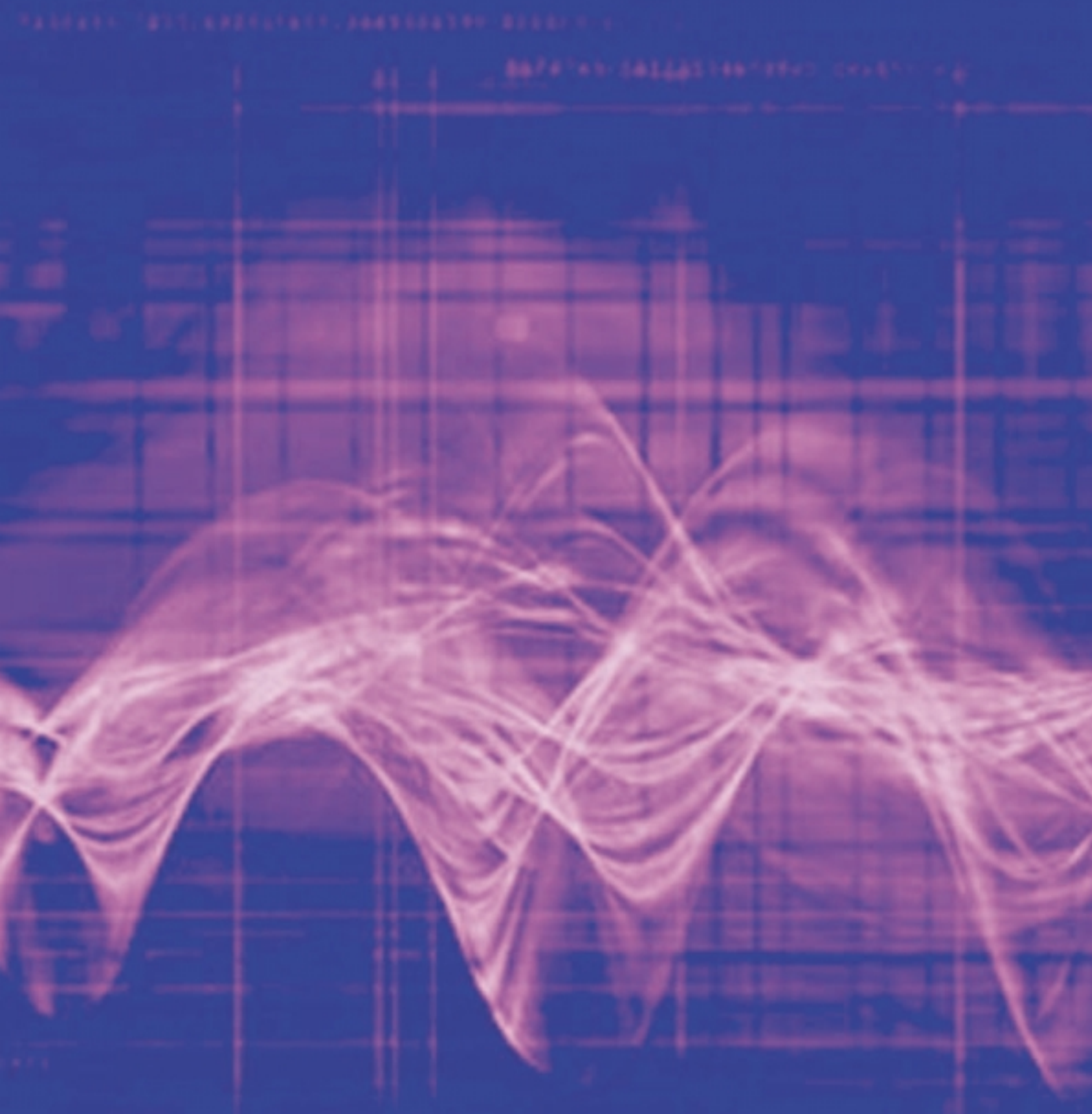


# Nuffield Council on Bioethics Annual Report 2002



**NUFFIELD  
COUNCIL ON  
BIOETHICS**

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# Foreword

This foreword is written from a distance. I retired from the Council in October, 2002. In large part, I will confine myself to commenting on the Council's activities during 2002. I will, however, also allow myself some brief valedictory remarks.



2002 was a busy year. It saw a number of pieces of work come to fruition, including two major Reports and a Discussion Paper. Not only were they important in their own right, but they also showed the breadth and reach of the Council, dealing, as they did, with research in developing countries, genetics and human behaviour and patenting DNA. I was particularly pleased that we were able to launch summaries of the Report on research in developing countries in French and Spanish versions. In this way we both signalled the global importance of the subject and our commitment as a Council to contribute to the development of policy at an international level.

In addition to our published work, there are three particular matters which I would single out for special mention. First, the Council can only do that which can be supported by its staff. It has been one of my aims as Chairman to increase the number of staff so as to allow us to take on the increasingly wide range of challenges posed by modern bioethics. Thus, the steady growth of the Secretariat has been of great importance. That they are all wonderfully able and hard-working warrants mention too. Secondly, the development of the Council's web-site and the increase in its

use is a source of great pleasure. We still need to do more to meet our obligation to promote public understanding of bioethical issues, especially as regards those in school, but the website represents solid and pleasing progress. Thirdly, it was a great pleasure to hold our first public meeting outside London. The meeting in Glasgow was a success, not least in the fact that it was attended by a number of schoolteachers concerned with introducing bioethics to their pupils.

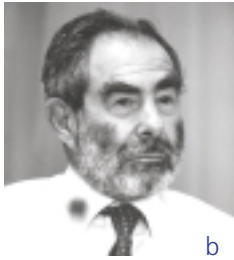
By way of valediction, may I thank all those who have made my period of service on the Council, whether as a Member or, later, as Chairman so enjoyable. It has been a privilege to work both with colleagues on the Council and those in the secretariat. I enjoyed the conversations and discussions enormously and will miss them. It is comforting to know that the Council is in good hands: Bob Hepple will be an outstanding Chairman.

A handwritten signature in black ink, which appears to read 'Ian Kennedy'.

