Reports

Genetic screening: ethical issues

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.nuffield.org/bioethics.

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Nuffield Council on Bioethics

Annual Report 2000

NUFFIELD COUNCIL ON BIOETHICS
The start of the new millennium found the Council seeking to apply the wisdom (and lessons) of the past millennia to developments which will occupy us in the future. No better example could be found than the publication of our Discussion Paper on Stem Cell Therapy in April 2000. We were pleased with the response which the Paper received and with the consequent assistance which the Council was able to give to policymakers and government. It is a continuing aim of the Council to provide such assistance across the broad range of bioethics: to set out the scientific and other evidence in as clear and comprehensive a manner as possible and to explore the moral, social and legal implications which arise.

The year 2000 saw a number of significant constitutional and administrative developments. A new funding arrangement was proposed to our three funders, the Nuffield Foundation, the Medical Research Council and the Wellcome Trust. The Council requested funding for five year periods, not only to bring greater financial stability but also to allow the Council greater flexibility in its forward planning. Quite properly, the Council’s work would be scrutinised by outside reviewers as a condition of continued support at the end of each five year period.

Our Secretariat has also grown, as we take on further work. Moreover, thanks to our host, the Nuffield Foundation, we now have a suite of rooms on one floor of the Foundation’s beautiful building in Bedford Square. We have also expanded the size of the Council, introduced fixed terms of membership and advertised for expressions of interest from those who might wish to be considered for membership. The dedication and commitment of my colleagues on the Council fills me with admiration. I am truly grateful. My thanks, and those of the Council are also due to the Secretariat without whom nothing would be possible.

Ian Kennedy
THE NUFFIELD COUNCIL ON BIOETHICS was established in 1991 to examine ethical issues raised by advances in biology and biomedicine. The Council is independent of government and was initially funded solely by the Nuffield Foundation. Since 1994 the Council has been funded by three bodies, the Medical Research Council, the Wellcome Trust and the Nuffield Foundation. These funding bodies do not seek to influence the Council’s choice of which topics to examine nor its policy. The Council aims to provide advice on bioethical issues to assist in the formation of public policy and to foster public understanding. Five major reports - dealing respectively with ethical issues associated with genetic screening, uses of human tissue, xenotransplantation, genetics and mental disorders, and genetically modified crops – have been published to date. The Council has also published two discussion papers, covering ethical issues associated with clinical research in developing countries and stem cell therapy.

Following a review of the regulatory framework for overseeing developments in biomedicine and biotechnology, the government decided not to create an over-arching national bioethics commission, as exists in many other countries. Instead, in 2000, two new Commissions with broad advisory roles in the field of bioethics were established, namely, the Human Genetics Commission (HGC) and the Agriculture and Environment Biotechnology Commission (AEBG). The Nuffield Council remains the only organisation in the UK which has broad terms of reference requiring it to consider issues in bioethics, rather than in specific areas, such as genetics.

To ensure appropriate collaboration with the new governmental bodies, the Council will have frequent formal and informal exchanges with them, and with the Department of Health. The Council will, however, continue to pursue projects which suggest themselves to the Council as fitting for its attention. Whilst duplication of effort is not desirable, the Council’s broad role and its independence of government have come to be seen as increasingly important, not least in light of the apparent diminution of public trust in government advisory bodies responsible for overseeing biomedicine and biotechnology.

Method of working
Council meetings are held quarterly. During these meetings the Council reviews recent biomedical and biological advances that raise ethical questions and selects topics for further exploration. The Council also consults a wide variety of external sources about future topics. In addition to its quarterly meetings, the Council considers broader themes at its annual ‘Forward Look’ meeting. The ‘Forward Look’ meeting 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. In 2000 Professor Linda Nielson, immediate past Chair of the Danish Council of Ethics spoke about the Danish Council’s role in policy-making and its experiences in dealing with the public. Professor Stephen Sykes, Principal, St John’s College, Durham,

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.
joined the Council at the evening
dinner to discuss the issues that arose
in translating ethical analysis into
public policy.

