
Nuffield Council on Bioethics
Annual Report 2001
Ten Year Anniversary

**NUFFIELD
COUNCIL^{ON}
BIOETHICS**

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Nuffield Council on Bioethics
28 Bedford Square
London WC1B 3JS

Telephone: +44 (0)20 7681 9619
Fax: +44 (0)20 7637 1712
Email: bioethics@nuffieldfoundation.org
Website: <http://www.nuffieldbioethics.org>

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Foreword

2001 was a year of considerable development for the Council. Work gathered pace on three major projects, all of which will be published by mid-2002. Meanwhile, I saw the need to continue to consolidate the funding and organisational structure of the Council. Throughout, I was able to call on the extraordinary generosity of my colleagues on the Council, who gave unstintingly of their time and energy, and on the dedication of the Secretariat. I record here my thanks.



The new funding arrangement is a very great boost for the Council. It provides stability and allows for longer-term planning. I am extremely grateful to the Council's three funders for their encouragement and support. Most critically, the arrangement secures for the Council the continuation of its most prized and important attribute, its independence. The Council quite properly must render an account of its activities and be judged as to whether it has properly met its responsibilities, as set down in its terms of reference. But, as regards what it chooses to consider, how it proceeds, and what it recommends, these the Council decides for itself. Therein lies the independence so greatly valued both by the Council and by those who look to its work.

As regards the Council's organisation, we were able through the generosity of the Nuffield Foundation to expand such that, by the end of 2001, we occupied much of the basement floor of the Foundation's building. This has significantly helped us to expand our staff and output, as well as raising the morale of everyone. Also, the various sub-groups which I have set up have begun to make their contribution on such matters as membership of the Council, external relations, and future work.

The Council's 10th Anniversary was marked by a reception. It was a very happy occasion and gave me very great pleasure. It was very gratifying to be able to thank all those who had helped us to chart our path in our first decade and to report on our plans and vision for the future.

That future looks busier than ever. We have a significant programme of work ahead of us, as well as plans to co-operate more actively with colleagues in the US, Europe and elsewhere. At the start of the new Millennium, I suggested that we were entering "the century of bioethics", so significant are the developments on biology, biomedicine and biotechnology. There is much to do and the Nuffield Council is now better placed than ever to play its part.

Introduction

Background

The Nuffield Council on Bioethics is an independent body established by the Trustees of the Nuffield Foundation in 1991 to consider ethical issues arising from developments in biological and medical research. The Council is funded jointly by the Nuffield Foundation, The Wellcome Trust and the Medical Research Council. The Council identifies and defines ethical questions raised by developments in biology and medicine in order to respond to and anticipate public concern. It seeks to contribute to policy-making and to stimulate discussion in bioethics.



The Council's Reports and Discussion Papers form the core of its work. Since 1991, the Council has produced five Reports and two Discussion Papers, relating, respectively, to: ethical issues associated with genetic screening; uses of human tissue; xenotransplantation; genetics and mental disorders; genetically modified crops; clinical research in developing countries; and stem cell therapy. The Council is due to issue Reports on three further topics during 2002: the ethics of research related to healthcare in developing countries; the ethics of research into genetics and human behaviour; and the ethics of patenting human DNA.

2001 marked the tenth anniversary of the Council. Over the past decade the Council has acquired international standing, providing analysis and advice that assists policy-making, addresses public concerns and stimulates debate. The landscape of policy-making in bioethics has changed significantly during this ten-year history. Throughout, the Council has perceived its independence as critical in ensuring that it maintains the trust of the public in its work.

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.

Council membership

(at December 2001)

Professor Ian Kennedy (Chairman)

Professor of Health Law, Ethics and Policy, School of Public Policy,
University College London

Professor Martin Bobrow CBE (Deputy Chairman)

Head of Department of Medical Genetics, University of Cambridge

Professor Tom Baldwin

Head of Department of Philosophy, University of York

Professor Sir Kenneth Calman KCB FRSE

Vice-Chancellor and Warden, University of Durham

(co-opted member of Council for the period of his Chairmanship of the Working Party on the ethics of health-related research in developing countries)

Revd Professor Duncan Forrester DD

Professor of Christian Ethics and Practical Theology, University of Edinburgh

Professor Sir Brian Heap CBE FRS

Master, St Edmund's College, University of Cambridge

Professor Bob Hepple QC

Master, Clare College, University of Cambridge

(co-opted member of Council for the period of his Chairmanship of the Working Party on genetics and human behaviour: the ethical context)

Lady Hornby

Chairman, The Kingwood Trust

Mrs Rebecca Howard

Executive Director of Nursing, Royal Liverpool Children's NHS Trust (Alder Hey)

Professor John Ledingham

Emeritus Professor of Clinical Medicine, University of Oxford

Mr Derek Osborn CB

Chairman of the European Environment Agency; Chairman of UK Roundtable on Sustainable Development