**By Professor Sir Ian Kennedy**



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## Members of Council

- (a) **Professor Ian Kennedy (Chairman)**  
Ethics and Policy, School of Public Policy, University College London
- (b) **Professor Martin Bobrow CBE (Deputy Chairman)**  
Department of Medical Genetics, University of Cambridge
- (c) **Professor Tom Baldwin**  
University of York
- (d) **Ms Rebecca Burke CBE**  
Liverpool Children's NHS Trust (Alder Hey)
- (e) **Professor Sir Kenneth Calman KCB FRSE**  
Vice-Chancellor and Warden, University of Durham
- (f) **The Rt Rev Richard Harries DD FKC FRSL**
- (g) **Professor Bob Hepple QC**  
Cambridge (co-opted member of Council for the period of his Chairmanship of the Working Party on genetics and human behaviour: the ethical context)
- (h) **Professor John Ledingham**  
Medicine, University of Oxford
- (i) **Professor Catherine Peckham CBE**  
Epidemiology, Institute of Child Health, University College London
- (j) **Professor Martin Raff FRSE**  
College London
- (k) **Mr Nick Ross**
- (l) **Professor Herbert Sewell**  
Professor of Immunology, University of Nottingham
- (m) **Professor Marilyn Strathern FBA**  
Cambridge and William Wyse Professor of Social Anthropology, University of Cambridge
- (n) **Professor Albert Weale FBA**  
Professor of Government, University of Essex
- (o) **Dr Alan Williamson FRSE**  
Consultant on Biotechnology

# Introduction

## Background

New developments in medicine and biology raise important ethical issues. The Nuffield Council on Bioethics was established in 1991 to identify, examine and report on the ethical questions raised by recent advances in biological and medical research. Now in its eleventh year, the Council has achieved an international reputation, providing advice that assists policy-making, addresses public concerns and stimulates debate.

The Council is funded jointly by the Nuffield Foundation, the Medical Research Foundation and the Wellcome Trust.

### Secretariat

The Secretariat is the executive arm of the Council.

**Dr Sandy Thomas** Director  
**Ms Susi Bull** Assistant Director (until April 2002)  
**Ms Tor Lezmore** Assistant Director  
**Mr Harald Schmidt** Assistant Director (from May 2002)  
**Mrs Julia Fox** PA to the Secretariat  
**Ms Nicola Perrin** Public Liaison Officer  
**Ms Yvonne Melia** Research Officer (until April 2002)  
**Ms Natalie Bartle** Research Officer (from June 2002)  
**Ms Amanda Jones** Secretary (until April 2002)  
**Ms Elaine Talaat-Abdalla** Secretary (from April 2002)  
**Ms Maria Gonzalez-Nogal** Information Assistant

*Details of the Council's method of working, including more information about Working Parties and publications is included on the Council's website at [www.nuffieldbioethics.org](http://www.nuffieldbioethics.org)*

### 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.

# 2002 Calendar



January	1st Council meeting
February	10th meeting of Working Party on Genetics and human behaviour: the ethical context
March	2nd Council meeting
April	Launch: The ethics of research related to healthcare in developing countries
May	Council Forward Look Meeting 11th meeting of Working Party on Genetics and human behaviour: the ethical context
June	3rd Council meeting
July	Launch: The ethics of patenting DNA
September	1st meeting of Working Party on Pharmacogenetics: ethical issues
October	Launch: Genetics and human behaviour: the ethical context International distribution of 10th anniversary CD-ROM with Nature journal 4th Council meeting Glasgow Public discussion: Genes and behaviour: ethical issues
November	Co-convenor of the Fourth Global Summit of National Bioethics Commissions, Brasilia, Brazil Launch of Consultation on Pharmacogenetics: ethical issues 2nd meeting of Working Party on Pharmacogenetics: ethical issues
December	Attended Meeting of National Ethics Commissions of member states of the EU (convened by Danish Ethics Council with EC) Meeting of Working Group on GM Crops follow-up Meeting of Steering Committee for Developing Countries follow-up Professor Sir Ian Kennedy retires as Chairman of Nuffield Council



## Report by the Director

The year 2002 has seen the completion of a number of projects, with the publication of two Reports and a Discussion Paper:



- The ethics of research related to healthcare in developing countries
- The ethics of patenting DNA: a discussion paper
- Genetics and human behaviour: the ethical context

More information about each of these publications, the launch and response, is set out in this annual report.

The Council has therefore begun a new programme of work during the past year. Two Workshops were held in 2001, on pharmacogenetics and on research involving animals. As a result of these meetings, it was decided that both topics merited further examination. The Council has established two Working Parties in 2002, one to consider *Pharmacogenetics: ethical issues*, the other to consider *The ethics of research involving animals*. More information about the progress of these Working Parties is included here.

As in previous years, the Council has also worked to promote debate of the issues raised by its publications. In October, the Council held a public discussion meeting in Glasgow on *Genetics and human behaviour: ethical issues*. The Council also met in Glasgow on the same day. This was the first time a Council meeting has been held at an out-of-London venue. Another highlight of 2002 was the production of a CD-ROM containing all the Council's publications. This was distributed internationally with the Journal Nature, enabling the Council to reach new audiences. More details of both these events and the Council's other external activities, both nationally and internationally, are described in this review.

### Personnel

Professor Sir Ian Kennedy retired as Chairman on 31 December 2002. Sir Ian, a founder-member of the Council, has served on the Council for eleven years, four of them as Chairman. His successor was appointed by the Nuffield Foundation, after consultation with the other funders. In December it was announced that Professor Bob Hepple, QC, would become Chairman of the Council from 1 January 2003.

There have been a number of staff changes in the Secretariat during 2002. Elaine Talaat-Abdalla replaced Amanda Jones as secretary to the Secretariat in March. In April the Research Officer, Yvonne Melia was succeeded by Natalie Bartle. Susi Bull, Assistant Director since October 1998, also left in April and has been replaced by Harald Schmidt. The Secretariat has also had the benefit of two interns during the year, Faith Hummerstone and Jai Shah.

## Forward Look meeting

The Council holds a 'Forward Look' meeting each year which provides the opportunity for discussion about broader themes and more strategic consideration of the role of the Council. Two main topics were discussed at the meeting held in May 2002: the method of working of the Council and follow-up of the Council's publications.

- **Method of working**

With the close of three projects in 2002, it was felt to be timely to reassess the framework for Working Parties and smaller Round Table Groups. The Council decided that it was no longer necessary to have the distinction between the two methods of working. In future, the Council will always establish a Working Party if a topic merits further examination and there will no longer be Round Tables. A Working Party will always be chaired and the process of deliberation should include fact-findings meetings and, where appropriate, a consultation exercise. However, it was felt that different styles of publication would still be appropriate for different topics. Some topics would merit a full-length Report, with a broad scope and making recommendations, while for other topics a shorter paper discussing the issues would be more appropriate. The number of members of the Working Party and the length of time for which they met would reflect the type of publication to be produced.