Selection of topics
In 2000, the Council established a
Subgroup on Future Work which meets
twice a year to identify and consider
new topics that may warrant
examination and to make
recommendations to the Council. The
Council also consults a wide variety of
external sources, including
government, learned societies,
industry, non-governmental bodies and
researchers engaged in biological and
biomedical research. The Council
discusses the recommendations from
its Subgroup and from other sources,
before selecting topics for its work
programme. The criteria adopted by the
Council for the selection of topics for its
future work programme are that the
topic:
• be within the Council’s terms of
  reference;
• be novel: be linked to substantial
  new developments in medicine or
  biology;
• raise ethical questions and
  concerns of some complexity;
• be timely: the Council should be
  proactive about selecting new
  topics;
• be such as to make it likely that a
  Report or Discussion Paper would
  have an important impact on
  policy or practice.

Typically, once the Council has
identified a potential topic for
consideration, it convenes a Workshop
which seeks to identify and discuss
relevant issues and to decide whether
an issue merits further examination.
Following a Workshop, if a topic is
considered to be appropriate for the
Council to examine in more detail, it
establishes a Working Party or Round
Table meeting to examine and report
on ethical, social and legal issues. The
Council endeavours to ensure that
members embrace a wide range of
views in the light of public disquiet
about certain developments in
biotechnology and biomedicine.

Working Parties
Working Parties comprise a Chair who
is not a member of the Council and
seven to 14 members. These are
appointed by the Council (including
one or more Council members) and
have a range of specialist experience
and expertise. The chair of the
Working Party is co-opted as a member
of the Council for the duration of the
Working Party so as to facilitate
communication between the Working
Party and the Council. During the
period taken to produce a Report,
typically eighteen months to two years,
the Working Party will have up to
twelve meetings to examine issues,
consider and develop arguments, and
draft the Report. Each Working Party
conducts a public consultation
exercise, primarily by correspondence
and via the internet. The results have
proved extremely useful and typically
comprise a range of views on almost all
the issues of concern. In addition, a
number of fact-finding meetings are
arranged on specialist topics.

A Report is produced by the Working
Party in consultation with the Council.
The Council reviews drafts of each
Report before it is submitted for peer
Membership (at December 2000)

**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 healthcare-related research in developing countries)

**Revd Professor Duncan Forrester DD**  
Professor of Christian Ethics and Practical Theology, University of Edinburgh

**Professor 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)

**Mrs Rebecca Howard**  
Executive Director of Nursing, Royal Liverpool Children’s Hospital, Alder Hey

**Lady Hornby**  
Chairman of The Kingwood Trust

**Professor John Ledingham**  
Emeritus Professor of Clinical Medicine, University of Oxford

**Mr Derek Osborn CB**  
Chairman of European Environment Agency and Chairman of UK Roundtable on Sustainable Development

**Professor Catherine Peckham CBE**  
Professor of Paediatric Epidemiology, Institute of Child Health, University College London

**Professor Martin Raff FRS**  
Professor of Biology, University College London

**Mr Nick Ross**  
Broadcaster

**Professor Herbert Sewell**  
Professor of Immunology, Department of Molecular & Clinical Immunology, University of Nottingham

**Professor Marilyn Strathern DBE FBA**  
Mistress of Girton College, Cambridge and William Wyse Professor of Social Anthropology

**Professor Albert Weale FBA**  
Professor of Government, University of Essex

**Dr Alan Williamson**  
Consultant, Abingworth Management Limited and biotechnology and genomics companies
review and then approves the final Report prior to publication. Once a Report is approved by the Council, it becomes the Report of the Council. Peer review is carried out by external experts, chosen after consultation with the Working Party and members of Council. They are selected to represent a spectrum of opinion and expected to comment rigorously on the Report and provide constructive criticism.