Professor Catherine Peckham CBE

Head, Centre for Paediatric Epidemiology and Biostatistics, Institute of Child Health, and Great Ormond Street Hospital

Professor Martin Raff FRS

Professor of Biology, University College London

Mr Nick Ross

Broadcaster

Professor Herbert Sewell

Professor of Immunology, University of Nottingham

Professor Marilyn Strathern FBA

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

Professor Albert Weale FBA

Professor of Government, University of Essex

Dr Alan Williamson FRSE

Consultant on Biotechnology

Secretariat

The Secretariat is the executive arm of the Council. Dr Sandy Thomas is the Council's Director. The Secretariat also includes Susan Bull and Tor Lezmore, Assistant Directors; Yvonne Melia, Research Officer; Julia Fox, PA; Amanda Jones, Secretary. During 2001 Maria Gonzalez-Nogal joined the Secretariat as Information Assistant and Nicola Perrin was appointed as the Public Liaison Officer.

Method of working

Members of the Council are drawn from a wide range of backgrounds. Some are drawn from the worlds of science, medicine, philosophy, theology, industry and law. Others have no professional engagement with bioethics, but have a commitment to the discussion and analysis of ethical issues. The Council appoints its own members after taking advice widely. Members serve on the Council for three years, with the possibility of an additional three-year term. During their membership, they serve as individuals and not as representatives of any group or interest. The Chairman of the Council is appointed by the Nuffield Foundation, after consultation with the other funders.

Full details of the Council's method of working, including more information about Working Parties, Round Table meetings and Workshops, are now included on the Council's website, at www.nuffieldbioethics.org

Members of the Council meet formally each quarter. During these meetings, the Council reviews work in progress and recent biomedical and biological advances that raise ethical questions with a view to identifying topics for further exploration. In addition to quarterly meetings, the Council considers broader themes at its annual 'Forward Look' meeting. This provides opportunities for discussion amongst Council members about the role of the Council and its methods of working and draws on the expertise of invited speakers. Separate sub-groups of the Council also meet to discuss specific matters in more detail, for example, finance, future work, membership, external relations and education.

Typically, once the Council has selected a potential topic for consideration, it sets up a Workshop to identify and discuss relevant issues and decide whether the issue merits further examination. If so, the Council will establish a Working Party or a smaller Round Table meeting to examine and report on the relevant ethical, social, legal, and practical issues.

A Working Party is usually established to consider an issue of considerable significance. Each Working Party consists of an independent Chair and a multidisciplinary group of seven to 14 Members appointed by the Council, including two (ordinarily) drawn from the Council. Members bring a range of specialist experience and skills. Producing a Report typically takes 18 months to 2 years, during which time the Working Party will have up to 12 meetings to examine issues, consider and develop arguments, and draft its Report. Alternatively, a Round Table meeting is held when a topic is more focused, and where a more rapid response is required. Typically, a Round Table meeting will have six to eight members and will deliberate for a six to 12 month period before producing a Discussion Paper.

The Council also aims to raise public awareness of the issues considered in its Reports. Currently, it is examining ways of developing liaison with other organisations, both in the UK and abroad.

New arrangements for funding

Since 1994, the Council has received funding annually from its three funders: the Nuffield Foundation, the Medical Research Council and The Wellcome Trust. In 2000, a different approach was proposed which would allow core funding for five years. The new funding structure, with core funding guaranteed until 2006, will allow the Council and the Secretariat more flexibility to plan future work, while maintaining independence, and giving greater financial stability.



The new arrangements for funding have been accompanied by a more structured relationship between the Council and its funders. The Council will submit an annual report to each, including details of its expenditure. Twice-yearly meetings will be held with funders at which comments and suggestions about the Council's programme and plans will be exchanged, although the funders will not seek to influence the Council's choice of topics or way of working. A review of the Council's work by an external group of national and international experts will also take place, in the fourth year of each five-year funding cycle as a condition of continued support.

In October, the funders agreed to contribute £803,182 each over five years. In addition, the Nuffield Foundation agreed to provide £993,000 to cover indirect costs over the same period.

“ It is to be welcomed that increasingly advisory groups are made up of a balance of the different disciplines and that education of future professionals, including scientists, is likely to incorporate the skills of ethical analysis. ”

Alastair Campbell,
Professor of Ethics in Medicine,
University of Bristol

“ There is a need to consider urgently the ethical issues of emerging technologies before the public and society is presented with a *fait accompli* and has not time to determine what is best both for society and for the individual. ”

Dr Michael Dexter,
Director, The Wellcome Trust

“ Debates about bioethics are not only debates about scientific and medical practices, but debates about how we, as a society, want to live. ”

Dr Ian Gibson, MP

The Council's Ten Year Anniversary

To mark its tenth year, a reception was held on 27 June 2001 for approximately 70 invited guests. They included current and former members of Council, the Secretariat and of Working Parties, representatives from the Council's three funding bodies, and individuals from the fields of bioethics, politics and public policy, medicine, science, law, philosophy, sociology and journalism. The Chairman gave a speech to mark the occasion and to convey the Council's appreciation to those who had contributed to its work over the ten-year period since its establishment, many of whom were able to be present.