- **Follow-up**

It is always difficult to evaluate the precise impact of a Report. Nevertheless, judging the impact of the Council's publications and assessing whether the recommendations have been influential is a difficult but necessary task, if the Council is to monitor its effectiveness. In making its recommendations, the Council hopes that they will be listened to and taken seriously by those at whom they are directed and others who have an interest in the topic. It is also hoped that a Report will contribute towards the establishment of an agenda for the consideration of a topic and help to set the terms of the debate.

An analysis of the implementation of recommendations in all past publications was completed for the Forward Look Meeting in 2002. This showed that there has been significant variation in the extent to which the recommendations made in each publication have been adopted, depending both on the topic and the stage that the debate was at when the Report was published. In light of this information, members of Council held a useful discussion about possible methods of follow-up for past and future publications.

The Council decided that, for the first year after publication, follow-up would take two forms. First, emphasis would be given to the dissemination of the Report and secondly, there would be strategic follow-up. The Secretariat will monitor developments in the field, and liaise with relevant policy makers, individuals and organisations as appropriate for specific recommendations. A more substantive follow-up activity should then be undertaken 18-24 months after publication. This activity could take a variety of forms, such as a workshop, a seminar, a conference or the production of a short publication.

In light of this decision, the Council has established a group to reconsider the topic of genetically modified crops in 2003, taking into account recent developments in the field. A follow-up conference will also be held on the topic of the ethics of research related to healthcare in developing countries. More information about both these projects is set out in this Report.

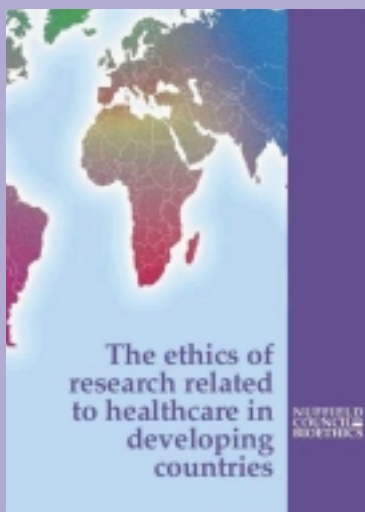


# Publications during 2002

## The ethics of research related to healthcare in developing countries

*The Report, **The ethics of research related to healthcare in developing countries**, was published on 25 April 2002.*

### Membership of Working Party



**Professor Sir Kenneth Calman (Chairman)**  
Vice-Chancellor and Warden, University of Durham  
Member of Nuffield Council on Bioethics

**Dr Fred Binka**  
Associate Professor of Epidemiology, School of Public Health, University of Ghana

**Professor Michael Elves**  
Former Director, Office of Scientific and Educational Affairs, Glaxo Wellcome plc

**Professor V I Mathan**  
Senior Consultant for Health Research, Indian Council of Medical Research, National Institute of Epidemiology, Chennai, India

**Professor Keith McAdam**  
Director, MRC Laboratories, Fajara, The Gambia

**Dr Anne McLaren**  
Wellcome/CRC Institute, Cambridge

**Professor Bhikhu Parekh**  
Centennial Professor, The Centre for the Study of Global Governance, London School of Economics

**Professor David Parkin**  
Professor of Social Anthropology, All Souls College, Oxford

**Professor Catherine Peckham CBE**  
Professor of Epidemiology, Institute of Child Health, University College London  
Member of Nuffield Council on Bioethics

**Professor Povl Riis**  
Copenhagen Ministry of Science

**Professor Nelson Sewankambo**  
Dean, Faculty of Medicine, Makerere University, Kampala, Uganda

**Mrs Shahwar Sadeque**  
Educational & ICT Consultant

**Professor Peter Smith**  
Head of the Department of Infectious and Tropical Diseases, London School of Hygiene & Tropical Medicine

**Dr Fabio Zicker**  
Coordinator, Research Capacity Strengthening, UNDEP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR)

### Terms of Reference

1. To review the importance of healthcare-related research in humans, supported by those in more affluent countries and conducted, at least partly, in developing countries.
2. To identify and consider the ethical and social implications of conducting such research including:
  - (a) who benefits from the research;
  - (b) consent;
  - (c) differences in cultural values;
  - (d) differences in levels of healthcare between countries;
  - (e) compatibility of ethical guidelines produced by international bodies;
  - (f) the respective responsibilities of local and non-local ethics review bodies, and mechanisms for review and monitoring;
  - (g) follow-up, including the possible implementation of findings, after the completion of research.
3. To make recommendations.

## Introduction

Developing countries urgently need research to help to address the enormous burden of disease that they carry. But many countries have limited funds and a lack of trained staff to conduct their own research. It is vital that those in wealthy countries, both in the public and private sectors, should help sponsor this research. However, the inequalities in resources between developed and developing countries pose a real risk of exploitation in the context of externally-sponsored research.

In 1999, the Council held an international Workshop to explore the ethics of conducting research related to healthcare in developing countries, and published a Discussion Paper summarising the deliberations of the meeting. In January 2000 the Council established a Working Party to consider the issues in more detail.

The multinational Working Party met eight times during 2000 and 2001, and also held a number of fact-finding meetings and a consultation with the public. The draft Report was peer reviewed by an international panel of experts at the end of 2001. In light of the comments received, and taking into account comments from members of the Council, the Report was revised at the beginning of 2002. It was submitted to the Council for approval in March 2002 and then published in April 2002.

## The Report

The Report concludes that medical research in developing countries that is funded by organisations from developed countries is vital but must be subject to rigorous ethical standards. Research must be appropriately planned and effectively reviewed on scientific and ethical grounds to ensure that there is no exploitation of those who take part. The Report provides a framework for anyone who is designing or conducting such research.

The recommendations focus on four main areas:

- standards of care
- consent
- ethical review of research
- what happens when the research is over.

The importance of considering the local social, cultural and economic context is highlighted, and the need for sponsors to assist developing countries to strengthen expertise in research is identified as a priority.

It is hoped that the Report will make a significant contribution to international debate on these topics and that it will be a useful reference for researchers, sponsors, pharmaceutical companies and policymakers.