**Round Table meetings**

Round Table meetings normally run for a six to 12 month period and are held when a topic is readily circumscribed and focused, and where a more rapid response is required, often indicated by the social or political context and the need for prompt policy guidance in the area being considered. Up to seven meetings will typically be held. Round Table meetings comprise six to eight members appointed by the Council (including one or more Council members). A Discussion Paper is produced by the Round Table Group and reviewed by Council and external reviewers in the same manner as the Report of a Working Party.

**Funding**

Since 1994, the Council has been funded by the Nuffield Foundation, the Medical Research Council and the Wellcome Trust (see Appendix 1). In 2000 an alternative funding structure was proposed which would allow core funding for five years. This would provide the Council and the Secretariat with greater flexibility to plan its future work while maintaining its intellectual independence. The funding structure would also introduce a more formalised relationship between the Council and its funders, building in a process of external review of Council’s performance and future work plans. The process of five-year funding was discussed further between the Chairman, the Director and representatives of the three funders at a meeting held in September 2000 and agreement was reached that a proposal for five-year funding would be prepared and submitted to the funders for consideration by the end of March 2001.

**Council membership**

The Chairman of the Council is appointed by the Nuffield Foundation. The Council appoints its own members, independently of the sponsors. Members are drawn from fields of expertise relevant to the Council and approximately half the Council members are from medical or scientific disciplines. The Council’s website contains an invitation to those who may be interested in joining the Council to submit an expression of interest.
# Working Parties

## 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.

Following the publication of the discussion paper on the ethics of clinical research in developing countries in October 1999, the Council convened a Working Party to consider this topic in more detail. The Working Party, which will run over two years, held its first meeting in January 2000 and four meetings thereafter throughout the year. Summaries of the minutes of Working Party meetings are available on the Council’s website. The report of the Working Party will be published in early 2002.

As part of its fact-finding activities, the fourth meeting of the Working Party was held in Oxford. The first day was dedicated to meeting researchers from a number of developing and developed countries. In addition, the Working Party has held fact-finding meetings with Dr Gill Samuels, Director of Science Policy, Pfizer (UK); Professor Daniel Wikler, Staff Ethicist for WHO and Professor Alan Maynard, Professor of Health Economics, University of York. Further fact-finding meetings were planned for 2001 in India, Africa and the United States.

The Working Party launched its public consultation exercise in July 2000. The consultation document was circulated to a wide range of interested parties and was made available on the Council’s website. By the end of 2000, responses had been received from 20 different countries from a number of relevant organisations, including research sponsors, research ethics committees and the pharmaceutical industry, and from individuals with expertise in ethics, law, medical research, epidemiology, pharmaceutical sciences and health policy.
Membership of the Working Party (at December 2000)

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

**Dr Fred Binka**  
Navrongo Health Research Centre and Ghana School of Public Health

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

**Professor V I Mathan**  
Division Director for Laboratory Sciences Division, International Centre for Diarrhoeal Disease Research, Dhaka

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

**Dr Anne McLaren**  
Wellcome/CRC Institute, Fajara, The Gambia

**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**  
Educational & ICT Consultant

**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 November 1999 the Council hosted a Workshop in London to encourage and stimulate debate regarding the ethical, legal and social implications of research in behavioural genetics. Following this meeting, the Council decided that a comprehensive review of the issues was required and established a Working Party to consider them in more detail.

The Working Party held its first two meetings at the end of 2000, at which the terms of reference were agreed. Initial discussions took place regarding core areas of research in behavioural genetics and the historical context of eugenic practices concerning behavioural traits and personality characteristics. Preparations to launch the Working Party to the public through existing contacts and the media were made, and thought was given to the preparation of a public consultation document for distribution in 2001.

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.

