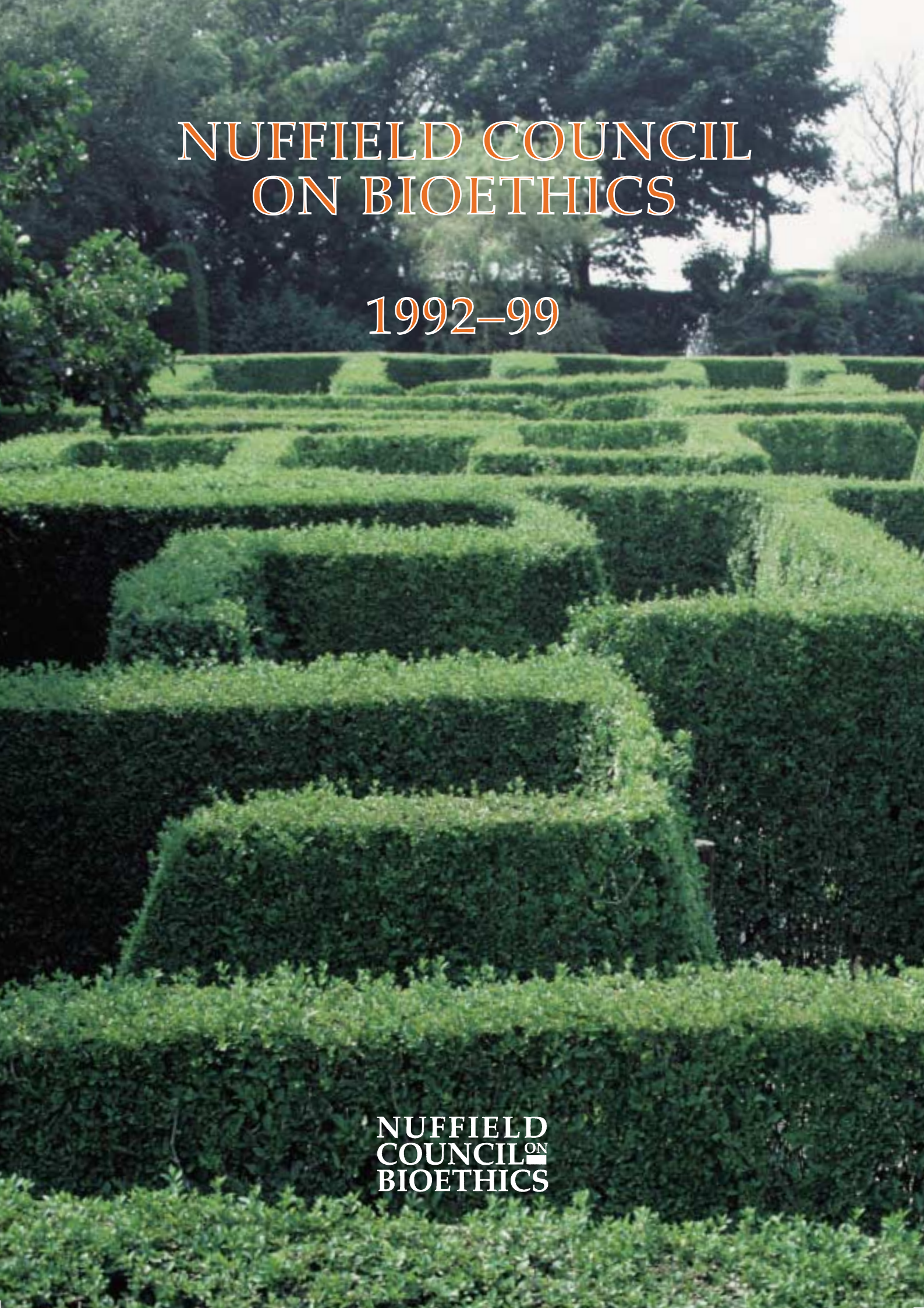

NUFFIELD COUNCIL ON BIOETHICS

1992–99

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Foreword

As we enter the new millennium, we thought it proper to render an account of what the Council has achieved over the past seven years. Furthermore, although we have not routinely produced an annual report hitherto, we will do so from this year onwards.

We owe it to those who have so generously supported the Council financially and otherwise to set out what we have achieved. We feel it important that the general public should be aware of the Council's work, both completed and projected. In addition, we are conscious of the position which the Council now occupies in the national framework of policy-making in bioethics and the responsibilities, not least to be open and accessible, which that position demands.

The Council owes its foundation in 1991 to the foresight of the Trustees of the Nuffield Foundation and the subsequent support of the Medical Research Council (MRC) and the Wellcome Trust in 1994. It was clear that the Government of the day was not minded to set up some form of national commission. The decision was taken, therefore, to establish an independent, free-standing council which could begin to examine the ethical issues raised by research advances and meet the undoubted need for well-researched, rigorously argued advice on policy. This decision was due, in particular, to the initiative of Lord Flowers, then Chairman of the Nuffield Foundation, and to the encouragement of Professor Sir David Weatherall, who became a founding member of the Council.

These ambitions continue to provide the Council's rationale, but the landscape has changed. After a consultation exercise in 1998-99, the present Government again decided against the creation of a single overarching body charged with the formulation of policy in bioethics. Instead, two discrete bodies have been set up, the Human Genetics Commission and the Agriculture and Environment Biotechnology Commission. Outside the areas covered by these, the Nuffield Council maintains its independent status and its commitment to research and analysis of the highest quality. The Council operates on both a national and international stage.

That the Council's work has acquired a high reputation is a tribute to my predecessors as chairmen. Sir Patrick Nairne guided the Council through its early years with consummate skill. It was he who saw clearly that the Council's standing and thus the weight and respect given to anything it might say, would depend entirely on the quality of its output. Under his leadership, the Council established its reputation through the reports of its expert working parties. The production of these reports remains the bed-rock of the Council's activities. The Council did not want to be in the business of 'instant comment'. Rather, it would seek to serve policy-makers through its carefully researched reports and its practical suggestions for action. Baroness O'Neill continued and consolidated this approach during her distinguished tenure. I have only had to follow in the wide wake of my predecessors.

Just as the role and responsibility of the Council has gradually grown, so has the Secretariat. In the beginning there was David Shapiro, juggling all of the different activities of the Council with a sure and experienced hand. Now, the Council has a director, a deputy director and two support staff. They are no less in the juggling business, of course, since the amount and pace of work has increased very considerably, particularly over the past two to three years. Moreover the Council will expand further over the coming years, both in terms of support staff and space.

But, the future is for future annual reports. I end this one by recording my warmest thanks to my fellow Council members, the Council's staff and to those who have given the Council and me such valuable advice over the years.

Professor Ian Kennedy
Chairman

Introduction

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; and
3. in the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.

THE ORIGINS of the Council go back to concerns expressed during the 1980s by leading scientists. In the absence of any government-sponsored national body, the Nuffield Foundation responded to informal approaches about the need for an authoritative independent body which could review research developments, identify the ethical issues, make policy recommendations, and stimulate public discussion. The Foundation engaged in very extensive consultations before deciding to establish the Council. In March 1991 this decision was welcomed by the Prime Minister, John Major, who encouraged the new Council to address, together with biomedical issues, ethical issues arising in agriculture and food and in the release of genetically modified organisms into the environment.

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 since 1994 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 topics or its policy. The Council aims to provide advice 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 produced between 1991 and 1999. A discussion paper, based on a workshop on the ethics of clinical research in developing countries held in February 1999 and drawing upon the views of an international group of experts, was published in October 1999.

Method of working

During its meetings the Council reviews recent advances in biological and medical research which raise ethical questions and selects topics for further exploration. The Council also consults a wide variety of external sources about future topics. In addition, it considers wider themes at its annual 'away day' meetings, the first of which took place in May 1999. Invited speakers included Dr Ann Somerville and Veronica English from the British Medical Association and Right Hon. Dr Jack Cunningham, then the Minister for the Cabinet Office.

Once the Council has identified a major ethical issue, it establishes a working party to examine and report on the issue. For the two most recent topics to be identified, the ethics of clinical research in developing countries, and genes and behavioural characteristics, the Council conducted workshops for invited participants to identify and discuss the relevant issues and to examine possible terms of reference for the working parties. Working parties comprise an independent chair and 7-12 members appointed by the Council (including

two or more Council members) with a range of specialist expertise. The chairman of the working party is now co-opted as a member of the Council for the duration of the working party. During the period taken to produce a report, typically eighteen months to two years, the working parties will have about ten meetings to debate the issues, consider and develop arguments and draft the reports.