## Report Launch

The Report was launched on 25 April 2002. A press conference was held at the Conference Centre of the British Library in London, followed by a seminar in the afternoon. The seminar was attended by nearly 100 practitioners from a wide range of organisations, including research institutes, hospitals, universities, charities, NGOs, pharmaceutical companies, HIV/AIDS organisations and Local Research Ethics Committees (LRECs).

The seminar was divided into four sessions: social and cultural issues and consent processes; standards of care; ethical review of research and what happens when research is over. Members of the Working Party presented the Report's recommendations, and each session was followed by a discussion with the audience. The seminar was chaired by Professor Kenneth Calman.

There was coverage of the Report in the press, particularly in technical journals. Members of the Working Party also gave a number of radio interviews, particularly to the BBC World Service.

## Highlights of press coverage

	Journal	Headline
25 Apr 02	SciDevNet	Best treatment 'not always practical' Editorial: Ethical Research requires ethical researchers
27 Apr 02	BMJ	Rich countries must not exploit poorer nations for research purposes
27 Apr 02	New Scientist	No double standards
3 May 02	Times Higher Education Supplement	Move to stop research exploiting third world
4 May 02	Pharmaceutical Journal	Ethical safeguards needed for research in developing countries
June 02	Good Clinical Practice Journal	Conducting ethical research in developing countries
Aug 02	Manufacturing Chemist	A question of ethics
Dec 02	Drug Discovery Today	Conducting research ethically in developing countries
Dec 02	European Pharmaceutical Contractor Manufacturing Chemist	Implications of the Report for the Pharmaceutical Industry

## Post-publication

In addition to the printed Report, French and Spanish translations of the conclusions and recommendations of the Report were published, and a CD-ROM, including the Report, the translations and the previous Discussion Paper was also produced. More than 1,000 printed copies and 1,500 CD-ROMS of the Report were distributed during 2002. The Report was also downloaded over 21,000 times from the Council's website. The Secretariat continues to receive orders for printed copies from around the world.

The Report has attracted considerable interest. Individual letters, highlighting relevant recommendations in the Report, have also been sent to sponsors of research, ethics committees, health authorities and to international organisations such as the WHO and CIOMS. A number of presentations are planned for 2003.

### Presentations:

- Partnering for Global Health Forum, Biotechnology Industry Organization and the Bill and Melinda Gates Foundation, Washington USA Dr Sandy Thomas December 02
- Global Forum for Health Research (Poster presentation) November 02

## Follow-up

The Council has decided that a follow-up meeting should take place in the autumn of 2003 to explore developments in the area since the publication of the Report. The meeting, to be held in South Africa, will bring together researchers who are actively involved in externally-sponsored research in developing countries. The focus of the meeting will be to discuss and debate ethical and regulatory issues raised by new and recently revised guidelines. A Steering Committee, including former members of the Working Party and representatives from the MRC and Wellcome Trust, met to initiate planning for the meeting in December 2002.

Funding will be sought during 2003. More details about the meeting will be available on the Council's website throughout the year.

# The ethics of patenting DNA

*The Discussion Paper, **The ethics of patenting DNA**, was published on 23 July 2002.*



## Membership of Round Table

### **Professor Tom Baldwin**

Head of Department of Philosophy, University of York  
Member of the Nuffield Council on Bioethics

### **Professor John Barton**

George E. Osborne Professor of Law, Stanford Law School, US

### **Professor Martin Bobrow CBE**

Head of Department of Medical Genetics, University of Cambridge  
Deputy Chairman of the Nuffield Council on Bioethics

### **Professor Sir Brian Heap CBE FRS**

Master, St Edmund's College, University of Cambridge  
Member of the Nuffield Council on Bioethics (until December 2001)

### **Hon Mr Justice Jacob**

Judge of the High Court, Chancery Division

### **Professor Dame Marilyn Strathern**

Mistress of Girton College, Cambridge and William Wyse Professor of Social Anthropology  
Member of the Nuffield Council on Bioethics

### **Professor Michael Stratton**

Head of the Cancer Genome Project, The Sanger Centre, Cambridge

### **Professor Joseph Straus**

Managing Director, Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, Germany

### **Dr Alan Williamson**

Consultant for biotechnology  
Member of the Nuffield Council on Bioethics

## Introduction



Several thousand patent applications have been made on genes and DNA sequences. But the substantial increase in the rate of patenting of DNA sequences has led to considerable debate about the acceptability of this practice. The Council established a Round Table Group in June 2000 to consider the ethical and legal issues raised by this form of patenting and the implications for healthcare.

The Group met nine times during 2000 and 2001. In February 2002, the Round Table held a closed meeting with patent lawyers, individuals from pharmaceutical and biotechnology companies, an academic and a member of an NGO. The meeting revealed different perspectives on the topic.

The Secretariat prepared the final draft during the spring of 2002, drawing on the expertise of several individuals. The Discussion Paper was then sent to peer review, before being approved by the Council in June 2002. The Discussion Paper was launched in July 2002.

### The Discussion Paper

The main conclusion of the Paper is that patents involving DNA sequences should be the exception rather than the rule. A number of recommendations for future policy in the area are made, including a call for significant changes to the way that such patents are granted. Most importantly, it argues that the tests of inventiveness and usefulness should be more rigorously applied when considering whether to award a patent.

The Paper also notes that some patents that have already been granted are of doubtful validity and makes recommendations to limit

the possible adverse effects of these patents. It is hoped that the Paper will help the Courts, patent offices and policy-makers to develop public policy and professional guidance and to promote public debate.

### Launch of the Discussion Paper

The Discussion Paper was launched on 23 July, 2002. A press conference was held in the morning at One, Great George Street which was attended by approximately 30 members of the press. This was followed by a lunchtime seminar. Sixty-five people registered for the seminar, including scientists, lawyers, policy-makers and representatives of consumer groups. Professor Martin Bobrow, the Director, Dr Sandy Thomas, and Assistant Director, Tor Lezmore, gave presentations, which were followed by a discussion. The meeting was chaired by Professor Albert Weale.

Coverage in the media of the Discussion Paper was considerable, with articles in the Times, the Financial Times, the Guardian, the Telegraph, Nature, the Lancet and Current Patents. On the day of the launch, the Director gave a number of radio and television interviews, including the Today programme, Radio 5 Live and British Satellite News.

