual concern between the national bioethics committees of EU countries. The Human Genetics Commission and the Council jointly hosted the NEC in London on behalf of the UK in November 2005. An evening reception and dinner took place on 17th November, followed by a full day meeting on 18th November. Around 50 delegates from 25 countries gathered to discuss the ethical issues surrounding public health, forensic databases and biometrics. Professor Roger Brownsword later attended a European Commission workshop on the Ethical and Social Implications of Biometric Identification Technology in Brussels on 15th-16th December to discuss these issues further.



The International Bioethics Committee (IBC) of UNESCO published its Universal Declaration on Bioethics and Human Rights in October 2005. The main aims of the Declaration are to provide a universal framework of principles and procedures to guide states in the formulation of their policies, and to promote respect for human dignity and protect human rights. Representatives of the Council attended a number of meetings during 2004 and 2005 to advise on the content of the Declaration and written comments on different drafts were submitted. The Council also commented on joint responses produced by UK stakeholders such as the Wellcome Trust, the Medical Research Council, and the British Medical Association. In particular, the Council suggested changes to the structure of fundamental, derived and procedural principles, the provisions relating to consent, and the use of the terms 'human being' and 'human dignity'.

European Group on Ethics in Science and New Technologies (EGE)

The task of the EGE is to advise the European Commission on ethical questions relating to sciences and new technologies, either at the request of the Commission or on its own initiative. As part of its work programme, the Group meets with



relevant organisations in the country holding the Presidency of the EU. Accordingly, members of the EGE visited the Council in November 2005 to discuss a number of topics of mutual interest, including pharmacogenetics and research involving animals.

Bilateral meetings with European bioethics committees

The Council holds regular bilateral meetings with the Comité Consultatif National d'Ethique (CCNE), France, and the Nationaler Ethikrat, Germany, to discuss issues of common interest and examine contrasting perspectives. The second meeting with CCNE was held in February 2005 in London, where participants discussed genetic screening and the risk of blood transmission of Creutzfeldt-Jakob disease (CJD). Visits to the CCNE in Paris and the Nationaler Ethikrat in Berlin are planned for early 2006.

COMETH

The European Conference of National Ethics Committees (COMETH) is composed of representatives of national ethics committees (or equivalent bodies) in Member States of the Council of Europe. The purpose of the Conference is to promote co-operation between national ethics committees, to help countries wishing to set up a national ethics committee and to promote public debate on ethical issues raised by progress in the fields of biology, medicine and public health. The 8th COMETH took place in Dubrovnik, Croatia, in April 2005, with the theme 'Meeting the challenges of changing societies'. Professor Roger Brownsword attended the meeting on behalf of the Council.

¹² The Council does not claim that any change in policy that coincides with a recommendation by the Council represents evidence of its impact. However, it is aware of changes in policy where research or personal contacts have revealed that the Council has been influential. Likewise, there may be cases where there is no direct evidence of policy-makers drawing on the Council's conclusions and recommendations, although, in fact, its reports have been considered in relevant deliberations. Any analysis of the Council's effect in influencing policy is subject to these limitations.

Annex A: Financial report

Financial Report for year to 31 December 2005

	2005 Actual £	2004 Actual £
Expenditure		
Salaries and staffing costs	342,392	318,101
Office costs including premises	7,642	8,923
Stationery and press cuttings	13,861	12,220
Photocopy, post, phone, fax	33,987	20,375
Committee and meeting costs	62,413	117,374
Printing of reports	23,893	19,577
(Less) reports sold	-2,939	(1,894)
Publicity of reports	5,520	500
Equipment (IT developments)	1,075	10,003
Net direct expenditure	488,384	505,179
Funding Due		
Nuffield Foundation	160,636	160,364
Medical Research Council	160,636	160,364
Wellcome Trust	160,637	160,364
Other income	9,219	92,876
	491,128	573,968
Surplus/ (Deficit)	2,744	68,789
Balance Brought Forward	158,432	89,643
Balance Carried Forward	161,176	158,432
Overheads met by Nuffield Foundation	266 202	201.056
Overheads met by Nuffield Foundation	266,283	201,056

Annex B: Publications

Genetic Screening: ethical issues
Published December 1993

Human tissue: ethical and legal issue Published April 1995

Animal-to-human transplants: the ethics of xenotransplantation
Published March 1996

Mental disorders and genetics: the ethical context
Published September 1998

Genetically modified crops: the ethica and social issues Published May 1999

The ethics of clinical research in developing countries: a discussion pape Published October 1999

Stem cell therapy: the ethical issues – discussion paper Published April 2000

The ethics of research related to healthcare in developing countries Published April 2002

The ethics of patenting DNA: a discussion paper
Published July 2002

Genetics and human behaviour: the ethical context
Published October 2002

Pharamcogenetics: ethical issues
Published September 2003

The use of genetically modified crops in developing countries: a follow-up Discussion Paper Published December 2003

The ethics of research related to healthcare in developing countries: a follow-up Discussion Paper Published March 2005

The ethics of research involving animals
Published May 2005

A CD-ROM containing the reports published before 2003 is also available.

All of these publications are available to download from the Council's website at: www.nuffieldbioethics.org. Short versions are also available for the more recent publications.

Printed copies may be ordered by contacting:

Nuffield Council on Bioethics 28 Bedford Square London WC1B 3JS Telephone: + 44 (0)20 7681 9619

Fax: + 44 (0)20 7637 1712

e-mail:

bioethics@nuffieldbioethics.org

Price for Reports: £10 per copy to all European countries (EU and non EU) including postage

 \pounds 15 per copy to countries outside Europe including postage

There is no charge for orders of single copies from developing countries