The Council also carried out a poll in association with Prospect magazine. Leading commentators and policymakers were invited to reflect on the following questions:

- What will be the most ethically controversial developments in medicine and biotechnology over the next ten years?
- Will attitudes towards currently controversial techniques such as genetic engineering and cloning change during the next ten years, and if so, in what way?
- What do you consider should be the role of the following groups in bioethical debate: moral philosophers, lawyers, scientists, parliament, government, the general public, the media?

Over 50 responded, from a wide range of backgrounds. The results will be published in 2002, both on the Council's website and in Prospect magazine. They are also included throughout this Report.

The responses to the first question gave a useful summary of topics that are predicted to raise important ethical questions over the next decade, and the Council will consider these when assessing its future programme of work. Perhaps unsurprisingly, the most frequent response related to cloning (both reproductive and therapeutic), but other topics, mentioned by several respondents, included the problems

of providing health care for the increasing number of elderly (and associated end-of-life issues), the provision and rationing of healthcare and global inequalities in health.

Another initiative planned to mark the Council's tenth anniversary is the production of a CD-ROM, containing the Council's publications. New prefaces by leading commentators have been commissioned for each Report published by the Council, to give a current response to the Report and to highlight developments in the area since publication. The CD-ROM, which will be produced in 2002, will also include the Council's other publications as well as background information about the Council's method of work and other activities.

“ It seems to me that too often people debating bioethics end up simply reacting to short-term concerns and controversies. Your exercise might be a good opportunity to focus our minds on some more long-term, principled thinking. ”
Dr Ian Gibson, MP

Working Parties

The ethics of research related to healthcare in developing countries

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.

Membership of Working Party (at December 2001)

Professor Sir Kenneth Calman (Chairman)

Vice-Chancellor and Warden, University of Durham and 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, National Aids Control Organisation, Ministry of Health, Government of India, New Delhi

Professor Keith McAdam

Director, MRC Laboratories, Fajara, The Gambia

Dr Anne McLaren

Geneticist, Research Associate, Wellcome/CRC Institute, Cambridge

Professor Bhikhu Parekh

Professor of Political Theory, University of Hull

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 and 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

Consultant for education & ICT

Professor Peter Smith

Head of Department of Infectious and Tropical Diseases, London School of Hygiene & Tropical Medicine

Dr Fabio Zicker

Coordinator, Research Capacity Strengthening and Tropical Diseases Research Programme, World Health Organization

In 1999, the Council convened an international Workshop to consider the ethics of conducting research related to healthcare in developing countries. The Discussion Paper arising out of the Workshop has now been downloaded more than 20,000 times from the Council's website, demonstrating the importance and timeliness of the topic. In January 2000, the Council established a Working Party to consider the issues raised in more detail.

The Working Party has examined the ethical issues raised when research involving human participants is conducted in a developing country, funded or undertaken by agencies or researchers from outside that country. Discussion has centred around four main themes: the standards of care provided to those participating in the research, particularly as members of a control group, cultural sensitivity and consent to research, review of the ethics of the research, and what happens when the research is over.

The Working Party has members drawn from a number of countries, so as to provide a global perspective, including Ghana, Uganda, The Gambia, India, Brazil, Denmark and the UK. The group met five times in 2000, and held a further four meetings during 2001. Summaries of the minutes of these meetings are available on the Council's website. In August, the Report was peer reviewed by an international panel of experts. In the light of their comments, and of contributions from Council members the draft report was revised towards the end of the year, and will be submitted to the Council for comment in March 2002, before being published in the Spring.

“ The most ethically controversial issue in the next ten years will be global inequalities in health, access to health care, and health research. This is in fact the number one issue now, but it isn't widely recognised as such.”
Richard Smith, Editor BMJ

As part of its research, the Working Party, and its Sub-groups, have held fact-finding meetings in Chennai, India and in the United States during the year.