#### Workshop

**Participants** at the closed meeting in February 2002:

Mr Daniel Alexander, Chambers of Michael Fysh QC  
 Dr Lee Beeley, Group Director, Global Research & Development, Pfizer  
 Dr Mark Edwards, Chief Scientific Officer, Oxagen  
 Dr Margaret Llewelyn, Reader in IP law, University of Sheffield  
 Mr Kevin Mooney, Simmons & Simmons  
 Mr Keith Percy, Principal Patent Attorney, BTG plc  
 Mr Tim Roberts, Patent Attorney  
 Mr Andrew Sheard, Patent Attorney  
 Mr Michael Stott, Corporate IP Department, GlaxoSmithKline and Vice President, **European Biopharma IP**,  
 Dr Helen Wallace, Deputy Director, GeneWatch UK

The Round Table is grateful to these people for their assistance.



## Highlights of press coverage

23 July	BBC News online The Times Financial Times The Daily Telegraph The Guardian Reuters Health	Call for tighter rules on DNA patents Human gene patents delaying research Bioethics report warns on number of DNA patents DNA patents 'hinder research' Patenting DNA 'not in public interest' Gene patents should be exception, not rule
25 July	Nature	Bioethics council demands tighter rules on gene patents
26 July	Wall Street Journal (Europe) (Networking) Times Higher Education Supplement Current Patents Gazette	Bioethics Group calls for limits on gene patents  Call for genetics patent rules to be applied  The ethics of patenting DNA
3 Aug	The Lancet New Scientist (Sandy Thomas)	DNA patents: putting an end to "business as usual" Comment and analysis: Their hands on your genes
1 Sept	Current Drug Discovery Science and Public Affairs Patent World	Patenting DNA: a rare exception or the norm?

## Post-publication

Approximately 500 copies of the Discussion Paper were distributed immediately after the launch, with letters sent to 50 relevant organisations and individuals. A further 500 copies have been sent out during 2002. The Discussion Paper has also been downloaded more than 12,000 times from the Council's website.

The Council has received a number of invitations to discuss the Paper's recommendations both with industry groups and with patent offices, for example the European Patent Office and the Norwegian Patent Office.

### Presentations:

Rockefeller Foundation, New York	Dr Sandy Thomas	Aug 02
Hong Kong University	Professor Brian Heap	Sep 02
BioMalaysia 2002	Professor Brian Heap	Sep 02
National University of Singapore	Professor Brian Heap	Sep 02
Global Health Forum, Tanzania	Dr Sandy Thomas	Nov 02
Genetics and Law Conference, London	Dr Sandy Thomas	Nov 02

Members of the Round Table Group will meet in the summer of 2002 to assess the response to the Discussion Paper and to consider possible follow-up activities.



# Genetics and human behaviour: the ethical context

*The Report, **Genetics and human behaviour: the ethical context**, was published on 2 October 2002.*

## Membership of Working Party

**Professor Bob Hepple QC (Chairman)**  
Master, Clare College, Cambridge

**Professor Martin Bobrow CBE**  
Head of Department of Medical Genetics, University of Cambridge  
Deputy Chairman of the Nuffield Council on Bioethics

**Professor Tom Baldwin**  
Head of Department of Philosophy, University of York  
Member of the Nuffield Council on Bioethics

**Professor Annette Karmiloff-Smith**  
Head of Neurocognitive Development Unit  
Institute of Child Health, University College London

**Professor Sandy McCall-Smith**  
Professor of Medical Law, University of Edinburgh

**Professor Terrie Moffitt**  
Social, Genetic and Developmental Psychiatry Research Centre  
Institute of Psychiatry, King's College London

**Dr Paul Pharoah**  
CRC Senior Clinical Research Fellow  
Strangeways Research Laboratories, Cambridge

**Professor Nicholas Rawlins**  
Professor of Behavioural Neuroscience, University of Oxford

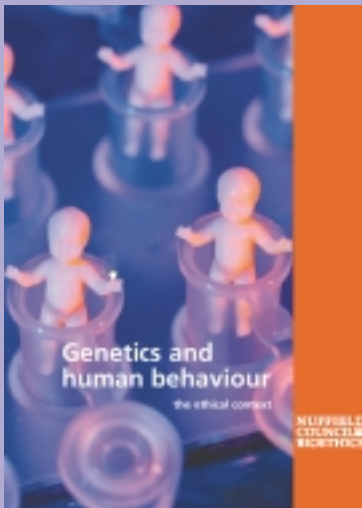
**Professor Martin Richards**  
Centre for Family Research, University of Cambridge

**Mr Pushpinder Saini**  
Blackstone Chambers, Temple

**Dr Tom Shakespeare**  
Policy, Ethics and Life Sciences Research Institute,  
International Centre for Life, Newcastle

**Professor Anita Thapar**  
Professor of Child and Adolescent Psychiatry,  
University of Wales College of Medicine

**Professor Andrew Wilkie**  
Wellcome Senior Clinical Fellow, Honorary  
Consultant in Medical Genetics,  
Institute of Molecular Medicine, University of Oxford



## Terms of Reference

1. To define and consider ethical, social and legal issues arising from the study of the genetics of variation within the normal range of behavioural characteristics.<sup>1</sup>
2. To survey the current field of research, in particular, to review:
  - (a) the evidence for the relative importance of genetic influences;
  - (b) the basis for characterisation and measurement of behaviour;
  - (c) the relationship between normal variation in behaviour and disease processes.
3. To consider potential applications of the research.
4. To consider:
  - (a) the ethics of undertaking research on the genetics of normal variation in behavioural characteristics<sup>2</sup> on human participants<sup>3</sup>;
  - (b) the implications of applying the findings of such research through the development of genetic tests to establish particular characteristics in practical contexts including education, employment, insurance, legal proceedings;
  - (c) the particular impact of the findings of a genetic test on the individual, including an individual child or fetus, on family members, and on various social groups;
  - (d) the broader impact of genetic knowledge on the perception of those with relevant behavioural characteristics, including questions about stigma

<sup>1</sup> And to identify the issues which are additional or complementary to those dealt with in the Council's Report: Mental Disorders and Genetics: The Ethical Context.

<sup>2</sup> Including, for example, research on intelligence, antisocial behaviour, sexual orientation and addiction.

<sup>3</sup> Including ethnic groupings, criminal offenders and children.

## Introduction

Research to find out how our genes influence the way we behave is complex and controversial. As yet there are no practical applications of research in behavioural genetics, but it is not too soon to examine the ethical, legal and social issues that it raises.