Each working party conducts a public consultation, primarily by correspondence. 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 following iterative consultation with the Council. The Council reviews an early draft and the final version of each report before it is submitted for peer review. Once Council approves the report, it becomes the report of the Council. The report is peer reviewed by a number of independent experts who are chosen after consultation with working party and Council members. Peer reviewers are selected on the basis of their ability to appraise the report rigorously and criticise it constructively. The dissemination of Council reports and representations made by the Council is discussed later in this report.

In 1999, the Council convened two workshops. The workshops serve two distinct purposes: they enable Council to consider and address areas of interest within a shorter time period than the eighteen months taken by a full inquiry, and allow an initial consideration of issues to determine whether it would be appropriate for a working party to address them (see page 20).

In 1999 the Council adopted a standardised regime for following up its published reports. Prior to this, whilst a range of follow-up activities had been adopted for monitoring the impact of Council reports, these had been undertaken in a relatively ad hoc fashion. Follow-up activities include meetings with the press and public, monitoring press coverage, encouraging reviews of the reports in periodicals and peer reviewed journals, liaising with bodies targeted in reports' recommendations, and reviewing their impact with working party members.

Funding

The Council is currently funded by the Nuffield Foundation, the Medical Research Council and the Wellcome Trust (see Appendix 1). For the first three years of the Council's existence, the running costs of the Council were wholly met by the Nuffield Foundation. In 1994 the Medical Research Council and the Wellcome Trust joined the Nuffield Foundation as co-funders of the Council. Further expansion of the Council is planned in 2000. Occasionally the Council also receives funds for specific projects: for example, in 1999 the Medical Research Council, Wellcome Trust and UK Department for International Development provided £40,000 to allow the Council to hold a workshop on the ethics of clinical research in developing countries and publish a discussion paper. The Council has also received indirect support through secondments from the Department of Health: from 1991 to 1996, the Department of Health seconded one official on rotation (Mr Warren Brown, Ms Judith David, Miss Margaret Chiverton, Mr Mat Otton-Goulder and Ms Julie O'Connell).

Council Membership

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.

Membership of Council at December 1999

Professor Ian Kennedy (Chairman) Professor of Health Law, Ethics and Policy, School of Public Policy, University College London	*founding member* Chairman since 1998
Professor Martin Bobrow CBE (Deputy Chairman) Head of Department of Medical Genetics, University of Cambridge	member since 1997
Reverend Professor Duncan Forrester DD Professor of Christian Ethics and Practical Theology, University of Edinburgh	member since 1996
Professor Brian Heap CBE FRS Master, St Edmund's College, University of Cambridge	member since 1996
Lady Hornby Chairman, The Kingwood Trust	member since 1996
Dr Anne McLaren DBE FRS Wellcome/CRC Institute, Cambridge	*founding member*
Dr Brian Newbould Former Director of International Research Affairs, ICI Corporate Research and Technology	*founding member*
Mr Derek Osborn CB Chairman of the European Environment Agency and Chairman of UK Roundtable on Sustainable Development	member since 1996
Professor Martin Raff FRS Professor of Biology, University College London	member since 1999
Mr Nick Ross Broadcaster	member since 1999
Professor Dame Margaret Turner-Warwick DBE Former President of the Royal College of Physicians	*founding member*
Professor Albert Weale FBA Professor of Government, University of Essex	member since 1998

Retired members of the Council

Professor Ingrid Allen CBE	1995–97
Mrs Beverley Anderson	*founding member*–1994
Mrs June Andrews	1995–99
Miss Margaret Auld	*founding member*–1994

Professor Margaret Brazier OBE	1994–99
Professor Canon Gordon Dunston CBE	*founding member*–1995
Professor Sir John Gurdon FRS	*founding member*–1995
Professor Eve Johnstone	*founding member*–1994
Mrs Caroline Miles	*founding member*–1996
Sir Patrick Nairne	*founding member*–1996
Baroness Onora O'Neill CBE FBA	*founding member*–1998
Ms Sally O'Sullivan	1995–98
Miss Jane Reed	*founding member*–1994
Dr Iram Siraj-Blatchford	1995–96
Professor Sir David Weatherall FRS	*founding member*–1996
Professor Sir David Williams	*founding member*–1994

Chairmen

The founding Chairman, Sir Patrick Nairne, was succeeded by Baroness Onora O'Neill (a founding member of Council) in May 1996. In May 1998 Baroness O'Neill was appointed Chairman of the Nuffield Foundation and she was succeeded as Chairman of the Council by Professor Ian Kennedy, Professor of Health Law, Ethics and Policy at University College London, also a founding member of Council. The Chairman of the Council is appointed by the Nuffield Foundation.

Secretariat

David Shapiro, Executive Secretary to the Council, retired in July 1997. Working with Sir Patrick Nairne, the founding Chairman, he established the Secretariat in 1991. He was succeeded by Dr Sandy Thomas in October 1997. Susan Bull succeeded Dr Rachel Bartlett as Deputy Director in October 1998. Yvonne Melia, Research Assistant, joined the Secretariat in May 1999. Jill Batty served as personal assistant to the Secretariat from 1991 to 1998 and Julia Fox took over this role in 1998.

The Council's position in the UK government policy framework

The Council is governed by its terms of reference. The significant recent policy developments, from the Council's point of view, are the creation of two major new commissions, with broad advisory roles which include reference to bioethics, and the concomitant decision of the Government not to create any over-arching national bioethics commission. Within this altered policy framework, the Council will continue to pursue projects which suggest themselves as fitting for the Council's attention, i.e. to identify, analyse and advise on ethical issues and to present a balanced view to promote public understanding at an early stage.

Many other countries have national committees to undertake this role. In the nine years since its establishment, however, the Council's role and its independence of government has come to be seen as increasingly important in the light of the apparent lack of public trust in government advisory bodies responsible for the areas of biomedicine and biotechnology. The pace of new developments in these areas is accelerating at a time when public concerns about biomedicine, not least in the field of genetics, and biotechnology have grown significantly. The Council perceives its independence as critical to its aim of maintaining public trust in its work.

Reports

1. Genetic Screening: Ethical issues

THE COUNCIL'S reports form the core of its work. This section summarises the main findings of the five reports together with their terms of reference, the membership of their working parties, and the public response and follow-up work by the Council for each.

Terms of reference

1 To survey and report on recent and prospective advances in genetic screening and its applications;

2 To review experience to date of current and potential benefits and difficulties of genetic screening and associated counselling;

3 To identify, define and discuss the ethical issues affecting both individuals and society which arise, or may arise in future from genetic screening, including such matters as:

(a) the general risk of stigma attaching or being attached to those perceived as genetically disadvantaged;
(b) the handling and holding of information;
(c) consent to being screened;
(d) confidentiality in all its aspects;
(e) the implications for employment and insurance;
(f) the storage and use of genetic information for legal purposes.

Summary of findings

Published in December 1993, this Report drew on experience of screening for diseases such as cystic fibrosis and sickle cell anaemia to examine issues such as consent, counselling, confidentiality, and the possible use of genetic information by insurers or employers. The Report recommended that the voluntary nature of all screening programmes should be emphasised and that adequately informed consent be a requirement. It also recommended that counselling should be readily available for those being genetically screened, as well as for those being tested on account of a family history of a genetic disorder.

The Report also considered the serious implications which the results of screening might have for a family. Potentially difficult problems might be posed in applying the longstanding ethical principle of confidentiality between the professional and the individual screened. When genetic screening revealed information that might have implications for the relatives of the person being screened, the Report recommended that health professionals should seek to persuade individuals, if persuasion should be necessary, to allow the disclosure of relevant genetic information to other family members.

Attention was also drawn to the difficulty of assessing individual health risks exposed by genetic screening. The Report recommended that such screening should only be undertaken in the context of employment if accompanied by safeguards for the employee after appropriate consultation. The Report went on to recommend that the Department of Health, in consultation with the appropriate professional bodies, should formulate detailed criteria for the introduction of genetic screening programmes and establish a central co-ordinating body to review genetic screening programmes and monitor their implementation and outcome. The recommendations also proposed that there should be early discussions between government and the insurance industry about the future use of genetic data. The Working Party considered that these recommendations on informed consent, confidentiality and the central co-ordination and monitoring of genetic screening programmes were essential safeguards against eugenic abuse.

Public response and follow-up

Press coverage of the Report focused on the proposal that there should be a moratorium on the use of genetic data for life insurance purposes. One of the public presentations of the Report attracted the interest of the House of Commons Select Committee on Science and Technology. The Committee decided to make human genetics its major subject for the parliamentary session 1994-95. The Council's Report was the starting point of the Select Committee's work. The Council submitted a formal memorandum to the Select Committee, gave oral evidence and provided much material for use by the Committee. Within the ambit of the Council's Report, the conclusions of the Select Committee drew largely on those of the Council.