Chennai, India, 21 January 2001

Dr Rani Balasubramanian, Tuberculosis Research Centre (TRC), Chennai
Professor MK Bhan, All India Institute of Medical Sciences, Delhi
Professor George Chandy, Christian Medical College (CMC), Vellore
Professor NK Ganguli, Indian Council of Medical Research (ICMR)
Dr M Gupte, National Institute of Epidemiology
Professor Ravi Jacob Korula, CMC, Vellore
Dr MS Jawahar, TRC, Chennai
Dr L Kameshwaran, Former President, National Academy of Medical Sciences
Dr C Kolapp, TRC, Chennai
Professor R Korula, CMC, Vellore
Justice Krishnaswamy
Dr Nandini Kumar, ICMR
Dr V Kumaraswami, TRC, Chennai
Dr HN Madhavan, Vision Research Foundation, Chennai
Dr M K Mani, Consultant Nephrologist, Chennai
Dr Rema Mathew, TRC, Chennai
Dr Vasantha Muthuswamy, ICMR
Dr MUR Naidu, The Nizam's Institute of Medical Sciences
Dr P R Narayanan, TRC, Chennai
Dr S Rajasekaran, TRC, Chennai
Dr Rajeswari Ramachandran, TRC, Chennai
Dr VD Ramanathan, TRC, Chennai
Dr Ravi Rengachari, ICMR
Dr K Sadacharam, TRC, Chennai
Dr M A Salam, The Centre for Health and Population Research (ICDDR-B), Bangladesh
Dr DK Sampath
Professor KR Sethuraman
Professor CH Shashindran, Department of Pharmacology, Pondicherry
Dr H Srinivasan
Dr VK Srinivasan, Indian Institute of Economics
Professor Manorama Thomas, Professor of Anatomy and Human Genetics, Bangalore
Professor Yogesh Tripathy, Kasturba Medical College
Dr KC Umapathi, TRC, Chennai

Boston, US, 22 March 2001

Professor George Annas, Boston University
Professor Barry Bloom, Harvard School of Public Health
Dr Chris Howson, March of Dimes
Professor Robert Levine, Yale University
Professor Ruth Macklin, Albert Einstein College of Medicine

Washington DC, US, 23 March 2001

Dr Finley Austin, Roche
Dr Melody Lin, Office for Human Research Protections (OHRP)
Dr Peter Lurie, Public Citizen
Dr Eric Meslin, National Bioethics Advisory Commission (NBAC)
Mr Paul Ndebele, Johns Hopkins University
Dr Godwin Ndossi, Johns Hopkins University
Dr Duncan Ngare, Johns Hopkins University
Ms Alice Page, NBAC
Ms Maureen Power, National Institute of Allergy and Infectious Diseases (NIAID)
Dr Regina Rabinovitch, Malaria Vaccine Initiative (MVI)
Sara Radcliffe, Pharmaceutical Research and Manufacturers of America (PhRMA)
Dr Gillian Woolet, PhRMA

London, UK, 13 June 2001

Dr Imogen Evans, Medical Research Council (MRC) UK
Dr Richard Lane, The Wellcome Trust

Genetics and human behaviour: the ethical context

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.¹
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 characteristics² on human participants;³
 - 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.

Membership of the Working Party (at December 2001)

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

Professor Martin Bobrow CBE
Head of Department of Medical Genetics, Cambridge Institute for Medical Research and Deputy Chairman of Nuffield Council on Bioethics

Professor Tom Baldwin
Head of Department of Philosophy, University of York and member of Nuffield Council on Bioethics

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

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

Professor Terrie Moffitt
Senior Researcher, Social, Genetic and Developmental Psychiatry Research Centre, Institute of Psychiatry, London

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

Professor Nicholas Rawlins
Professor of Behavioural Neuroscience, University of Oxford

Professor Martin Richards
Director of the Centre for Family Research, University of Cambridge

Mr Pushpinder Saini
Barrister, Blackstone Chambers, London

Dr Tom Shakespeare
Director of Outreach, Policy, Ethics and Life Sciences Research Institute, Newcastle

Professor Anita Thapar
Professor of Child and Adolescent Psychiatry, University of Wales

Professor Andrew Wilkie
Wellcome Trust Senior Research Fellow, Honorary Consultant in Medical Genetics, Weatherall Institute of Molecular Medicine, Oxford

¹ And to identify the issues which are additional or complementary to those dealt with in the Council's report on **Mental Disorders and Genetics: the ethical context**.

² Including, for example, research on intelligence, antisocial behaviour, sexual orientation and addiction.

³ Including ethnic groupings, criminal offenders, and children.

A Working Party on Genetics and human behaviour was established in November 2000. The Council's previous Report in 1998 on ethical issues arising from genetics as applied to mental disorders drew attention to but did not address issues about normal behavioural traits. A Workshop was subsequently held in 1999 to consider whether they warranted a separate investigation. As a result of this meeting, the Council decided that a comprehensive review of the issues was required, and a Working Party was established charged with examining the ethical, legal and social implications of research in behavioural genetics.

The main focus of the Working Party has been on issues that arise from the study of the genetics of variation within the normal range of behavioural characteristics. Reviews have been commissioned of the current scientific evidence related to behavioural characteristics such as intelligence, anti-social behaviour, sexual orientation and addiction. The Working Party has examined the ethics of undertaking such research; the potential applications of this type of research; the particular impact of the findings of a genetic test on an individual, on family members, and on various social groups; and the impact of new genetic knowledge on discrimination and stigma.

The Working Party met eight times during 2001. The minutes of these meetings are available on the Council's website. It is expected that the Working Party's Report will be published in Autumn 2002.