The Council held a Workshop in 1999 to encourage debate about implications of research in behavioural genetics. As a result of this meeting, the Council decided that a comprehensive review of the issues was required. A Working Party was established in 2000, charged with examining the ethical, legal and social implications of research in behavioural genetics.

Two meetings took place at the end of 2000 and a further eight meetings were held during 2001. The Working Party also held a series of fact-finding meetings throughout the UK and conducted an exercise of consultation with the public during the summer of 2001.

The Working Party held its final two meetings in 2002. In March 2002 the draft Report was sent for peer review by an international panel of experts. The Report was revised in light of the comments received and was then submitted to the Council for approval in June 2002. The Report was launched in October 2002.

### The Report

The Report considers the ethical, legal and social issues that are raised by research into behavioural genetics. It focuses on human behaviour within the normal range of variation, looking at traits such as intelligence, antisocial behaviour, personality and sexual orientation, rather than at diseases or disorders.

After discussing the historical and scientific background to the research, the Report considers its implications and possible

applications. Issues discussed include: the responsibilities of those who report research; the responsibilities of research sponsors; changing or selecting behavioural traits on the basis of genetic information, for example by somatic and germline gene therapy or using prenatal selection; the medicalisation of normal behaviour; legal responsibility; and the use of genetic information in employment, education, and insurance. The Report makes several recommendations for future policy and practice.

### Launch of the Report

The Report was launched on 2 October 2002. Coverage of the Report was considerable both in the broadsheets and scientific journals, and members of the Working Party and the Secretariat also gave a large number of radio and television interviews. Much of the coverage focused on the recommendations relating to legal responsibility and prenatal selection.

A seminar was held in the afternoon at Senate House, University of London. Over 100 participants attended including scientists, philosophers, representatives of research ethics committees, genetic interest groups and members of the press. Presentations discussing the findings of the Report and its recommendations for policy were given by Professor Bob Hepple, Professor Martin Richards, Professor Andrew Wilkie, Professor Terrie Moffitt and Professor Tom Baldwin. A discussion then took place with members of the audience.



## Highlights of press coverage



2 Oct	The Guardian Daily Telegraph The Times Daily Mail This is London (Evening Standard) Reuters	Warning on linking genes and human behaviour Call for ban on designer babies chosen for IQ Criminal gene 'should mean lighter sentence' Genes search brings warning over ethics of designer babies Genes may help villains escape jail  Judges urged to consider criminal genes
3 Oct	Nature	Criminal courts 'should take genetics into account'
4 Oct	Financial Times The Biochemist The Scientist Times Higher Education Supplement	Behavioural genetics warning The ethics of embryo selection Genetics of behaviour assessed Genes 'may be used as mitigating factor'
5 Oct	BMJ	Safeguards needed now to prevent unethical genetic selection in future
6 Oct	The Sunday Times	Freedom is a better bet than the gene genie

### Radio and TV coverage

Independent radio news	Interview with Prof Bob Hepple
BBC Radio 4, Today	Interview with Prof Bob Hepple
BBC Breakfast news - discussion	Interview with Prof Annette Karmiloff-Smith
BBC Radio 5 Live Morning Reports	Interview with Dr Sandy Thomas
BBC World Service, British News programme	Interview with Prof Terrie Moffitt
ABC Radio National (Australia)	Interview with Dr Sandy Thomas
Talk Radio, Cape Town	Interview with Prof Terrie Moffitt

## Post-publication

Nearly 100 letters highlighting particular recommendations were distributed with copies of the Report to relevant organisations and individuals. By the end of 2002, more than 1000 copies had been sent out. Over 30,000 copies have been downloaded from the Council's website within the first three months of publication.

Response to the Report has been positive. A number of presentations were made in 2002, and more are planned for 2003. Issues relating to research in behavioural genetics have remained extremely topical, and there have been frequent references to the Report.

### Presentations:

- 10th World Congress on Psychiatric Genetics, Brussels Professor Anita Thapar 12 Oct 02
- Cambridge University Bioethics Group Professor Martin Bobrow, Professor Tom Baldwin
- Public discussion meeting, Glasgow Science Centre 24 Oct 02
- Science communication group, Fiocruz, Brasilia Dr Sandy Thomas 5 Nov 02
- Center for Strategic and International Studies, Washington, USA Professor Sandy McCall-Smith, Dr Sandy Thomas 12 Dec 02

It is still too early to assess the long-term impact of the Report. However, members of the Working Party will meet towards the end of 2002 to consider follow-up activities.





# New work

## Pharmacogenetics: ethical issues

*A Working Party on **Pharmacogenetics: ethical issues** was established in September 2002.*

### Membership of Working Party

**Professor Peter Lipton (Chairman)**

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

**Professor Haleh Afshar**

Department of Politics, University of York

**Professor Martin Bobrow CBE**

Head of Department of Medical Genetics, University of Cambridge Deputy Chairman of the Nuffield Council on Bioethics

**Professor John Caldwell**

Dean, Faculty of Medicine, University of Liverpool

**Professor Klaus Lindpaintner**

VP Research Director, Roche Genetics, Switzerland

**Professor Sir Michael Rawlins**

Chairman, National Institute for Clinical Excellence and Professor of Clinical Pharmacology at the University of Newcastle

**Professor Nikolas Rose**

Professor of Sociology, London School of Economics and Political Science

**Dr Nigel Starey**

Director, Centre for Primary Care, University of Derby

**Professor Albert Weale**

Professor of Government, University of Essex and Member of the Nuffield Council on Bioethics

### Terms of Reference

1. To explore what pharmacogenetics offers now and is likely to offer in the near future;  
In particular to examine the effect of pharmacogenetics on:
  - (a) the design of medicines, the promotion of efficacy and safety in the administration of medicines to individuals;
  - (b) the conduct of clinical trials in the context of pharmaceutical research and development;
  - (c) clinical practice.
2. To consider ethical issues specifically raised by pharmacogenetics;  
In particular to examine the following areas:
  - (a) consent, privacy and confidentiality;
  - (b) the management of information about the likelihood of response to treatment;
  - (c) the implications of differentiating individuals into groups based on the likelihood of response to treatment.
3. To consider the implications for the provision of healthcare

## Background

People vary in their response to the same medicine. Few medicines are effective for everyone; all may cause adverse reactions or occasionally death in some patients. Some of the variation between individuals in response to medicines is due to differences in their genetic make-up. Pharmacogenetics is the systematic study of the source of this variation, and has a role in improving the efficacy and the safety of medicines.