The Department of Health announced its response in January 1996 by establishing the Advisory Committee on Genetic Testing (ACGT). After further Select Committee hearings, the Government announced in June 1996 that it would establish a non-statutory Human Genetics Advisory Commission (HGAC). These two bodies provided the mechanisms for government to organise co-ordination of work on the ethical and social implications of genetic research, as envisaged in the Council's Report.[1]

Much attention has been given to the issues concerning insurance discussed in the Report. In December 1997 the Human Genetics Advisory Commission published *The Implications of Genetic Testing for Insurance* and recommended that a mechanism be put in place to evaluate the scientific and actuarial evidence presented in support of the use of specific genetic tests for insurance products. The Government responded in November 1998 and established the Genetics and Insurance Committee (GAIC). The Association of British Insurers (ABI) published a Code of Practice in December 1997 which met some of the Council's and HGAC's concerns. A revised version of the Code of Practice was published in August 1999. Also in 1999, the UK Forum for Genetics and Insurance was set up, with a mission 'to analyse the implications of advances in genetic knowledge for insurance in all its forms and to serve the public interest by reporting on its findings'. The Council is one of the ten founding members of the Forum, along with organisations such as the Royal Society, the Wellcome Trust, the Faculty and Institute of Actuaries and the Association of British Insurers (ABI).

Members of Working Party

Professor Dame June Lloyd DBE (Chairman), formerly Nuffield Professor of Child Health in the University of London
Dr Elizabeth Anionwu, Lecturer in Community Genetic Counselling at the Institute of Child Health, London
Professor Keith Ewing, Professor of Public Law, King's College, London
Mrs Lesley Greene, Director of Support Services, Research Trust for Metabolic Diseases in Children
Professor Peter Harper, Professor of Medical Genetics at the University of Wales College of Medicine, Cardiff
Dr Anne McLaren DBE FRS, Principal Research Associate at the Wellcome/CRC Institute of Cancer and Developmental Biology, Cambridge
Mrs Caroline Miles, Ian Ramsey Fellow, St Cross College, Oxford, and formerly Chairman of Oxfordshire Health Authority
Dr Bernadette Modell, Consultant in Perinatal Medicine, University College and Middlesex Medical School, London

[1] The Human Genetics Advisory Commission (HGAC) continued its work in this area and in July 1999 published *The Implications of Genetic Testing for Employment*. The HGAC was dissolved following a government review of the regulatory framework for overseeing developments in biotechnology. Its role is now part of the remit of the Human Genetics Commission (HGC), which will be established in early 2000 as a result of the government review. The remit of the HGC will be broadly to advise on genetic technologies and their impact on humankind. It will report jointly to Health and Science Ministers.

2. Human Tissue: Ethical and legal issues

Terms of reference

1 To survey and report on the current and prospective medical and scientific uses made of sub-cellular structures, cells and their products, tissue and organs hereinafter referred to as human tissue;

2 To give some account of developments in research and exploitation of tissue, identifying current and potential benefits and current and potential difficulties;

3 To identify and define ethical issues and questions of public policy and current practices arising from the use and exploitation of human tissue, including such matters as:

(a) the source of the tissue, e.g. patient, healthy volunteer, cadaver, fetus;

(b) the relationship between the person using the tissue for research or therapeutic purposes and the source from which it derives;

(c) consent, particularly as regards the potential foreseeable consequences flowing from the intended use;

(d) rights in and exploitation of knowledge acquired from research:

- particularly claims to exclusive use of such knowledge through use of intellectual property rights;
- and generally the notion of regarding human tissue as a commodity, in particular as a commodity in some cases of significant commercial value.

Summary of findings

Advances in medical treatment, scientific research and biotechnology involve the use of human tissue in an ever-increasing variety of ways. These uses include organ and tissue transplantation, the use of human tissue for research on new medicines and the use of human cell lines and genetic material for studying fundamental biological processes. This Report, published in April 1995, dealt with the ethical and associated legal questions raised by the medical and scientific uses of human tissue.

The Report considered that there was an important and urgent need to consider, clarify and, where necessary, strengthen the ethical and legal framework within which the clinical and research uses of human tissue take place. The ethical issues related directly to the core of respect for human beings, namely that they and their bodies should not be injured and that nothing should be done to them without their consent. In the UK the legal status of human tissue was unclear and a coherent approach was needed to guide any further regulation. The need to clarify the law was important in so far as its uncertainty may impede legitimate uses or even encourage illegitimate uses of tissue.

The Working Party recommended that when a patient consented to medical treatment involving the removal of tissue, that consent should be taken to include consent to subsequent disposal, storage or acceptable use of the tissue, provided that such a use was regulated by appropriate ethical, legal and professional standards. Genuine consent needs to be based on adequate understanding of the treatment and explanations used in the consent procedures need to make it clear that consent covers acceptable further uses of tissue removed during treatment. On the matter of the disposal of tissue, the Report recommended that organisations handling and disposing of human tissues, including fetal tissues, ensure that they meet both the requirements of law and professional standards and also ensure that major body parts, such as limbs, and tissue subject to special public concern or scrutiny, such as fetal tissue, are handled and disposed of in ways that show respect.

The Report also discussed removal of tissue from children or those deemed incompetent to consent and noted the difficulties raised by the legal uncertainty in this area. It proposed that the removal of tissue from children and those incompetent to consent would only be acceptable if the procedures involved were of negligible risk and burden, and if the donor did not object, or appear to object, to the procedures. In addition, with regard to children, the consent of the person with parental responsibility should be sought, and, where appropriate, the children themselves should be consulted and their agreement obtained. Where tissue was removed from the dead for purposes which were acceptable, in that they contributed directly or indirectly to medical treatment, but might not have been

expressly provided for by statute, the Working Party recommended that if the appropriate consent from the deceased or next-of-kin had been obtained, these removals should be regarded as lawful.

The Report discussed the arguments for and against the commercial organisation of the procurement of tissue and concluded that there were strong arguments against organising such procurement along commercial lines. It therefore recommended that organisations responsible for removing donated human tissue should operate on a non-commercial basis. Payments to donors should only cover their reasonable expenses and inconvenience incurred and should not act as an inducement. Tissue banks should continue to operate on a non-profit-making basis and the Department of Health should establish a central register of approved tissue banks. Human tissue used in the development of products for direct or indirect therapeutic use should only be obtained from such sources. Considering whether a person has or retains any claim over tissue removed from his or her body, the Working Party recommended that the law should proceed on any such claim by examining the basis of the consent given to the procedure that resulted in the removal of tissue. In particular, it should be entailed in consent to medical treatment that tissue removed in the course of treatment would be regarded as having being abandoned by the person from whom it was removed.

Public response and follow-up

Press reports following publication of the Report gave prominence to the assertion that a commercial trade in body parts was unethical. The legal uncertainty about the status of human tissue and whether it is property that can be owned also attracted attention, as did the difficulties raised by proposals to remove tissue from those not legally competent to consent to such removal. The Report's recommendations commanded professional approval. The Department of Health indicated informally that it found almost all the recommendations acceptable. The Department had, in parallel, carried out an unpublished review of tissue banks in the UK. It was understood, however, that by the end of 1996, the Department was likely to take steps to implement some of the major recommendations both of its tissue bank review and of the Council's Report. However, issues were left unresolved until the Secretary of State reacted in early October 1999 to growing pressure for clarification of the law and guidance on good practice, following announcements that hospitals had retained organs from infant cadavers without parental permission.

With regard to consent procedures, there was general agreement with the Report's recommendation that consent to treatment should, provided adequate explanation was given, be taken to include consent to disposal, storage and any other acceptable use of removed tissue. There was also broad agreement that, when tissue is removed from volunteers, information must be explicit about the range of intended uses of the tissue. The recommendations of the Report on consent have a significance that transcends the important moral principles embodied in the need for consent. This is because the legal ownership of human bodies and, by extension, of removed human tissue is uncertain. The Report therefore recommends that questions of ownership should be treated by reference to the form of consent given for its removal.

The acquisition and supply of tissue needs to be organised on a cost recovery basis. This recommendation of the Report is not uncontroversial for it bears on the supply of human gametes for *in vitro* fertilisation. Nevertheless, in other aspects the recommendation has commanded general agreement, particularly in the light of the consequences in some other member states of the European Union of the commercial export of poor quality human tissue from Eastern Europe. This is an area which has still not been addressed by government. However, the MRC published its Interim Operational and Ethical Guidelines entitled *Human Tissue and Biological Samples for Use in Research* for consultation in November 1999. A final version of the guidelines is being produced in 2000. Perhaps because of the continuing lack of a clear regulatory framework in the UK, the Council's report on human tissue remains one of its most widely-read publications.