“If a defined genetic basis for anti-social and psychopathic behaviour, for aggression and for sexual deviance can be substantiated it will undoubtedly become extremely controversial whether such genetic tests should be done at all and, if so, in what circumstances.”

Peter Lachmann, President,
The Academy of Medical Sciences

Fact-finding meetings

As part of its research, the Working Party, and its Sub-groups, have held five closed fact-finding meetings with experts in the field of behavioural genetics, philosophy and sociology in the UK, during the year:

3 October 2001, London

- **Professor Jonathan Glover**
Director, Centre of Medical Law and Ethics, King's College, London
- **Professor Søren Holm**
Reader in Bioethics, Institute of Medicine Law and Bioethics, University of Manchester
- **Professor Nikolas Rose**
Professor of Sociology, Goldsmiths College, University of London

26 September 2001, London

- **Professor Nick Craddock**
Wellcome Trust Senior Research Fellow in Clinical Sciences and Professor of Molecular Psychiatry, and Honorary Consultant Psychiatrist, University of Birmingham
- **Professor Robert Plomin**
Deputy Director, Social, Genetic and Developmental Psychiatric Research Centre, Institute of Psychiatry, London

9 July 2001, Cambridge

- **Professor Dorret Boomsma**
Professor of Biological Psychology, Vrije Universiteit, Amsterdam
- **Professor John DeFries**
Professor, Department of Psychology, and Director, Institute for Behavioral Genetics, University of Colorado at Boulder, USA
- **Professor Nick Martin**
Senior Principal Research Fellow, Queensland Institute of Medical Research and Adjunct Professor, Department of Pathology, University of Queensland, Australia
- **Associate Professor Irwin D Waldman**
Associate Professor of Psychology, Emory University, USA
- **Professor Thomas Bouchard**
Professor of psychology, University of Minnesota, Director of the Minnesota Center for Twin and Adoption Research and Principal Investigator on the Minnesota Twin Registry
- **Professor Richard Rose**
Professor of Psychology and Medical Genetics, Indiana University
- **Professor Matthew McGue**
Associate Chair, and Director, Graduate Program in Individual Differences and Behavioural Genetics, Department of Psychology, University of Minnesota and Principal Investigator, Minnesota Twin Family Study

● Professor Lindon Eaves

Professor of Psychiatry and Distinguished Professor of Human Genetics, Medical College of Virginia, Richmond and Director, Virginia Institute for Psychiatric and Behavioral Genetics

4 July 2001, London

- **Professor Andrew Heath**
Professor of Psychology in Psychiatry and Associate Professor of Genetics, University of Washington St Louis and Director, Missouri Alcohol Research Center, USA

12 June 2001, London

- **Professor Sir Michael Rutter**
Senior Researcher, Department of Social, Genetic and Developmental Psychiatric Research, Institute of Psychiatry, London, UK
- **Professor Steven Rose**
Joint Professor of Physics, Gresham College, London, UK
- **Dr Jonathan Flint**
Wellcome Trust Senior Clinical Fellow, Wellcome Trust Centre for Human Genetics, Oxford, UK

Additionally, in November, members of the Working Party participated in a fact-finding trip to Washington DC. The Hastings Center and AAAS (American Association for the Advancement of Science) have set up a group engaged in a project entitled 'Crafting Tools for Public Conversation about Behavioral Genetics'. Representatives from the Working Party attended a meeting of the group which focused on research into genetic influences on intelligence. It covered issues such as race and IQ, the meaning of IQ tests, and coverage by the media of such research. The Working Party's participation provided a valuable opportunity for members to discuss issues with researchers on behaviour genetics and other experts from the US.

Consulting the Public

The Working Party organised a process of consulting the public between March and July 2001. The launch of this process attracted a considerable amount of attention from the media, with coverage on the BBC, the Today programme, Newsnight and Radio Five Live.

The public were consulted on a number of specific questions such as:

- Should there be limits to scientific inquiry in the field of behavioural genetics?
- Should genetic tests for behavioural traits and personality characteristics be developed? Why, or why not? Does this apply to all types of behavioural trait?
- Would the pre-natal selection of behavioural and personality traits within the normal range be morally acceptable?
- Is there a moral difference between the correction of a trait thought to be the result of a genetic abnormality or defect, and the enhancement of that same trait for a 'normal' individual?

110 responses were received from a wide range of interested individuals and organisations. The replies will inform the discussions of the Working Party.

“Some developments in medicine start controversial and then become acceptable (such as in-vitro fertilisation). Others start controversial and stay controversial (such as abortion). I believe that if it is ever attempted, cosmetic genetic engineering may come in the second category as ambitious parents constantly push the envelope to see how they can improve their offspring's genes. Cosmetic surgery

suggests there will be plenty of takers. The only consolation is that with 30,000 genes to improve, most customers will soon be overwhelmed by choice and may decide not to change any. Side effects will lead to occasional disasters. But the real problem with cosmetic genetic engineering is that it will be impossible to define. Is the altering of an inherited weight problem cure or enhancement?”