Researchers in pharmacogenetics are already investigating current and future treatments for diseases such as HIV/AIDS, cancer and depression. Some pharmacogenetic tests are already in clinical use, and while the prospect of the routine use of pharmacogenetic testing is some way off, it is already important to consider ethical and legal issues which may arise.

The Nuffield Council held a Workshop in December 2001 to initiate discussion in the area, with experts from pharmaceutical and genomics companies, and from the fields of toxicology, medical ethics, primary care medicine and human molecular genetics. As a result of the meeting it was decided that it would be useful to examine the likely developments in more detail. The Council established a Working Party in September 2002.

The Working Party held its first meeting in September 2002, during which the terms of reference were agreed and the main topics for discussion identified. A second meeting was held in November 2002. Initial discussions concerned issues of stratification of patients based on their genetic characteristics, including the implications of pharmacogenetics for different racial groups and for access to healthcare, and also issues raised by the handling of genetic information. The economic impact of pharmacogenetics on the pharmaceutical industry was also considered.

## Consultation

A consultation exercise was launched in November 2002. The consultation document was circulated to a wide range of practitioners, industry, patient groups and professional institutions, and was also available on the Council's website. Interested individuals and organisations were invited to contribute and the replies will inform the discussions of the Working Party.

The consultation paper posed 20 questions, including:

- Will the applications of pharmacogenetics increase inequalities in the provision of healthcare?
- What are the implications of finding a genetic variant that influences the response to a medicine in a particular racial or ethnic group?
- What would be appropriate methods of regulating scope, storage and access with respect to pharmacogenetic information used in clinical practice?
- Should a GP be responsible for providing a pharmacogenetic test or should tests be available directly to patients over the counter?

The closing date for responses is February 19, 2003. By the end of 2002, 1,500 copies of the consultation document had been downloaded from the Council's website.

## Fact-finding

As part of its research, the Working Party has held fact-finding meetings with the following experts:

- Professor David Goldstein, Wolfson Professor of Genetics, University College London
- Dr Rashmi Shah, Medicines Control Agency
- Mr Adrian Towse, Office of Health Economics

The Working Party is grateful to them for their assistance. Further fact-finding meetings are planned for 2003 in the following areas: health economics, law, healthcare insurance and patient organisations.

# Future work

## The ethics of research involving animals



There is widespread discomfort about the use of animals in research, but also a widespread acceptance of the need to do medical research involving the use of animals. In November 2001, the Council held a Workshop which brought together a number of experts to consider ethical issues raised by likely developments in research involving animals.

During the Workshop, several areas were identified that might warrant further consideration:

- the ethical implications of the rising trend in the number of genetically modified animals;
- whether there are morally relevant distinctions to be made between different species;
- the ethical implications of alternatives to animal research;
- regulatory issues, including the classification and assessment of welfare of genetically modified animals,
- and difficulties with the cost-benefit analysis of the use of animals in research;
- variations between international regulations; and
- the importance of public information and education.

As a result of this meeting it was decided that the topic merited further examination. The Council has therefore established a new Working Party to consider the ethics of research involving animals. The Council appointed a Chair and members for the Working Party during 2002. The first meeting will take place in January 2003.

Further information will be available on the Council's website at:  
[www.nuffieldbioethics.org/animalresearch](http://www.nuffieldbioethics.org/animalresearch)

## Genetically modified crops: Follow-up work

In 1999 the Council published a Report, **Genetically modified crops: ethical and social issues**. The Report provoked considerable discussion in the context of a heated debate. As part of its follow-up activities, the Council has decided to return to the topic. The conclusions and recommendations of the Report will be re-assessed in the light of recent developments in the area.

The Council has therefore convened a Working Group which comprised some former members of the original Working Party, together with a member of Council. The Group held its first meeting in December 2002 and decided to focus on the potential application of GM crops in developing countries, an area often neglected in the UK debate. The Council will publish a Discussion Paper on the topic in the summer of 2003. It is hoped that this paper will contribute to the national debate on GM taking place in 2003.



# External activities

The Council's terms of reference include examination of and reporting on questions in bioethics 'with a view to promoting public understanding and discussion'. The Council therefore works to promote debate of the issues considered in its Reports and also liaises with other organisations, both in the UK and abroad, to increase awareness of the Council.

## Promoting public discussion

Members of the Council and Secretariat have participated in a wide range of events throughout the year, both in the UK and abroad. Representatives of Council gave over 35 presentations during 2002, more than in any previous year, and also attended a large number of conferences, lectures and workshop meetings.

### Highlights of presentations

January	Genetics, Genomics & Ethics – who owns your genes? Conference at ESAT Young Scientist of the Year Exhibition, Dublin, Ireland	Dr Sandy Thomas: 'Our genetic future: who decides?'
February	17th Annual Emerging Issues Forum, North Carolina, US	Dr Sandy Thomas: 'Our genetic future'
February	Science of Public Understanding AS-level conference, London	Professor Albert Weale: 'The ethics of xenotransplantation'
April	HUGO Human Genome meeting, Shanghai, China	Dr Sandy Thomas: 'Patenting the Genome'
May	'Genetics after the Genome' EMBO conference, Brno	Dr Sandy Thomas: 'Patents in a genetic age'
July	Irish Bioethics Council, Dublin	Dr Sandy Thomas: 'Best practice for Commissions of Bioethics'
September	Forest Biotechnology Forum, Edinburgh	Dr Sandy Thomas: 'Impending Barriers, Policy and Implications'
December	Green Alliance, European Parliament, Brussels	Professor Tom Baldwin: 'Stem cells'

These talks are in addition to presentations relating to the Reports published in 2002 which are listed elsewhere in the annual report.



## Glasgow: public discussion meeting

On 24 October 2002, the Council held a public meeting in the Glasgow Science Centre on the topic of '**Genes and behaviour: ethical issues**'. This was a new venture for the Council: an evening discussion meeting at an out-of-London venue.

Approximately 60 people attended the evening, including several members of the University of Glasgow and a group of school teachers. Members of the Working Party on **Genetics and human behaviour: the ethical context**, gave brief presentations highlighting the main issues and recommendations in the Report. Questions were then invited from the audience and a lively panel discussion took place, chaired by Professor Sir Ian Kennedy. The meeting was followed by a reception in the atrium of the Science Centre.

