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 Council

- Professor Sir Bob Hepple QC, FBA (Chairman)
- Emeritus Master, Clare College, and Emeritus Professor of Law, University of Cambridge; Barrister at Blackstone Chambers
- Professor Catherine Peckham CBE (Deputy Chairman)
  Professor of Paediatric Epidemiology, Institute of Child Health, University College London
- Professor Tom Baldwin
  Department of Philosophy, University of York
- 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 Care decisions in fetal and neonatal medicine: ethical issues)
- Professor Roger Brownword
  Centre for Medical Law & Ethics, King’s College, London
- Professor Sir Kenneth Calman KCB FRSE
  Vice-Chancellor and Warden, University of Durham
- The Rt Reverend Richard Harries
  DD FEC FSL
  Bishop of Oxford
- 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
- Professor Peter Lipton
  Head of the Department of History and Philosophy of Science, University of Cambridge
- Lord Plant of Highfield
  Centre for Medical Law & Ethics, King’s College, London
- Baroness Perry of Southwick
  (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)
- Professor Martin Raff FRS
  (until May 2005) Professor of Biology (Emeritus), University College London
- Mr Nick Ross
  (until May 2005) Broadcaster
- Professor Herbert Seawell
  Pro-Vice-Chancellor and Professor of Immunology, University of Nottingham
- Professor Peter Smith CBE
  Professor, Infectious Disease Epidemiology Unit, Department of Infectious Tropical Diseases, London School of Hygiene and Tropical Medicine
- Professor Dame Marilyn Strathern FBA
  Mistress of Girton College, Cambridge, and William Wyse Professor of Social Anthropology, University of Cambridge
- 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 August 2005)
  PA to the Director and Secretariat Administrator
- Ms Catherine Joynson
  (from January 2005) Communications & External Affairs Manager
- Ms Caroline Rogers
  Research Officer
- Ms Julia Trusler (from October 2005)
  Research Officer
- Ms Elaine Talaat-Abdalla (from August 2005)
  Secretary
- Ms Clare Stephens (from September 2005)
  Information Assistant

2005 Calendar

January
- 1st Council meeting

February
- 3rd meeting of Working Party on Critical Care Decisions in Fetal and Neonatal Medicine: Ethical Issues 1
- Meeting with members of Comité Consultatif National d’Ethique
- 2nd Council meeting
- Launch: The ethics of research related to healthcare in developing countries: a follow-up Discussion Paper

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

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

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
- Meeting with members of the European Group on Ethics in Science and New Technologies
- 4th Council meeting

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

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

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

1Positions correct as of 1 January 2006

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

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.
publications during 2005

The ethics of research involving animals
The ethics of research involving animals

Nuffield Council on Bioethics 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 wide range of organisations involved in the debate welcomed the Report and it was downloaded from the website more times in its first year than any other publication produced by the Council. A short Guide to the Report was published in November 2005, and a number of dissemination activities, including public meetings and a parliamentary briefing, were carried out in the months after publication.

Acknowledging that many people feel very deeply about this topic, the Council established a Working Party in February 2003 to consider the issues surrounding research involving animals. It was comprised of academics 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 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.

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.

1 See page 13 for some examples of comments in response to the Report.

www.nuffieldbioethics.org/go/ourwork/animalresearch/introduction
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 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.

Comment in response to the Report

“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

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

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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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Media</th>
<th>Headline</th>
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<tbody>
<tr>
<td>25 May</td>
<td>Today Programme, BBC Radio 4</td>
<td>Feature on the findings of the Report</td>
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<tr>
<td>25 May</td>
<td>The Times</td>
<td>Call for review of animal testing</td>
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<tr>
<td>25 May</td>
<td>The Guardian</td>
<td>Scientists told: reduce animal experiments</td>
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<tr>
<td>25 May</td>
<td>BBC One O’clock and Six O’clock News</td>
<td>Feature on the findings of the Report</td>
</tr>
<tr>
<td>26 May</td>
<td>Nature</td>
<td>UK panel urges animal researchers to go public</td>
</tr>
<tr>
<td>7 June</td>
<td>Cambridge Evening News</td>
<td>University welcomes new animal research report</td>
</tr>
<tr>
<td>7 July</td>
<td>Hospital Doctor</td>
<td>Honesty is the best policy for animal research</td>
</tr>
<tr>
<td>25 August</td>
<td>The Times</td>
<td>Use of animals still vital to progress, say top scientists</td>
</tr>
<tr>
<td>August</td>
<td>The Chemical Engineer</td>
<td>Animal research: unravelling the ethical debate</td>
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<tr>
<td>October</td>
<td>BBC Focus Magazine</td>
<td>What are the alternatives?</td>
</tr>
<tr>
<td>Winter issue</td>
<td>European Pharmaceutical Contractor</td>
<td>Research involving animals: the ethical issues (article by Lady Perry)</td>
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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 2005.1

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 Mr Michelle Three 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 Broom and Mr David Thomas (British Union for the Abolition of Vivisection). The event was fully booked and around 80 people attended.