Members of Working Party

Professor Dame Rosalinde Hurley (Chairman), Professor of Microbiology, Institute of Obstetrics and Gynaecology, Royal Postgraduate Medical School and Chairman of the Medicines Commission 1982-94
Mrs Kathleen Baker, writer, counsellor and Vice President of Greater Manchester Relate
Professor Sir Colin Berry, Professor of Morbid Anatomy and Dean of the London Hospital Medical College
Professor Gerald Dworkin, Herbert Smith Professor of European Law, King's College, London
Professor Trevor M Jones, Director-General of the Association of the British Pharmaceutical Industry, formerly R&D Director of the Wellcome Foundation
Professor Ian Kennedy, Professor of Medical Law and Ethics, Head of the School of Law and President of the Centre of Medical Law and Ethics, King's College, London
Mr Kevin Mooney, solicitor with Simmons & Simmons specialising in biotechnology and patents issues
Dr Onora O'Neill, Principal of Newnham College, Cambridge

3. Animal-to-Human Transplants: The ethics of xenotransplantation

Terms of reference

1 To review recent and prospective advances in xenografts and the current and prospective applications of such procedures. For these purposes xenografts are defined as the transplantation of animal cells, tissues or organs into human beings.

2 To identify and consider the ethical issues arising from current and prospective uses of xenografts, including in particular:

(a) the ethical aspects of the case for xenografts in the light of alternative procedures or practices, taking into account current and potential benefits and current and potential difficulties;

(b) the use of animals as sources of cells, tissues or organs;

(c) the special care and maintenance of the animals intended for that use;

(d) the ethical implications of transferring human genes into animals to allow the subsequent transplantation of animal cells, tissues or organs into human beings;

(e) any other ethical issues arising from experimentation with transgenic animals to enable their use as sources of xenografts – taking account, in particular, of the possibilities of the transmission of disease across species boundaries.

Summary of findings

Published in March 1996, this Report provoked a greater media response than the Council's two previous reports. Xenotransplantation raises complex ethical and safety issues which demand resolution. Nonetheless, due consideration of the potential benefits which xenotransplantation might hold resulted in the Report's primary conclusion that the development of xenotransplantation should continue, subject to rigorous regulation. This conclusion was justified by the prospect that xenotransplantation might be able to significantly supplement the present inadequate supply of human organs for transplantation, ultimately saving human lives. It was emphasised that the needs of patients could not be met effectively at present.

The Report considered that there was no reason for xenotransplantation not to be offered to suitable patients once necessary safeguards had been put into place. This was with the proviso that strict ethical procedures relating to consent be followed, and that patients unwilling to consent to xenotransplantation should not be disadvantaged in any way. It was also considered important that the impact of xenotransplantation on individual patients be properly researched should xenotransplantation be introduced into clinical practice. The Working Party concluded that early patients in trials of xenotransplantation would need special consideration. Their consent would need to be sought with great care and the Report emphasised the requirements of an estimation of the likely success, attendant risks and subsequent quality of life.

The Report concluded that there were a number of issues to be resolved. The UK has afforded special protection to primates. The Council recommended that non-primate species should be regarded as the source animals of choice for xenotransplantation. It viewed the use of pigs and their necessary genetic modification as ethically acceptable. In matters of practice, the Report concluded that the role of the Home Office's Animal Procedures Committee may need to be reviewed to ensure that the Animals (Scientific Procedures) Act 1986 sets the appropriate standards in the rearing of animals as sources for xenotransplantation.

An additional major concern was the possible transfer to humans of new infectious diseases. A regulatory framework to control the safety and quality of animal organs and tissue for xenotransplantation was called for. A code of practice, preferably internationally agreed, was recommended to specify which organisms should be excluded to qualify source animals to be designated as pathogen-free.

The Working Party concluded that a general regulatory regime for xenotransplantation should be established, which should be administered by a non-statutory advisory committee in the first instance. It was also considered necessary, as a matter of urgency, to determine what further scientific and

experimental work was required before the first experiments on human beings could be justified. The Report concluded such considerations should form part of the remit of the proposed advisory committee, which should also be responsible for the safety and quality of animal organs and tissue used in xenotransplantation.

"Mr Smith got the liver, Mr Jones the kidneys — but Mr McTavish is our real triumph!"

Public response and follow-up

While the headlines accompanying articles inevitably simplified the Report's message, such as 'Ethics group paves way for human use of animal organs' (*The Times*, 7 March 1996), the cautious stance of the Report was duly noted. Working Party members were quoted emphasising that the development of xenografts should proceed with caution, paying attention to maintaining the highest standards of animal welfare and the risks of introducing new infections into the human population.

The announcement a day later of the cloning of the sheep Megan and Morag at the UK Roslin Institute naturally set the Council's Report in a context of continuing discussion of animal use for human purposes. Much of that discussion on xenotransplantation centred on the risk of the transmission of new diseases to humans. This issue was highlighted both by the presumed animal origins of HIV/AIDS and by the subsequent acceptance by the UK Government of a significant risk of bovine spongiform encephalopathy (BSE) being transmitted to humans in the form of variant Creutzfeldt-Jakob disease (vCJD). This drew attention to the need for any human trials of xenotransplantation to be done within a framework of government supervision as recommended in the Council's Report. The conclusions and recommendations were generally welcomed by the transplantation community and by the public. Animal rights organisations, even if they did not accept the conclusions, felt that animal issues had been raised with sympathy and given appropriate prominence.

In the follow-up to the Report, a joint workshop was held on 24 July 1996 with the US Institute of Medicine (IOM) to coincide with the publication of its report on the topic. The workshop was held in Washington and attracted about 150 of the leading authorities concerned with xenotransplantation. Professor Albert Weale, Professor John Ledingham, Professor David Morton, Dr Brian Newbould, the Executive Secretary and the Deputy Secretary attended on behalf of the Council. In September 1996, members of the Norwegian Biotechnology Advisory Board and additional representatives from Sweden and Denmark, including directors of Sandoz in both these countries visited the Council following specific interest raised by the issues surrounding xenotransplantation. More recently, in 1998 the Council's Deputy Director, Rachel Bartlett, participated in the WHO (World Health Organization) consultation on xenotransplantation.

The Department of Health's Advisory Group on the Ethics of Xenotransplantation, chaired by Professor Ian Kennedy, published its report *Animal Tissue into Humans* in January 1997, together with a detailed government response. The main recommendations of the Advisory Group were very similar to those of the Council's Report. The conclusions, however, were carefully framed to avoid any indication that a green light was being given to xenotransplantation. As a result, some press comments were inclined to give the impression that

xenotransplantation was in effect being banned. The Advisory Group accepted that a National Standing Committee should be established to ensure that the issues raised were addressed and to consider the science of xenotransplantation as new evidence became available. The Government implemented this recommendation by establishing the UK Xenotransplantation Interim Regulatory Authority (UKXIRA).

In 1998, UKXIRA published a document to guide applications to undertake xenotransplantation on human subjects together with a report on the distribution of Porcine Endogenous Retroviruses (PERVs) in pigs, their possible effects on humans and the risk of pig to human transmission. In 1999 the UKXIRA Biosecurity Steering Group published draft guidance on biosecurity and animal husbandry and the UKXIRA Infection Surveillance Steering Group published a draft report outlining concerns such as the possibility of viral transmissions occurring during pregnancy or as a result of sexual contact in recipients of xenografts.