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.
Membership of the Working Party (at December 2000)

**Professor Bob Hepple QC (Chairman)**  
Master, Clare College, University of Cambridge and member of Nuffield Council on Bioethics

**Professor Martin Bobrow CBE**  
Head of Department of Medical Genetics, University of Cambridge 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, University College London

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

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

**Mr Pushpinder Saini**  
Barrister, 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
On 29 September 1999 the Council held a Round Table meeting to discuss the ethical issues arising from the derivation and use of stem cells. A presentation outlining the main findings of the meeting was made to the Chief Medical Officer’s Expert Advisory Group on Therapeutic Cloning in November 1999 and a Discussion Paper was published in April 2000.

Summary of findings
The Round Table meeting noted that the ability to culture human stem cells over the long term, and possibly indefinitely, and to control how such cells specialise to form the different tissues of the body offered the possibility of major advances in healthcare. Stem cells had been isolated and cultured, but a great deal of research was required to develop cell lines which could generate replacement cells and tissues to treat many diseases. The use of human pluripotent stem cells was controversial primarily because much of the current research was focused on deriving these cells from human embryos and cadaveric fetal tissue. The Discussion Paper therefore focused on the ethical issues raised by the potential use of stem cells derived from donated embryos, embryos created specifically for research purposes, cadaveric fetal tissue and somatic cell nuclear transfer (SCNT).

The Discussion Paper concluded that the removal and cultivation of cells from a donated embryo did not indicate lack of respect for the embryo. There were no grounds for making a moral distinction between research into diagnostic methods or reproduction which was permitted under UK legislation and research into potential therapies which was not currently permitted. Consequently, the Discussion Paper recommended that research involving human embryos be permitted for the purpose of developing tissues from derived embryonic stem (ES) cells to treat diseases and that the relevant regulations be amended accordingly. As long as there were sufficient and appropriate donated embryos from IVF treatments for use in research, the Council took the view that there were no compelling reasons to allow additional embryos to be created merely to increase the number of embryos available for ES cell research or therapy. However, it was suggested that this issue be kept under review.

The Round Table meeting concluded that the Code of Practice set out in the Polkinghorne Review provided an adequate framework for the use of fetal
tissue in the derivation of embryonic germ (EG) cells. It suggested, however, that the question of consent for the use of donated fetal tissue for the purpose of deriving EG stem cells be re-considered in the context of the current guidance and regulation. While the Round Table meeting recommended that research be permitted, it also recommended that as a safeguard to protect all donors of embryos that they be specifically asked to consent to this research and any subsequent use of the cell line, since they could theoretically be identified by analysis of DNA of an ES cell line.

The Discussion Paper concluded that research into SCNT and other forms of reprogramming the nuclei of human somatic cells might potentially offer very significant medical benefits. If the regulations were amended to permit research involving embryos for the additional purpose of developing tissue therapies from the derived ES cells, as recommended by the Council, then research involving embryos derived from SCNT could also be licensed for this purpose. Further recommendations were made about regulatory issues surrounding the use of non-human oocytes to derive ES cells, patenting and public health concerns.

Public response and follow-up

The Council presented its findings at briefing meetings at the House of Lords and House of Commons, and annual political party conferences. The Chief Medical Officer’s Expert Group’s Report Stem Cell Research: Medical Progress with Responsibility was launched on 16 August 2000 and the Government’s response was released to coincide with this. The recommendations in the Report were broadly in line with those made by the Council. The principal recommendation was that the relevant regulations should be amended to allow research on stem cells to proceed. The Government, in its response, welcomed this and the other recommendations and announced that the debate about whether to amend the regulations to permit such research would be followed by a free vote. In December 2000 the House of Commons voted in favour of the additional research purposes (and in January 2001 the House of Lords voted similarly). The regulations governing embryo research have been amended to permit research aimed at increasing knowledge about the development of embryos and serious diseases and enabling such knowledge to be applied in developing treatments for such diseases.
Many companies and universities around the world are seeking to acquire patenting rights relating to gene sequences and proteins. Questions remain, however, over the moral implications of protecting rights to property in this kind of way. The Council set up a Round Table meeting to consider the ethical and legal issues raised by this form of patenting and its implications for healthcare.