1 Available at: http://www.nuffieldbioethics.org/fileLibrary/pdf/NuffShortReport.pdf
Critical care decisions in fetal and neonatal medicine: ethical issues

The Working Party met seven times in 2005 and the minutes of these meetings are available on the Council’s website. The Report will be published in the autumn of 2006.

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:

1. How should decisions be made about whether or not to intervene to prolong the life of a fetus or newborn baby?
2. Who is best placed to judge the quality of life for a child?
3. How much weight (if any) should be given to economic considerations in determining whether to prolong the life of fetuses or the newborn?
4. 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
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.

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

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.

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<thead>
<tr>
<th>Date</th>
<th>Media</th>
<th>Item headline/description</th>
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<tbody>
<tr>
<td>6 January</td>
<td>The Guardian</td>
<td>Study reveals hazards facing premature babies (comments from Professor Neil Marlow)</td>
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<tr>
<td>25 January</td>
<td>BBC Radio 4</td>
<td>Case notes – Premature babies (participation by Professor Neil Marlow)</td>
</tr>
<tr>
<td>10 March</td>
<td>BBC News Online, BBC Radio 5 Live and BBC Radio Wales</td>
<td>Coverage of the Council’s public consultation</td>
</tr>
<tr>
<td>24 March</td>
<td>Operating Theatre Journal</td>
<td>Nuffield Council on Bioethics seeks views on prolonging life in fetuses and the newborn</td>
</tr>
<tr>
<td>6 June</td>
<td>The Daily Mail</td>
<td>Let premature babies die, says ethics expert</td>
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<tr>
<td>21 June</td>
<td>BBC Radio 4, Woman’s Hour</td>
<td>Feature on treating premature babies (participation by Ms Bonnie Green)</td>
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<tr>
<td>30 July</td>
<td>BBC News Online</td>
<td>Premature babies ‘need advocates’ (comments from Professor Andrew Whitelaw)</td>
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<tr>
<td>31 July</td>
<td>BBC Radio 5 Live</td>
<td>Too Young to Live (participation by Professor Neil Marlow, Ms Bonnie Green, Dr Philippa Russell and Professor Andrew Whitelaw)</td>
</tr>
<tr>
<td>September</td>
<td>Journal of Neonatal Nursing</td>
<td>Decisions at the beginning of life (article by Dr Catherine Moody and Professor Margot Brazier)</td>
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</table>
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.³ 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.

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<table>
<thead>
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<th>Membership of Working Party</th>
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<tr>
<td><strong>Professor Sir John Krebs (Chair)</strong>&lt;br&gt;Principal, Jesus College, Oxford</td>
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<tr>
<td><strong>Professor Sir Kenneth Calman KCB FRSE</strong>&lt;br&gt;Vice-Chancellor and Warden, University of Durham, Member of Council</td>
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<tr>
<td><strong>Professor Christine Godfrey</strong>&lt;br&gt;Professor of Health Economics, Centre for Health Economics and Department of Health Sciences and Clinical Evaluation, University of York</td>
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<tr>
<td><strong>Professor Tom Baldwin</strong>&lt;br&gt;Department of Philosophy, University of York, Member of Council</td>
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<tr>
<td><strong>Professor Roger Brownsword</strong>&lt;br&gt;Professor of Law, King’s College London, Member of Council</td>
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<tr>
<td><strong>Professor Trisha Greenhalgh OBE</strong>&lt;br&gt;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</td>
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<tr>
<td><strong>Professor Sally McIntyre</strong>&lt;br&gt;Director, Medical Research Council Social and Public Health Sciences Unit, University of Glasgow</td>
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<tr>
<td><strong>Professor Jonathan Montgomery</strong>&lt;br&gt;Professor of Health Care Law, University of Southampton School of Law</td>
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<tr>
<td><strong>Julia Unwin</strong>&lt;br&gt;Senior Associate, Kings Fund and Deputy Chair, Food Standards Agency</td>
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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


Accessed on: 21 March 2006
follow-up work

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. 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.