Members of Working Party

Professor Albert Weale (Chairman), Professor of Government at the University of Essex
Ms Virginia Beardshaw, Director of Commissioning at Barnet Health Agency
Dr Roger Crisp, Fellow and Tutor in Philosophy at St Anne's College, Oxford
Professor Celia Davies, Professor of Health Care at the Open University
Ms Annabel Ferriman, freelance medical journalist
Professor Tim Ingold, Professor of Social Anthropology at the University of Manchester
Professor John Ledingham, formerly Professor of Clinical Medicine, University of Oxford, John Radcliffe Hospital
Professor David Morton, veterinary surgeon and Professor of Biomedical Science and Biomedical Ethics at the University of Birmingham
Dr Brian Newbould, member of the Nuffield Council on Bioethics and formerly Director of International Research Affairs, ICI Corporate Research and Technology
Professor Mark Walport, Professor of Medicine at the Royal Postgraduate Medical School, Hammersmith Hospital, London

4. Mental Disorders and Genetics: The ethical context

Terms of reference

1 To survey the current field of research relating to the genetics of mental disorders and to report on recent and prospective advances.
2 In particular, to review:
  (a) whether there are sufficiently firm criteria for diagnosis;
  (b) how substantial the evidence is implicating genetic influences.
3 To review the potential clinical applications of the research.
4 To define and consider ethical, social and legal issues arising from work on the genetic aspects of mental disorders and identify those which are additional or complementary to the issues dealt with in the Council's report *Genetic Screening: Ethical issues*. Such matters may include:
  (a) the ethics of research on the genetics of mental disorders involving human subjects, including particular groups such as children and detained patients;
  (b) when is it appropriate to translate research findings into clinical or social practice?
  (c) genetic counselling for mental disorders in the context of adult onset disorders, of children and in prenatal diagnosis;
  (d) the particular impact of the diagnosis of a genetic risk on the individual, including an individual child or fetus, or on other members of the family;

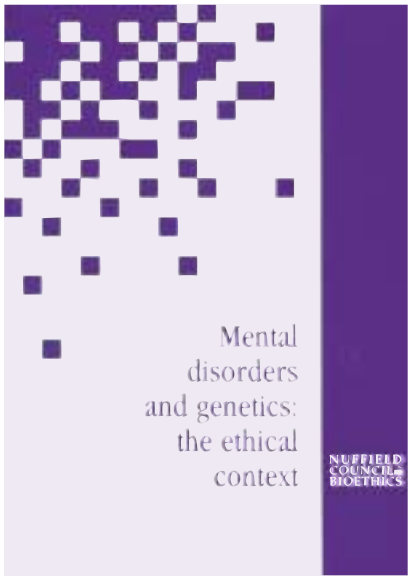
continued

Summary of findings

Genetics and mental health are both areas which raise significant and sometimes distinctive ethical, social and legal concerns. This Report, published in September 1998, examined the ethical issues that may arise when these two fields come together in the course of genetic research into mental disorders and in the application of that research in clinical and other settings. A broad and humanistic perspective considered two ethical requirements as basic: the limitation of harm to and suffering of all human beings and respect for them and their dignity.

The Working Party considered the rare single gene disorders for which Huntington's disease and early onset Alzheimer's disease provided the main examples, and the common mental disorders influenced both by susceptibility genes and by environmental factors, such as schizophrenia and the more common late onset form of Alzheimer's disease. The ethical issues associated with mental disorders concern the implications for reproductive decisions, the stigma associated with mental disorders and the fact that some disorders may impair the capacity to make decisions.

The Working Party concluded that genetic tests for prenatal diagnosis or population screening will not be particularly useful in the near future in diagnosing mental disorders with more complex causes. It is more probable that identifying genes implicated in susceptibility to common mental



disorders will lead to the development of more effective drug treatments. Even if a number of susceptibility genes were identified for a particular disorder, the Report concluded that, without an understanding of their interaction, they would not be an adequate tool in predicting individual risk.

The Working Party recommended that genetic testing for susceptibility genes which offer relatively low predictive or diagnostic certainty be discouraged, unless there was a clear medical benefit to the patient. The genetic testing of children requires special safeguards and the Working Party recommended that predictive genetic testing and testing for carrier status for mental or indeed other disorders in children be strongly discouraged. The Report also drew attention to the fact that genetic testing

Terms of reference (continued)

(e) stigma and responsibility: will genetic knowledge increase or decrease the stigma suffered by those with mental disorders and the responsibility perceived by or assigned to relatives?
(f) the implications of the use of genetic findings in the courts and other legal proceedings;
(g) the implications of the use of genetic findings for access to insurance, employment, education and healthcare.

for mental and other disorders in adoption raised important and complex issues which required appropriate guidance.

While the best safeguard against new eugenic pressures was felt to be freely given, properly informed consent, guidelines for the establishment and maintenance of genetic registers were needed. The Report recommended that the confidential nature of genetic information be maintained but recognised that, exceptionally, disclosure might be justified. Recommendations were also made about the use of genetic information in insurance and employment.

For most people with a mental disorder, arrangements about consent to research participation should not be any different from those required by others. However, for those who were only intermittently competent, the Report recommended that consent should be sought only when they were competent. For the incompetent, the Report concluded that participation in non-therapeutic research was considered to be ethical, subject to strict safeguards.

Public response to the Report and follow-up

The Report received coverage in a range of broadsheet newspapers, scientific journals and the medical press. Particular attention was given to the Report's recommendations that genetic testing for susceptibility genes which offer relatively low or predictive diagnostic certainty be discouraged. The Report was also widely read within the psychiatric profession, where it has been well received at a national and international level. This was the first Nuffield Report to be released electronically onto the internet at the launch, and during 1999 over 500 copies were downloaded by a wide range of individuals and organisations.

The Report has had particular relevance to organisations concerned with mental health in the context of ageing. The Council responded to two major consultations on this topic. One, by the Advisory Committee for Genetic Testing, had established an inquiry on genetic testing for late onset disorders and reported in September 1998. The Council also submitted a response to the Lord Chancellor's Department on their consultation document, *Who Decides? Making decisions on behalf of mentally incapacitated adults*.

The Director, Dr Sandy Thomas, gave a presentation on the ethical issues surrounding ageing and genetics at the joint Research into Ageing and MRC Health Span Conference held in October 1998. Dr Thomas was also the lead speaker at the HUGO workshop on 'Genetic Susceptibility Testing' as part of the Human Genome Meeting held in March 1999 in Brisbane, Australia. She discussed the ethical issues surrounding genetic testing for susceptibility genes, focusing on complex diseases. More recently, Professor Martin Richards, Dr Andrew Wilkie and Professor Peter McGuffin, members of the Working Party, gave presentations at a two-day conference in July 1999 on 'Genetics, Identity and Responsibility'.

Members of Working Party

Dame Fiona Caldicott (Chairman), Principal of Somerville College, University of Oxford, and formerly President of the Royal College of Psychiatrists
Mr Chris Barchard, Chairman of VOICES, the user group within the National Schizophrenia Fellowship
Professor John Haldane, Professor of Philosophy and Director of the Centre for Philosophy and Public Affairs, University of St Andrews
Lady Hornby, Chairman of Gloucestershire Royal NHS Trust and member of the Nuffield Council on Bioethics
Professor Peter McGuffin, Professor of Psychological Medicine, University of Wales College of Medicine
Nigel Pleming QC, Vice Chairman of the Mental Health Act Commission from 1994 to 1996
Professor Martin Richards, Director of the Centre for Family Studies, University of Cambridge
Professor Pamela Taylor, Professor in Special Hospital Psychiatry at Broadmoor Hospital and the Department of Forensic Psychiatry, Institute of Psychiatry
Dr Andrew Wilkie, Wellcome Trust Senior Research Fellow in Clinical Science at the Institute of Molecular Medicine, University of Oxford, and an Honorary Consultant in Clinical Genetics
Ms Sally Young, Personnel Executive, Occupational Health, Welfare Services and Equal Opportunities, Marks and Spencer

5. Genetically Modified Crops: The ethical and social issues

Terms of reference

1 To briefly review the developments on the genetic modification of crops and their impact on human food consumption and the environment.

2 To identify and consider the ethical and social implications of these developments including:

(a) issues of food safety and public health;
(b) issues of environmental protection;
(c) the public interest and the maintenance of consumer choice and public confidence;
(d) the appropriateness of the criteria used at present by regulatory bodies in the UK and in the EU;
(e) the implications for less developed countries;
(f) the implications of intellectual property issues;
(g) the responsibilities of scientists in advising policy-makers on these issues.

and to make recommendations.

Summary of findings

This Report, published in May 1999, examined the ethical issues which are raised by the development and application of GM plant technology to world agriculture and food security. The perspective on GM crops was guided by consideration of three main ethical principles: the principle of general human welfare, the maintenance of people's rights and the principle of justice. The Working Party found some of these considerations, such as the need to ensure food security for present and future generations, safety for consumers and care of the environment, to be relatively straightforward and broadly utilitarian. Others, stemming from the concern that GM crops are 'unnatural', were found to be more complex.

The Working Party accepted that some genetic modifications were truly novel but concluded that there was no clear dividing line which could prescribe what types of genetic modification might be unacceptable because they were considered by some to be 'unnatural'. It took the view that the genetic modification of plants did not differ to such an extent from conventional breeding that it was in itself morally objectionable. There was recognition that GM technology did, however, have the potential to lead to significant changes in farming practices, in food production and in the environment. The Report concluded that it was now necessary to maintain and develop further a powerful public policy framework to guide and regulate the way in which GM technology is

developed in the UK. It recommended that an over-arching, independent biotechnology advisory committee be established to consider, within a broad remit, the scientific and ethical issues together with the public values associated with GM crops.