Six meetings were held in 2000. The first meeting was held in June 2000 at the Sanger Centre, Cambridge. Further meetings were during the second half of 2000, including a fact-finding session with Professor Richard Nelson from the School of International and Public Affairs, Columbia University, New York.

Research into DNA and proteins offers the possibility of many different kinds of developments in healthcare. New gene-based diagnostic tests and drugs for a wide range of common diseases may be developed on the basis of knowledge about the human genome and the genomes of bacteria and viruses. The questions being considered by the Council include: will broad patents covering genes such as those genes associated with breast cancer restrict the development of affordable diagnostic tests; what is the proper role of patent offices: are they custodians of the public good; does the patent system encourage innovation in biomedical research?

The members of the Round Table meeting have backgrounds in moral philosophy, clinical genetics, genomics, patent law, pharmaceuticals and anthropology. The Round Table meetings will produce a Discussion Paper in 2001 which will aim to help
Pursuant to its terms of reference, the Council has attached importance to the need to promote discussion of the issues raised by its Reports. A Report is launched at a press conference. Interviews in the media by the Director and members of the Working Party or Round Table Group are co-ordinated by a media consultant. The responses of the media to each publication are closely monitored. Detailed reviews in specialist journals are encouraged. The coverage of publications by the media frequently assists with the further dissemination of the Council’s work, which in turn stimulates public debate.

Complimentary copies of each Report and Discussion Paper are distributed to all those involved in its production, including respondents to public consultation exercises. Copies are also widely distributed to organisations and individuals with an interest in the topic. Following the launch of a Report, the Secretariat liaises with bodies identified in the Report’s recommendations, with a view to monitoring any responses, including changes in regulations or policy. The Secretariat also briefs representatives of the media on topics examined by the Council. Members of the Council, Working Parties and Round Table Groups, together with the Secretariat, also make invited presentations about the Council’s publications at a wide range of public and professional meetings. Most activity occurs in the first year after publication and assists in the dissemination of the Council’s work. In general, the Council limits its public comments to issues addressed in its published work.

The Council’s website (http://www.nuffield.org/bioethics) remains a core part of the Council’s dissemination strategy. Up to 8000 people visit the site each month, a significant proportion of whom download Reports and public consultation documents. The Council’s most recently published Report, on genetically modified crops, was downloaded over 11,000 times during the year 2000. The website provides details of the Council’s work, including summarised minutes of meetings of the Council and Working Parties, press releases, terms of reference of Working Parties and Round Table Groups, public consultation materials for current Working Parties, and copies of previously published Reports and Discussion Papers. Further expansion of the site is planned, including links to other national and international organisations, materials for educational activities and background materials on topics being considered by Council.

Developing public discussion and awareness
The Council’s Subgroup for External Relations was set up in 2000 to advise the Council about its relations with national and international organisations. The Council receives formal invitations to a wide range of national, international and bilateral meetings. In Europe, the two main international institutions concerned with bioethics are the Council of Europe and the European Group on Ethics in Science and New Technologies (EGE). The Council sends representatives to the Council of Europe Round Table for European Bioethics Committees and members of Council have also been members of the EGE. The Council participates in meetings on bioethics organised by the WHO, UNESCO, and the Global Bioethics Forum. In September 2000, the Council co-hosted the 3rd Global Summit of National Bioethics Commissions in London.

The Council maintains close contact with national organisations with an interest in bioethics, including the Human Genetics Commission and the Department of Health. It also maintains close relations with international organisations such as the US National Bioethics Advisory Commission, the Hastings Center in New York, the Australian Health Ethics Committee, the Danish Council of Ethics and the Comité Consultatif National d’Éthique, France. The Council provides briefings for members of the House of Commons and the House of Lords on relevant topics.
## Annex A. Financial statement

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