See External Relations section for more information.
The ethics of research related to healthcare in developing countries: a follow-up Discussion Paper

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. 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.

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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.

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.

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

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<tr>
<td>17 March</td>
<td>Medical News Today</td>
<td>Discussion Paper on ethics of research in developing countries finds problems in practice</td>
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<tr>
<td>19 March</td>
<td>British Medical Journal</td>
<td>Nuffield Council calls for ethical framework for developing world research</td>
</tr>
<tr>
<td>30 March</td>
<td>Financial Times</td>
<td>US under fire over clinical trials in developing world</td>
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Highlights of presentations

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<th>Date</th>
<th>Meeting</th>
<th>Title</th>
<th>Speaker</th>
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<tr>
<td>19 March</td>
<td>Global Forum on Bioethics in Research VI, Blantyre, Malawi, Africa</td>
<td>The ethics of research related to healthcare in developing countries</td>
<td>Sandy Thomas</td>
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<tr>
<td>1 August</td>
<td>African Malaria Network Trust Workshop, Dar es Salaam, Tanzania</td>
<td>The ethics of research related to healthcare in developing countries</td>
<td>Sandy Thomas</td>
</tr>
<tr>
<td>29 September – 2 October</td>
<td>3rd Pugwash Workshop on Science, Ethics and Society, Corsica, France,</td>
<td>Ethical Dimensions of HIV/AIDS</td>
<td>Catherine Peckham</td>
</tr>
</tbody>
</table>
Genetic screening involves testing members of a population (or sub-population) 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 together several themes for future work. The Council plans to publish the update as a supplement to the original Report on its website in 2006.

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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.

**Follow-up work**

**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.

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**external relations**
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

<table>
<thead>
<tr>
<th>Publication</th>
<th>Number of downloads</th>
</tr>
</thead>
<tbody>
<tr>
<td>The ethics of research involving animals</td>
<td>53,746</td>
</tr>
<tr>
<td>The ethics of research related to healthcare in developing countries</td>
<td>39,659</td>
</tr>
<tr>
<td>Genetically modified crops: the ethical and social issues</td>
<td>25,897</td>
</tr>
<tr>
<td>Genetic screening: ethical issues</td>
<td>23,364</td>
</tr>
<tr>
<td>The ethics of research related to healthcare in developing countries: a follow-up discussion paper</td>
<td>17,149</td>
</tr>
<tr>
<td>Genetics and human behaviour: the ethical context</td>
<td>12,812</td>
</tr>
<tr>
<td>Human tissue: ethical and legal issues</td>
<td>11,090</td>
</tr>
<tr>
<td>Mental disorders and genetics: the ethical context</td>
<td>11,120</td>
</tr>
<tr>
<td>Animal-to-human transplants: the ethics of xenotransplantation</td>
<td>8,648</td>
</tr>
<tr>
<td>The ethics of patenting DNA: a discussion paper</td>
<td>8,284</td>
</tr>
<tr>
<td>The ethics of clinical research in developing countries: a discussion paper</td>
<td>6,945</td>
</tr>
<tr>
<td>Pharmacogenetics: ethical issues</td>
<td>6,616</td>
</tr>
<tr>
<td>The use of genetically modified crops in developing countries: a follow-up discussion paper</td>
<td>3,841</td>
</tr>
<tr>
<td>Stem cell therapy: the ethical issues</td>
<td>1,696</td>
</tr>
</tbody>
</table>

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: 

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 bioethics

<table>
<thead>
<tr>
<th>Date</th>
<th>Media</th>
<th>Item headline/description</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 February</td>
<td>BBC News</td>
<td>Genes and behaviour: cosmetic neurology (Interview with Professor Sandy Thomas)</td>
</tr>
<tr>
<td>25 February</td>
<td>News Radio 93.8FM, Singapore</td>
<td>Reproductive and therapeutic cloning (Interview with Professor Sandy Thomas)</td>
</tr>
<tr>
<td>3 March</td>
<td>Material World, BBC Radio 4</td>
<td>Gene patenting (Interview with Professor Sandy Thomas)</td>
</tr>
<tr>
<td>27 August</td>
<td>BBC News 24</td>
<td>Death on television, Edinburgh Television Festival (Interview with Professor Sandy Thomas)</td>
</tr>
<tr>
<td>December</td>
<td>The Royal Edinburgh Society</td>
<td>Pharmacogenetics: ethical issues (article by Professor Peter Lipton)</td>
</tr>
</tbody>
</table>