Recommendations about the need for improved risk assessment methods, post-release monitoring and the evaluation of cumulative and indirect environmental impacts were made. The Working Party did not believe that there was enough evidence of actual or potential harm to justify a moratorium on GM crop research, field trials or limited release into the environment at this stage. Public concern about the introduction of GM crops had led to calls for bans on GM food and a moratorium on plantings. The Working Party concluded that all the GM food so far on the market in this country was

safe for human consumption. It recommended that a genuine choice of non-GM foods should remain available, with foods which contain identifiable GM material being appropriately labelled. The Working Party urged the Government and the scientific community to share their responsibilities in disseminating reliable information about the underlying science and to respond to public concerns.

The Working Party concluded that the application of genetic modification to crops had the potential to bring about significant benefits, such as improved nutrition, enhanced pest resistance, increased yields and new products such as vaccines. The moral imperative for making GM crops readily and economically available to developing countries which want them was considered compelling. Consequently, the Working Party recommended a major increase in financial support for research into GM crops directed at the employment-intensive production of food staples together with the implementation of international safeguards.

Public response and follow-up

The report was first released on the internet in May 1999, followed by the printed edition in June 1999. Launched during a period of extensive public debate about GM crops, the Report received wide coverage in the media and contributed to opening up the debate from its relatively narrow focus on UK environmental issues to broader issues concerning the potential application of GM in developing countries. Reactions to the Report and its findings were rather polarised. While some organisations strongly disagreed with the findings of the Report, the UK Government, international agricultural organisations, the agrochemical industry, many within the plant biotechnology research community and others welcomed the recommendations. The Report prompted considerable correspondence in the broadsheet press.

The Council hosted a two-day meeting in September on behalf of ISAAA (International Service for the Acquisition of Agri-biotech Applications), a non-profit international organisation involved with the transfer of agrotechnology applications from industrial to developing countries. A distinguished delegation of senior scientists from East Asia met representatives from several organisations to acquaint themselves at first-hand with views from UK supporters and opponents of GM crops.

Since the Report's launch, the Director, on behalf of the Council, has advised a range of organisations which are considering the ethical and wider issues raised by the introduction of GM crops. These have included the North Carolina Biotechnology Centre and the British Crop Protection Council. The Director and members of the Working Party have made invited presentations to: the IBC East Asian Conference on GMOs, Singapore; the British Council (Germany); The Royal Society for the Encouragement of Arts, Manufactures and Commerce, and the Oxford Union. Professor Michael Lipton gave the Sir John Crawford Memorial Lecture at a CGIAR (Consultative Group on International Agricultural Research) meeting in Washington. A visit to New Zealand at the invitation of the New Zealand Life Sciences Network to make a series of presentations on the Report was also made. The Council is continuing its activities to follow up the Report and the implementation of its recommendations. It will also continue to participate in the debate and advise those bodies who are dealing with the issues.

Between May and December 1999, the Report was downloaded from the Council's website nearly four thousand times. UK web users predominated, followed by users in North American and Australasian countries, with interest from European nations increasing towards the end of 1999. In addition to being frequently accessed by the private sector, the Report was accessed by several organisations having an interest in the application of GM technology in developing countries. Demand for the printed version of the Report has remained high.

Members of Working Party

Professor Alan Ryan (Chairman), Warden of New College, University of Oxford
Professor Derek Burke CBE, former Vice Chancellor of the University of East Anglia, and Chairman of the Advisory Committee for Novel Foods and Processes (1988-97)
Professor Mike Gale FRS, Director, The John Innes Centre, Norwich
Professor Brian Heap CBE FRS, Master of St Edmund's College, University of Cambridge, Foreign Secretary of the Royal Society and a member of the Nuffield Council on Bioethics
Miss Prue Leith OBE, Vice President of the Royal Society of Arts
Ms Julie Hill, Programme Adviser to the Green Alliance, an environmental charity, and a member of the Advisory Committee on Releases to the Environment (ACRE) until June 1999
Professor Steve Hughes, Unilever Research Professor at the Department of Biological Sciences, University of Exeter
Professor Michael Lipton, Poverty Research Unit, University of Sussex
Mr Derek Osborn CB, Chairman of the European Environment Agency, Chairman of UNED/UK and a member of the Nuffield Council on Bioethics.

Workshops (1999)

In 1998 the Council decided to hold meetings involving a range of invited experts who would convene over a one to two day period. These meetings had two purposes: first, they enabled the Council to explore areas of interest which might not otherwise have been given attention due to the demands of Working Parties already in progress. The first example was the Roundtable Meeting on ethical issues arising from stem cell therapy held in September 1999 (see page 22). Secondly, workshops provide a valuable opportunity for preliminary discussion of potential topics for Council Working Parties. The workshops held in February 1999 on the ethics of clinical research in developing countries (see below) and in November 1999 on genes and behaviour (see page 22) are examples of these meetings.

The Ethics of Clinical Research in Developing Countries

In 1998 the Council determined that it would be timely to discuss ethical issues arising from the conduct of clinical research in developing countries. Ethical concerns surrounding research in developing countries that is sponsored by agencies or companies in developed countries, or is carried out in collaboration with scientists from developed countries, have received relatively little international attention. Some of the concerns were highlighted in the recent debate concerning large-scale trials conducted in developing countries to test treatment with zidovudine (AZT) to prevent perinatal transmission of the human immuno-deficiency virus (HIV). The ethical issues raised in that debate, such as whether there should be a level of care to which trial participants should be entitled, irrespective of their country of residence, were not new nor were they confined to the trials being discussed. Indeed, many of the concerns about clinical research conducted in developing countries also apply to research being conducted in developed countries. They tend, however, to be exacerbated when only very limited resources are available, as may be the case in developing countries.

In February 1999 the Council hosted an international workshop in London to encourage and stimulate debate in this important area. The workshop was attended by 30 leading experts from 18 countries and was sponsored by the UK Medical Research Council, the Wellcome Trust and the UK Department for International Development. In October 1999, the Council published a discussion paper based on the workshop's discussions and background papers.

Summary

The paper drew attention to the fact that a wide range of ethical and social issues needed to be addressed. The duty to conduct scientifically sound research, to act in the participant's best interests and to respect the participant's autonomy was fundamental to all clinical research, but might be more difficult to achieve in poor countries where basic healthcare was not widely

available. Questions about justice were also particularly relevant where limited resources meant that effective treatments might not be affordable in the countries in which the research was being carried out.

In view of the potential risk of harm in clinical research, the paper emphasised that sound ethical standards had to be observed, irrespective of the geographic and economic setting in which such research was undertaken. The view was taken that the mechanisms and procedures for ethical review in some developing countries were under-developed. Moreover, the discussion paper suggested that while the Declaration of Helsinki and international biomedical guidelines were both necessary and useful, they had weaknesses which needed to be addressed. Furthermore, it pointed out that such guidance could only facilitate the protection of the interests of trial participants if training and resources were available for its interpretation and implementation.

A range of ethical and social issues was identified as warranting consideration by research sponsors, intending collaborators and relevant authorities in poor countries. These included the relevance of the research to the country's health needs, the availability of effective treatments after research has been completed, the need to respect cultural traditions when conducting research and issues relating to consent. The participants in the workshop agreed that there was clearly a very considerable distance between the broadly based principles outlined in international guidance and the practical issues being considered by local research ethics committees reviewing individual protocols. One suggested way forward was the production of 'intermediate' guidelines linking these two levels of ethical assessment. International bodies undertaking inquiries on this topic have acknowledged the importance of collaboration in developing new, coherent guidance.

Workshop Steering Group

Dr Imogen Evans
Research Strategy Manager for Clinical Sciences, The Medical Research Council, London
Ms Marion Kelly
Research Specialist, Department for International Development, London
Dr Richard Lane
Head of International Programmes, The Wellcome Trust, London
Professor Peter Smith
Head of Department of Infectious and Tropical Diseases, London School of Hygiene & Tropical Medicine, London

The Working Party

Following the workshop, Council determined that this was a matter of such importance that it should be the subject of a full working party. Members of the Working Party were drawn from both developing and developed countries, and will begin work in January 2000. The Working Party, chaired by Professor Sir Kenneth Calman, will report in 2001.