## Reaching out to young people

The Council continues to attach importance to reaching a wide audience with its Reports and is particularly interested in targeting educational groups. Following discussions during 2002, a new Sub-group will be established in 2003 to consider methods of reaching out to young people. This group will explore the possibility of collaborating with other organisations on educational projects and will also examine ways of producing shorter, more accessible, summaries of Reports.

The Council received more than 100 general enquiries during 2002, many of which came from students. These enquiries included questions about topics the Council had investigated in detail and also more general questions about bioethics.

## CD-ROM

As one of the initiatives to mark its tenth anniversary, the Council produced a CD-ROM during 2002. This included all the publications of the Council, together with background information about the Council's method of work and other activities. New prefaces by leading commentators were also commissioned for each Report, to provide a current perspective on the Report and to highlight developments that have arisen since publication.

The aim of the CD-ROM was to reach new audiences and make the Council's publications available more widely. 66,000 copies were distributed internationally with the science journal *Nature* in October 2002.

## Website

The Council's website has become an increasingly important part of the Council's dissemination strategy. During 2002, more than 152,000 people visited the site: approximately 400 visitors each day. This is more than double the number of visitors to the site in 2001. The distribution of the CD-ROM with *Nature*, and interest in the new Report on *Genetics and human behaviour: the ethical context*, meant that visitor figures were particularly high during October: an average of 1,881 people visited the site each day. Visitors are also spending longer browsing the site, with the average length of visit lasting over 12 minutes. There are now more than 200 pages on the website (not including browseable versions of Reports). The website will be expanded during 2003 to ensure that visitors to the site are aware of the extent of the information included and are able to navigate the site as easily as possible.







## Highlights of media activities

The Council frequently receives request to give interviews to the media. In addition to coverage relating to the Reports published during 2002, highlights of media activities included:

IBBC World Service	Transplantation of frozen organs
ITN news	Stem cells
Channel 4	The Anatomists, 'Body Worlds' exhibition
Radio 4, Analysis	Fragility of science
The Observer	Body Worlds exhibition
Radio 4, Today programme	Redesigning humans
Radio 4, You and Yours	Intellectual Property rights in developing countries
CNN	Reproductive cloning
Reuters	Reproductive cloning

## External relations

In the UK, the Council continues to maintain close contact with the Department of Health and the Human Genetics Commission, meeting annually to exchange information about current and future work programmes. The Council also liaises with governmental departments, professional organisations and consumer groups as relevant for its work.

### Consultations and Evidence submitted:

The Council is regularly asked to respond to consultative documents produced by other organisations. In general the Council responds only to those which specifically address issues which it has previously considered in detail in its publications. The Council responded to the following consultations in 2002:

- **Department of Health**
  - The Removal, retention and use of human organs and tissue
  - The import and export of body parts (draft code of practice)
  - Consultation on Draft code of practice on Families and post mortems: draft interim statement on the use of human organs and tissue
- **Department for Environment, Food & Rural Affairs**
  - Implementation of the Cartagena Protocol/Regulation of the European Parliament and of the Council on the transboundary movement of genetically modified organisms.
  - Implementation of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms
- **Food Standards Agency**
  - Consultation document of the EC on the Novel Food Regulation (EC) No 258/97
- **Human Genetics Commission**
  - Genetic testing services supplied directly to the public
- **The Retained Organs Commission**
  - Consultation Document on unclaimed and unidentifiable organs and tissues and a regulatory framework



## International activities

The Council also has close links with other ethics bodies abroad, especially those in the European Union. Representatives from the Council attended a *Forum of National Ethics Committees and similar bodies*, which was arranged by the European Commission and the Danish Ethics Council in December 2002. The Council also acted as co-convenor for the Fourth Global Summit of National Bioethics Commissions in Brasilia.

Members of the Council participated in a wide range of international meetings throughout 2002. The Council also received a number of international visitors, including:

- Dr Arnold Naimark, Chair, Biotechnology Advisory Committee, Canada
- Dr. Siobhán O' Sullivan, Irish Bioethics Council
- Professor Tan Chorh and Mr Jeffrey Chan, Singapore Bioethics Advisory Committee
- Delegation from Taiwan ELSI
- Dr Tohru Masui, Cell Bank, National Institute of Health Sciences, Tokyo
- Robert Triendl, Center for Life Sciences and Society, Japan
- Dr Tomoatsu Shibata, The Sasakawa Peace Foundation
- British Council tour for Brazilian science journalists



## Global Summit of National Bioethics Commissions

The Fourth Global Summit of National Bioethics Commissions took place in Brasilia, Brazil in November 2002. The Council acted as co-convenor for the Summit, with the Comité Consultatif National d'Ethique of France and the Department of Science and Technology of the Ministry of Health, Brazil. The meeting was attended by delegates and observers from 27 countries.

The Global Summit provides one of the few settings where international implications of issues in bioethics can be debated. A communiqué was produced during the meeting, drawing attention to the need for national commissions to pay greater attention to the wider impact of their decision-making. The main topic for discussion on the first day was ethical issues arising from stem cell therapy. On the second day, a series of breakout groups were held to allow more focused debate, on issues relating to pharmacogenetics, DNA databases and the role of the media in debates concerning bioethics.

The next Global Summit will take place in the autumn of 2004 in Australia. The Council has been invited to be a member of the Steering Committee, together with the Australian Health Ethics Committee and the new National Bioethics Commission of Brazil.

# Annex A

## Financial and funding Report on the calendar year 2002

Expenditure	2002 Actual £	2001 Actual £
Salaries and staffing costs	281,084	239,023
Office costs including premises	25,934	34,367
Stationery and press cuttings	11,807	8,099
Photocopy, post, phone, fax	28,497	11,857
Committee and meeting costs	55,800	115,414
Printing of reports	82,797	2,361
(Less) reports sold	(2,458)	(2,029)
Publicity of reports	21,193	971
Equipment (IT developments)	3,796	4,704
<b>Net expenditure</b>	<b>508,449</b>	<b>414,767</b>
Funding Due		
Nuffield Foundation	160,666	231,729
Medical Research Council	160,667	100,000
Wellcome Trust	160,667	83,038
Other income (Nuffield Foundation)	27,000	-
	<b>509,000</b>	<b>414,767</b>
Balance Carried Forward to 2004	551	-
Overheads met by Nuffield Foundation	143,083	88,461

### Notes

Reconciles to expenditure published by the Nuffield Foundation, adding overheads and recording sales against income, not expenditure