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

**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**

<table>
<thead>
<tr>
<th>Date</th>
<th>Meeting</th>
<th>Title</th>
<th>Speaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 February</td>
<td>MHRA Conference on Pharmacogenetics, London</td>
<td>Pharmacogenetics: the ethical issues</td>
<td>Professor Peter Lipton</td>
</tr>
<tr>
<td>25 February</td>
<td>UNESCO French Commission Conference</td>
<td>Information and the public debate</td>
<td>Mr Nick Ross</td>
</tr>
<tr>
<td>7 March</td>
<td>‘Pharmacogenetics: Primum non nocere’</td>
<td>Ethics in pharmacogenomics</td>
<td>Professor Sandy Thomas</td>
</tr>
<tr>
<td>31 May</td>
<td>2nd Meeting of the Conference of the Parties</td>
<td>The use of GM crops in developing countries – ethical and regulatory issues</td>
<td>Mr Harald Schmidt</td>
</tr>
<tr>
<td>26 May</td>
<td>King’s College, Cambridge</td>
<td>Ethics in pharmacogenomics</td>
<td>Professor Peter Lipton</td>
</tr>
<tr>
<td>13 July</td>
<td>2nd Annual Pharmacogenomics and Clinical R&amp;D Conference, London</td>
<td>Ethics in pharmacogenomics</td>
<td>Professor Peter Lipton</td>
</tr>
<tr>
<td>11 October</td>
<td>Cambridge University Horizon Conference</td>
<td>Ethics in pharmacogenomics</td>
<td>Professor Peter Lipton</td>
</tr>
<tr>
<td>29 October</td>
<td>34th ESCP Symposium on Clinical Pharmacy, Amsterdam</td>
<td>Pharmacogenetics: ethical issues</td>
<td>Professor Sandy Thomas</td>
</tr>
<tr>
<td>22 November</td>
<td>Foresight Brain Science Addiction and Drugs Project – Beckley Foundation Meeting, London</td>
<td>Ethical dilemmas</td>
<td>Mr Harald Schmidt</td>
</tr>
</tbody>
</table>

**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.

**Engagement with policy makers**

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

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.
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.

### 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. 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.

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

### 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 Brownwood 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.

#### UNESCO

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 Welcome 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 Brownwood attended the meeting on behalf of the Council.
### Annex A: Financial report

#### Financial Report for year to 31 December 2005

<table>
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<tr>
<th></th>
<th>2005 Actual £</th>
<th>2004 Actual £</th>
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</thead>
<tbody>
<tr>
<td><strong>Expenditure</strong></td>
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<td></td>
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<tr>
<td>Salaries and staffing costs</td>
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<td>Office costs including premises</td>
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<td>Stationery and press cuttings</td>
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<td>12,220</td>
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<tr>
<td>Photocopy, post, phone, fax</td>
<td>33,867</td>
<td>20,375</td>
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<tr>
<td>Committee and meeting costs</td>
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<td>117,374</td>
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<tr>
<td>Printing of reports</td>
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<tr>
<td>(loss) reports sold</td>
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<td>Publicity of reports</td>
<td>5,520</td>
<td>500</td>
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<tr>
<td>Equipment (IT developments)</td>
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<td>10,003</td>
</tr>
<tr>
<td>Net direct expenditure</td>
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<td>505,179</td>
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<tr>
<td><strong>Funding Due</strong></td>
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<tr>
<td>Nuffield Foundation</td>
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<td>Medical Research Council</td>
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<tr>
<td>Wellcome Trust</td>
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<td>160,364</td>
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<tr>
<td>Other income</td>
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<td></td>
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<td><strong>Surplus/ (Deficit)</strong></td>
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<td>68,789</td>
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<tr>
<td>Balance Brought Forward</td>
<td>158,432</td>
<td>89,643</td>
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<tr>
<td>Balance Carried Forward</td>
<td>161,176</td>
<td>158,432</td>
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<tr>
<td>Overheads met by Nuffield Foundation</td>
<td>266,283</td>
<td>201,056</td>
</tr>
</tbody>
</table>

#### Annex B: Publications

**Genetic Screening: ethical issues**
- Published December 1993

**Human tissue: ethical and legal issues**
- 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 ethical and social issues**
- Published May 1999

**The ethics of clinical research in developing countries: a discussion paper**
- Published October 1999

**Stem cell therapy: the ethical issues – a 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

**Pharmacogenetics: 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:

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Fax: + 44 (0)20 7637 1712
e-mail: bioethics@nuffieldbioethics.org

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