Members of Working Party (at December 1999)

Professor Sir Kenneth Calman (Chairman)
Vice-Chancellor and Warden, University of Durham
Professor Michael Elves
Former Director, Office of Scientific and Educational Affairs, Glaxo Wellcome plc
Professor V I Mathan
Division Director, Laboratory Sciences Division, International Centre for Diarrhoeal Disease Research, Dhaka, Bangladesh
Professor Keith McAdam
Director, MRC Laboratories, Fajara, The Gambia
Dr Anne McLaren
Wellcome/CRC Institute, Cambridge
Dr David Nabarro
Director, Roll Back Malaria, World Health Organization
Professor Bhikhu Parekh
Professor of Political Theory, University of Hull
Professor David Parkin
Professor of Social Anthropology, Oxford University and Fellow of All Souls College, Oxford
Professor Povl Riis
Ministry of Science, Copenhagen, Denmark
Mrs Shahwar Sadeque
Educational & ICT Consultant
Dr Jaime Sepulveda
Director General, Instituto Nacional de Salud Publica, Mexico
Professor Nelson Sewankambo
Dean, Makerere University, Uganda
Professor Peter Smith
Head of Department of Infectious and Tropical Diseases, London School of Hygiene & Tropical Medicine

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.

Participants attending the workshop on clinical research in developing countries

Ethical issues associated with genetic conditions other than serious medical ones

The scope of the Council's report *Genetic screening: ethical issues* was limited to serious diseases. In focusing on the major disorders, the scope of the report on *Mental disorders and genetics: the ethical context* was similarly restricted. This raised the question of whether there were important issues relating to the genetics of other conditions within the normal range that merited examination by the Council. In particular, the issues raised by research into the genetics of traits such as intelligence, sexuality and addictive behaviour were considered. Because the rapid rate of scientific progress in human genetics will lead to the identification of an increasing number of genes associated with behavioural traits, it was agreed by Council that it was important to anticipate the ethical and social implications raised by this research.

In line with the Council's new practice, a workshop was held on 3 November 1999 to examine the topic and consider the terms of reference. A group of 15 invited experts with a breadth of expertise in areas such as ethics, genetics, psychiatry, psychology, sociology and law convened to take part in a one-day discussion. The first half of the meeting focused on the broad scientific, ethical and social issues raised by research in this area, with the second half considering whether the establishment of a working party was appropriate, what its terms of reference might be and the kind of expertise which should be represented in the membership. The workshop helped to underline the diversity of views on the issues which broadly surround the area of genes and behaviour. The next stage involves the appointment of a Chairman and Working Party members. It is planned that the membership of the Working Party will be finalised and able to begin work in the autumn of the year 2000.

Stem cell therapy: the ethical issues

In June 1999, Council agreed to hold a small workshop the following autumn on ethical issues arising from therapeutic cloning. The government subsequently announced a review under the direction of the Chief Medical Officer (CMO) by an Expert Advisory Group on Therapeutic Cloning, and in August the Council contacted the Group. The idea that the workshop should meet to discuss ethical concerns and convey its views so as to inform the deliberations of the CMO's Group was welcomed. A round table meeting was held on 29 September 1999. The participants were Professor Alexander McCall-Smith, Professor Thomas Baldwin, Professor Martin Bobrow, Dr Anne McLaren and Lady Hornby. A presentation outlining the main findings of the meeting was made to the CMO Expert Group in November 1999. A short discussion paper will be published in April 2000.

Developing public discussion and awareness

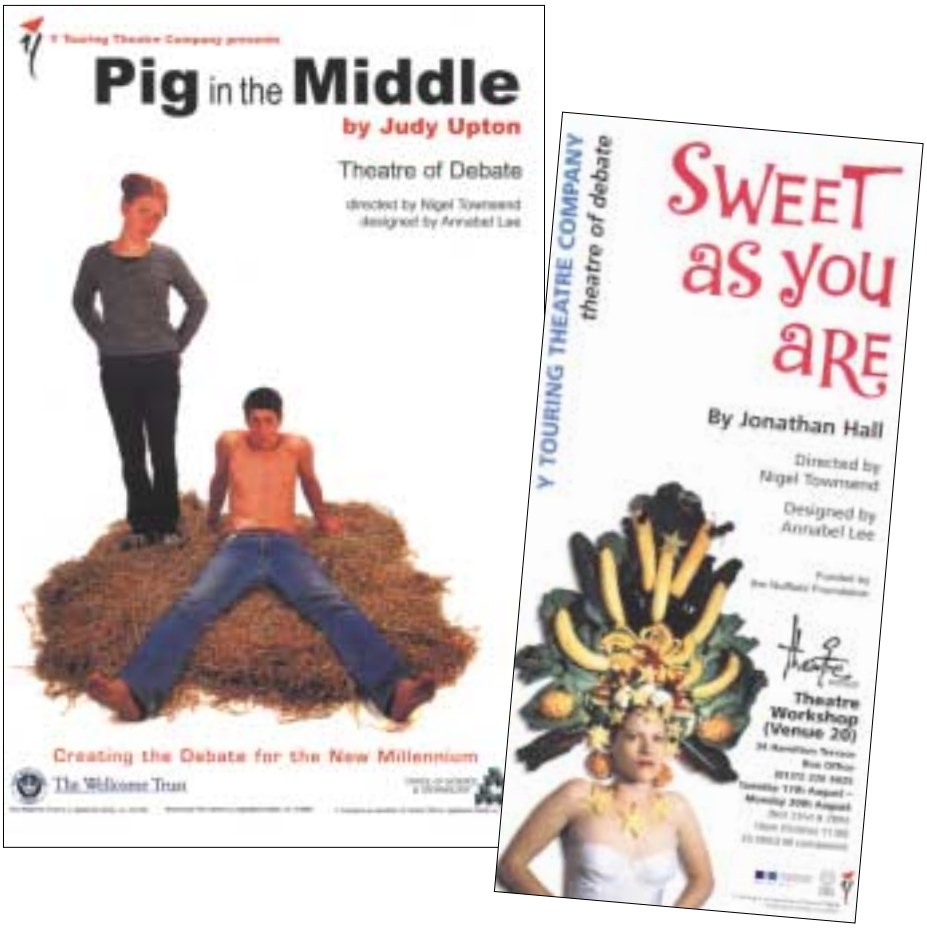
THE COUNCIL'S reports represent the core of its work. Pursuant to its terms of reference, the Council has also attached importance to the need to promote discussion of the issues raised by the reports. A media consultant organised press conferences for the launch of reports and co-ordinated media interviews for working party members and the Director of the Council. Media responses to reports have been closely monitored and detailed reviews in specialist journals encouraged. The media coverage of the reports has frequently assisted with the further dissemination of the Council's work, which in turn has stimulated public debate.

Complimentary copies of each report have been distributed to all those involved in its production, including respondents to the public consultation which has always been a feature of a working party's research. Copies have also been distributed to organisations and individuals with a particular interest in the topic. Several months after a report is launched the Secretariat has liaised with bodies targeted in the report's recommendations, with a view to monitoring any responses from these organisations, including any regulatory or policy changes. The Secretariat has also devoted time to briefing the media on topics that the Council has reported on as part of its follow-up activity. Members of Council and each working party together with the Secretariat have taken part in relevant professional and public meetings.

The Council introduced additional activities following the publication of its report entitled *Animal-to-Human Transplants: The ethics of xenotransplantation*. These included a joint sixth-form conference with the MRC entitled *Animal to Human Transplantation* at Birmingham University School of Education. The Chairman of the Working Party, Professor Albert Weale, presented the ethical issues raised by xenotransplantation, based on the Council's report. The main aims of the conference were to raise awareness about the issues raised by xenotrans-plantation, provide information about the science which underpins it, enable students to make balanced judgements and provide an opportunity to canvas their views and allow them to question experts in the field. The conference received positive feedback from participants, assessed through evaluation forms which were circulated to both delegates and speakers. A reported strength was the informative documentation for the students to consider in advance, as well as workshop sessions where issues were discussed, followed by presentations made to the whole conference. The conference was re-run at Chetham's School of Music in Manchester in 1997. During the 1996 Science Education (SET) Week, Professor Albert Weale also sat on a panel of experts participating in a public debate on animal-to-human transplants. This event attracted about 160 people, divided between sixth-form students and adults. Those schools agreeing to attend were sent briefing packs before the event and follow-up information packs and a copy of the report for schools after the event. Those who attended the event felt it had helped to improve their understanding of xenotransplantation.

In partnership with Y Touring, the Central YMCA's national touring theatre company, the Council developed a drama project which toured schools. The performance of an hour-long play *Pig in the Middle*, written by Judy Upton, was followed by a structured debate and supported by an education pack. The event aimed to encourage discussion about animal-to-human transplants through an accessible and stimulating medium. During its tour of schools and its short run at the Edinburgh International Science Festival, *Pig in the Middle* was seen by 12,560 students, teachers, governors, MPs and members of the public.