Matt Ridley, journalist and author

Round Table Meetings

The ethics of patenting DNA

In June 2000 the Council established a Round Table Meeting to consider ethical and legal issues raised by patenting DNA, and any consequent implications for healthcare. The establishment of the Group was timely, following the publication of the DNA sequence of the human genome. Further developments in 2001, for example controversy over the cost of diagnostic tests for breast cancer, underlined the need to examine the ethical implications of protecting claims to human DNA by the use of patent law.

In 2002 the Council plans to convene a small Workshop to which a range of interested parties would be invited, including representatives of the pharmaceutical and biotechnology industries, non-governmental organisations, patent lawyers and research scientists. Delegates will be appraised of the draft recommendations of the Round Table Meeting and the Workshop will provide an opportunity for an exchange of views and discussion.

A Discussion Paper will be published in the summer of 2002 which will aim to assist the Courts, patent offices and policy-makers to develop public policy and professional guidance and to promote public debate.

“A contentious development will be the increasing use of human genetic material, whether embryonically derived or from other sources, that will allow commercial profit. The boundaries currently drawn in patent law, already quite easily breached, will be further eroded.”

Alastair Campbell, Professor of Ethics in Medicine, University of Bristol

Membership of the Round Table Meeting

Professor Tom Baldwin

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

Professor John Barton

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

Professor Martin Bobrow CBE

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

Professor Sir Brian Heap CBE FRS

Master, St Edmund's College, University of Cambridge and member of the Nuffield Council on Bioethics

Hon Mr Justice Jacob

Judge of the High Court, Chancery Division

Professor Marilyn Strathern

Mistress of Girton College, Cambridge and

William Wyse

Professor of Social Anthropology and member of the Nuffield Council on Bioethics

Professor Michael Stratton

Head of Cancer Genome Project, The Sanger Centre, Cambridge

Professor Joseph Straus

Head of Patent Department, Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, Germany and Professor of Law, University of Munich and University of Ljubljana

Dr Alan Williamson

Consultant for biotechnology and member of the Nuffield Council on Bioethics

Workshops

Ethics and research involving animals

A Workshop was held on 28 November involving fifteen invited experts, to discuss the ethics of research involving animals. A number of factors were regarded by the Council as warranting consideration of this topic, particularly the rising trend in the number of genetically modified animals, and the developments regarding Huntingdon Life Sciences and the activities of animal rights organisations.

The first half of the meeting focused on four presentations which set out: the current context in terms of science and policy in the UK; ethical issues arising; future trends; and the use of genetically modified animals. There followed a discussion of ethical issues that might be raised by future developments in the use of animals in research and an assessment of the possible role the Council could play in exploring these questions.

Over recent years, the total number of animals used in scientific procedures each year has been falling. However, within this overall decrease, there has been a substantial increase in the use of genetically modified animals. Discussion during the Workshop therefore focused on this trend. Much research is now being undertaken to identify the effect of individual genes, by "knocking out" each gene in sequence and then in combination to understand their effects. Such research is already underway in fish, worms and flies, and is beginning in mice. It was agreed that these developments raise ethical questions that could merit examination.

As a result of the Workshop, a number of areas were identified that might warrant further consideration. First, certain ethical issues whilst not necessarily 'new', would benefit from clarification. Examples included whether or not there are morally relevant distinctions to be made between different species, and questions raised by genetic modification. Secondly, there

are several areas of existing regulation that need reconsideration, including the classification and assessment in the context of welfare of genetically modified animals and the cost-benefit analysis of the use of animals in research. Other areas that could be examined include variations between international regulations, the ethical implications of alternatives to animal research, and the importance of informing and educating the public.

The Workshop concluded that there were important ethical questions surrounding potential future developments in research involving animals that could usefully be addressed. As a result, the Council has decided to take the topic forward and will establish a Working Party in the Autumn of 2002.

“The use of animals in medical research will be one of the most ethically controversial developments in biotechnology over the next ten years. There is a very real need for major programmes of public education.”

Lord Walton of Detchant,
House of Lords Science and
Technology Committee

Ethics and pharmacogenetics

A Workshop was held on 5 December involving invited experts to discuss ethical issues raised by developments in pharmacogenetics. Participants included representatives from pharmaceutical and biotechnology companies and from the fields of toxicology, medical ethics, primary care medicine and human molecular genetics.

Adverse drug reactions account for over 120,000 deaths annually in the US, making them the fourth most common cause of death. In addition, there is currently wide variation in response to medicines, with many drugs being only selectively effective. Pharmacogenetics is the study of how genetic differences influence the variability in patients' responses to medicines. The pharmaceutical industry is adopting a pharmacogenetic approach to the development of drugs, aiming to tailor drug treatment to the patient's genotype, rather than continuing with its current approach of developing 'blockbuster' drugs aimed at genotypically diverse populations of patients. This new approach is expected to lead to improvements in the safety and efficacy of drugs and to improve knowledge about the nature of health and disease.

Some of the ethical issues raised by pharmacogenetics may not differ considerably from those issues raised by genetics research more generally, whilst others may be quite distinct. Equally, there may be practical dilemmas associated with pharmacogenetics not yet apparent because the research is at such an early stage. The Council therefore agreed that a Workshop would be a useful way to initiate discussion and to establish whether a Working Party or Round Table Meeting would be appropriate.

The Workshop's programme paid particular attention to the implications of pharmacogenetics for the identification of genes indicating susceptibility to certain conditions, and for the conduct of clinical trials. The wider implications of pharmacogenetics for healthcare policy and practice were also addressed. The view emerged that very few new ethical issues would be raised by developments in pharmacogenetics and that on balance, most ethical concerns would relate primarily to the management of healthcare and the future provision of primary care. However, it would be worth examining the likely developments in more detail and producing a short paper that would clarify the issues. The Council will therefore develop the topic by producing a Discussion Paper in Autumn 2002 or 2003.

“A future ethically controversial development will be the prospect of the almost routine use of DNA chips for a wide range of simultaneous genetic tests.”

Revd Dr Sir John Polkinghorne,
KBE FRS Fellow, Queen's College

External Activities

The Council's terms of reference include a responsibility to examine and report on questions in bioethics 'with a view to promoting public understanding and discussion'. The Council therefore continues to attach importance to the need to promote debate of the issues raised by its published work and to increase awareness of the Council. In 2001, the Council was able to spend time consolidating its strategy with regard to promoting the public's awareness both nationally and internationally.



One of the main themes of the Council's Forward Look meeting in May was how the Council might effectively engage in public discussion. Professor Ian Hargreaves, Director of the Centre for Journalism Studies at Cardiff University, was invited to speak on ways to bridge the gulf of understanding between the public, the media and science, based on his Report 'Who's misunderstanding whom?' for the Economic and Social Research Council.

Meetings

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 spoke at more than 20 conferences in 2001. Professor Tom Baldwin, Dr Alan Williamson and Susan Bull gave presentations at the British Council International Symposium on Society and Genetic Information in Budapest. Dr Sandy Thomas, the

Director presented on legal frameworks for the protection of intellectual property related to genomic research at the UNESCO International Symposium in Paris on Ethics, Intellectual Property and Genomics. In April, the Director spoke on stem cell therapy at the Human Genome Organisation (HUGO) Human Genome meeting in Edinburgh, which was followed by presentations at the BIO 2001 International Biotechnology Convention in San Diego and the American Society of Human Genetics (ASHG) 51st Annual meeting. The Director also gave three seminars to university students.

Council representatives also frequently attend external events. Nearly forty conferences, lectures and meetings were attended in 2001 both nationally and internationally. These included:

- Global 5 of the Global Forum on Health Research in Geneva;

Consultations and Evidence submitted

The Council is regularly asked to respond to consultative documents produced by other organisations. It is the practice of the Council to respond only to those which specifically address issues which the Council has previously considered in detail in its Reports or Discussion Papers. In 2001, the Council submitted responses to five calls for views:

- Council of Europe on its Draft Additional Protocol to the Convention on Human Rights and Biomedicine, on Biomedical Research
- The Human Genetics Commission's public consultation 'Whose hands on your genes?'
- The Animal Procedures Committee consultations on the cost/benefit assessment and the Animals (Scientific Procedures) Act 1986.
- European Parliament Temporary Committee on Human Genetics and Medicine
- The House of Lords Select Committee on Stem Cell Research: submitted written evidence, and the Deputy Chairman and Director gave a verbal submission to the Committee in July.



- the Annual meeting of the Behavior Genetics Association (BGA) in Cambridge;
- The Office of Health Economics 8th Annual Lecture on 'The Links of Public Health and Economic Development?' by Professor Jeffrey Sachs.

The Council also received visits from German MPs, US academics, delegates from the British Council and a group of senior federal officials from Canada.

External relations

The Council's external relations Sub-group held its first meeting in February 2001 to consider and formalise the Council's approach. Discussions gave particular emphasis to the need for Council to play a larger role in Europe and internationally. Initial recommendations include a series of meetings to be held in the US and in Europe with relevant organisations in 2002.

The Council will also spend time in the next year developing a more active strategy for external relations, and liaising with governmental departments, professional organisations and consumer groups. The Chairman and Director met officials from the Department of Health in May 2001 and it was agreed that twice-yearly meetings between officials should take place. As a result of this discussion, a meeting with the Human Genetics Commission was also held in May. Various members of the Commission met the Chairman and members of the Council and

the Secretariat to exchange information about the current work programmes of the two bodies and to discuss future plans.