Following the publication of the GM crops report, the Nuffield Council was one of the advisers to Y Touring in the production of *Sweet As You Are*, a play discussing genetically modified crops. *Sweet As You Are* made its debut at the Edinburgh Fringe Festival. Following excellent reviews, the play was awarded a prize as a 'Fringe First'. Performances have subsequently taken place in London and a performance at the British Association Science Festival in Sheffield resulted in an invitation to appear at the Cambridge Science Week. Funding is currently being sought to allow *Sweet As You Are* to undertake a tour of schools.



Since its inception, the Council has been aware of its obligation to make its work accessible to the general public and given the level of public concern about GM crops, it was thought that this would be a very suitable topic for a shorter, more readily accessible, report. In collaboration with the Nuffield Curriculum Projects Centre a 36-page version of the report entitled *Genetically Modified Crops: The ethical and social issues* is being produced for older schoolchildren and the general public. This will be published in 2000.

The Council launched its web site in 1998 (http://www.nuffieldfoundation.org/bioethics). This originally provided details of Council membership and terms of reference, current Working Parties, press releases and publications, some of which were made available in full text versions. Towards the end of 1999, the site was developed to include edited minutes of Council meetings, and an advertisement for 'expressions of interest' in Council membership. Further expansion is planned to incorporate the entire text of all the Council reports, the terms of reference and composition of future working parties and information about additional projects such as workshops and the joint project with the Curriculum Projects Centre on GM crops. A page containing links to other relevant organisations is also being set up.

The website receives about two thousand visitors per month. The increasing popularity of accessing the Council's publications on line was illustrated when *Genetically Modified Crops: The ethical and social issues* was downloaded approximately four thousand times between May and December 1999. The discussion paper entitled *The Ethics of Clinical Research in Developing Countries* was downloaded about five thousand times between October and December 1999.

International activities

THE COUNCIL has been formally invited to a number of international and bilateral meetings. In Europe the two main institutions active in bioethics are the Council of Europe and the European Commission. The Council of Europe is an inter-governmental body which has a membership that goes wider than that of the European Union. The Council of Europe's activity in bioethics began in the late 1970s and has recently seen the drafting of a convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine. The Council has been represented at the Council of Europe round table for European committees and bodies concerned with bioethics.

The European Commission (EC) has become increasingly active in bioethics. The Commission's BIOMED research programme has dedicated funds for the promotion of collaborative research into bioethics. The Directorate General (DG) XII has been responsible for two committees, one on human embryos and reproduction (HER) and another on the ethical, legal and social aspects of the human genome (ELSA). Council representatives have been members of ELSA (Professor Dunstan) and HER (Dr Anne McLaren). David Shapiro (Executive Secretary 1991-97) and his successor, Dr Sandy Thomas, have also acted as assessors for the BIOMED programme.

The Commission also established the Group of Advisers on the Ethical Implications of Biotechnology (GAEIB). GAEIB, which operated from 1994 to 1997, was originally designed to resolve the deadlock in some of the debates within the EC on ethical aspects of biotechnology. The group received a new mandate at the start of 1998, together with new members and a new title, namely the European Group on Ethics in Science and New Technologies (EGE). It has now developed into an institution that draws up outline guidance for more general use. Dr Anne McLaren, a founding Council member, has served as a member of GAEIB (and subsequently EGE) from 1994.

UNESCO invited David Shapiro (Executive Secretary 1991-97) to serve on its preparatory Bioethics Working Party. He served subsequently on UNESCO's International Bioethics Committee (IBC) from 1991 to 1997. He was responsible for much of the drafting of the IBC's report on Genetic Screening, which drew largely on the Nuffield Council's 1993 Report.

The Council also maintains close contact with counterparts abroad such as the US National Bioethics Advisory Commission, the Australian Health Ethics Committee and European Commissions such as the Danish Council of Ethics and the Comité Consultatif National d'Éthique, France.

Summary of international meetings

Dr Rachel Bartlett (Deputy Executive Secretary 1994-98) acted as rapporteur for the WHO Consultation on 'Xenotransplantation: Infectious disease prevention and ethical considerations' and participated in the preparation of the WHO Statement on Xenotransplantation. Dr Onora O'Neill, Chair of the Council from May 1996 to May 1998, was represented by Professor Ruth Chadwick at the first International Summit of National Bioethics Commissions 1996 in San Francisco. The Council was also represented by the Director, Dr Sandy Thomas, at the second International Summit of National Bioethics Commissions 1998 in Tokyo. Delegates and observers representing a wide range of bodies from 31 countries attended this meeting. The UK was represented by the Director of the Nuffield Council on Bioethics, the Chairman of the HGAC (Sir Colin Campbell), and Dr Donald Bruce from the Church of Scotland Technology Project. A number of UK observers also attended. The main theme of the meeting was 'International Issues in Research involving Human Subjects: Perspectives from National Commissions and Other Countries'.

The Council has also been an active participant in European meetings of national bioethics committees. The Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) held a Conference for European Commissions in 1998 in Brussels at which the Director spoke on UK policy for bioethics. In June 1988, the Council hosted a reception for a delegation of members of the European Group on Ethics in Science and New Technologies (formerly GAEIB), led by Mme Noëlle Lenoir at Bedford Square. In November of the same year, the Council was represented by Professor Dame Margaret Turner-Warwick at the Council of Europe European Conference of National Bioethics Committees in Oporto. Lady Hornby represented the Council at a symposium to celebrate the 10th anniversary of the Swiss Society of Biomedic Ethics in Lugano.

During 1999 the Council was invited to participate in several international meetings, including two recent National Institutes of Health (NIH) meetings organised by the Fogarty International Center for Advanced Study in the Health Sciences on clinical research in developing countries. The Comité Consultatif National d'Éthique of France held their Journées Annuelles d'Éthique which the Director was invited to address. The Director also attended a consultation meeting on 'Ethical Issues in Genetics, Cloning and Biotechnology: Possible future directions for WHO' in December 1999.

Appendix 1: Financial statement

STATEMENT OF INCOME AND EXPENDITURE 1991-1998

	1991 £	*1992* £	*1993* £	*1994* £	*1995* £	*1996* £	*1997* £	*1998*[1] £
EXPENDITURE								
Salaries	51,594	59,968	74,829	75,794	99,199	104,700	107,381	118,281
Office costs	10,217	11,404	11,404	12,190	16,152	16,342	26,784	61,340
Stationery & press cuts	3,249	4,926	4,967	4,309	4,339	4,821	1,535	11,076
Photocopying/post/phone/fax	237	2,432	6,812	7,003	11,339	11,759	18,862	5,223
Committee & meeting costs	4,601	8,236	9,959	9,448	16,706	15,595	8,525	10,571
Printing of reports	–	–	8,251	–	5,935	8,042	3,153	10,632
(less) sales of reports	–	–	(708)	(3,777)	(4,393)	(7,619)	(4,647)	(4,102)
Publicity of reports	–	–	10,777	1,140	6,102	8,484	3,152	7,487
Equipment	–	–	–	6,187	–	–	11,652	14,664
TOTAL	**69,898**	**86,966**	**126,291**	**112,294**	**155,368**	**162,124**	**176,397**	**235,172**
INCOME								
Nuffield Foundation	69,898	86,966	126,291	112,294	55,368	62,124	58,064	115,172
MRC					50,000	50,000	60,000	60,000
Wellcome Trust					50,000	50,000	58,333	60,000
TOTAL	**69,898**	**86,966**	**126,291**	**112,294**	**155,368**	**162,124**	**176,397**	**235,172**

Other projects separately funded since 1998

Conference on the ethics of clinical research in developing countries (budget £40,000), funded jointly by the Nuffield Foundation, the Medical Research Council, the Wellcome Trust and the Department for International Development.

EU Xenotransplantation Partnership (budget £13,350), funded by the EC

[1] In 1998 the accounting base was changed to include the Nuffield Foundation's core costs.

Appendix 2: Summary of publications

Genetic screening: ethical issues
Published December 1993

Human Tissue: Ethical and legal issues
Published April 1995

Animal-to-Human Transplants: The ethics of xenotransplantation
Published March 1996

Mental Disorders and Genetics: The ethical context
Published September 1998

Genetically Modified Crops: The ethical and social issues
Published May 1999

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

All publications are now available on the Council's web site at: www.nuffieldfoundation.org/bioethics/ in both pdf and html versions. Alternatively, printed copies of publications may be obtained from the Secretariat. Order enquiries can be made by telephone: 020 7681 9619, fax: 020 7637 1712 or by emailing bioethics@nuffieldfoundation.org. Publication prices per report range from £7.50 to £20.00 and are inclusive of postage within Europe only.

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