A public liaison officer was appointed in November who is responsible both for development and maintenance of links with other organisations and the implementation of new initiatives in promoting the public's awareness of the Council's work.

Education

At the Council's Forward Look meeting, the Council's future role in education was discussed. It was agreed that the independent status and breadth of expertise of the Council makes it well placed to liaise with organisations involved in education and to engage in educational activities. It was also noted that there is a lack of suitable resources available to discuss bioethics in schools. The Council intends to collaborate with other organisations on educational projects, and will work to develop materials suitable for use in the classroom in the next year. The brief of the external affairs sub-group will be expanded in 2002 to include education.

Dissemination of Reports

All of the Council's Reports have continued to be accessed on the Council's website and frequently requested in the last year. The Report on **Genetically Modified Crops: the ethical and social issues** remained the most frequently sought during 2001 with over 12,000 copies distributed during the year. The

The new web address is:
www.nuffieldbioethics.org

Discussion Paper **Stem cell therapy: the ethical issues** also attracted considerable interest.

It is difficult to evaluate the precise impact of a Report. Responses to Reports in the media are closely monitored, and the Secretariat liaises with bodies identified in the Report's recommendations. The Council will devote time in 2002 to establishing a more systematic approach. The Council will also concentrate on surveillance of the implementation of recommendations in its Reports, liaising with relevant departments of government. The Council is also examining ways to make its Reports more accessible to wider audience, and will be producing shorter summaries of Reports during 2002.

Website

The Council's website remains a core feature of the Council's efforts to promote the public's awareness of its work. Approximately 200 people visit the site every day; a total of over 75,000 visitors during the year. All of the Council's publications are available to download from the site or to browse on-line. Over 15,000 copies of Reports were

downloaded in just six months during 2001. The website has been expanding rapidly since it was launched in 1998. As a result of this growth, the site was redeveloped and relaunched with a new design in December 2001. The site has been enlarged to contain more details about the Council and its members, background information about the Council's previous activities, and further news about current work. The Council is often asked for general information about bioethics. In response to this demand, a new section is being added which will provide information and resources for the public, media and specialists about bioethics issues.

Media

The Council frequently receives requests to give interviews to the media. In 2001, the Council responded to 30 such requests, usually on topics which the Council has examined in detail. Interviews are an effective way of letting the public know that there is an independent voice which responds to issues in bioethics. The current Working Party on genetics and human behaviour in particular has attracted a large amount of interest.

Highlights of media activities

- | | |
|-----------------------------|--|
| ● Newsnight, BBC | Genetics and human behaviour Working Party |
| ● Nature | Genetics and human behaviour Working Party |
| ● BBC World Service | Stem cells |
| ● Associated Press | Stem cells |
| ● Today programme (Radio 4) | Genetics and human behaviour consultation |
| ● ABC Radio (Australia) | Genetics and human behaviour consultation |
| ● Women's Hour | |
| ● Sunday Business | DNA patenting |
| ● Radio 5 Live | Genetics and insurance |
| ● BBC News | Reproductive cloning |
| ● CNN News | Reproductive cloning |

Annex A

Financial and Funding Report on the calendar year 2001

Expenditure	2001 Actual £	2000 Actual £	1999 Actual £
Salaries and staffing costs	239,023	215,249	184,697
Office costs including premises	34,367	30,872	47,446
Stationery and press cuttings	8,099	13,921	9,566
Photocopy, post, phone, fax	11,857	13,285	7,730
Committee and meeting costs	115,414	52,326	12,625
Printing of reports	2,361	3,693	20,993
(Less) reports sold	(2,029)	(3,270)	(5,400)
Publicity of reports	971	2,081	8,571
Equipment (IT developments)	4,704	7,707	12,021
Net expenditure	414,767	335,864	298,249
Funding			
Nuffield Foundation	231,729	92,902	178,249
MRC	100,000	100,000	60,000
Wellcome Trust	83,038	136,963	60,000
Other Income	0	6,000	0
	414,767	335,864	298,249

Notes

Overheads (met by Nuffield Foundation & not included above)

	143,083	88,461	20,895
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Reconciles to expenditure published by the Nuffield Foundation, adding overheads and recording sales against income, not expenditure

Annex B

Reports

Genetic screening: ethical issues

Published December 1993, Reprinted 1995,1996,1997. Out-of-print.

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

**Genetic modification of crops:
the ethical and social issues**

Published May 1999

Discussion Papers

**The ethics of clinical research in
developing countries**

Published October 1999

Stem cell therapy: the ethical issues

Published April 2000

All of these publications are available to download from the Council 's website at <http://www.nuffieldbioethics.org/>.

Printed copies may be ordered by contacting:

Nuffield Council on Bioethics
28 Bedford Square
London WC1B 3JS
United Kingdom
Tel:+44 (0)20 7681 9619
Fax:+44 (0)20 7637 1712
Email:bioethics@nuffieldfoundation.org



