

THE IRISH COUNCIL FOR

BIOETHICS

COMHAIRLE BITHEITICE NA HÉIREANN

The Irish Council for Bioethics
2002 - 2005

TERM OF OFFICE REPORT

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Foreword

This document provides an overview of the work conducted by the Irish Council for Bioethics during its first term of office (2002-2005). Initially, the Council established three working groups to address the following issues: Research Ethics Committees, Human Biological Material, and Genetically Modified Organisms. The three documents published by the Council during its first term were the culmination of the efforts of each of the working groups in examining, reviewing and reporting on their designated topics. The Council believes that these documents will contribute to the constructive discussion of these issues in the future.

I want to express my sincere thanks and appreciation to the members of the individual working groups, both those from the Council and those co-opted externally, for giving so generously of their time, energy and expertise, which has contributed to the success of the Council over the last three years. The Council is also extremely grateful to all those who took the time to respond to the public consultations, as their input greatly benefited the Council's considerations.

I would like to thank my predecessor Professor Patrick Fottrell under whose expert stewardship the Council was established and chaired until September 2003. I would also like to extend my gratitude to Vice-Chair Professor Peter Whittaker for his support and commitment to the Council since its inception.

The work programme of the Council was not confined to the remit of the working groups and included numerous other activities both nationally and internationally. Since its inauguration, the Council has established links with its European and worldwide counterparts such as the Forum of National Ethics Councils, the European Group on Ethics and the Global Summit of National Bioethics Commissions. These links have fostered the exchange of information and experience in the field of bioethics.

At a national level the activities of the Council have been many and varied incorporating the debate and discussion of ethical issues surrounding science and medicine with policy makers, stakeholders, government bodies, second and third level institutions, the media and the general public. The diversity of the functions carried out by the Council necessitated the expansion of the secretariat and three Researchers have joined the Council since 2002.

The last three years have seen a number of important developments in the fields of medicine and science such as, the cloning of embryos, ICT implants in humans and the development of human-animal hybrids. There is no doubt that the next three years will see the advent of similar technological advances, with their associated ethical issues. As the Irish Council for Bioethics enters its second term of office I look forward to working with the new members of the Council and the general public in addressing such issues.

A handwritten signature in blue ink, appearing to read 'Dermot Gleeson'. The signature is fluid and cursive, written over a light blue background.

Dermot Gleeson SC
Chairman



Report from the Scientific Director

This report aims to give readers an overview of the work of the Irish Council for Bioethics during its first three year term (2002-2005). The report provides a narrative of key events that give an impression of the scope and diversity of the Council's work both nationally and internationally.

The Council's role is to inform the public, promote public dialogue, and to provide independent advice. During its first term of office the Council produced a guidance document for Research Ethics Committees (2004), a report on Human Biological Material (2005) which contained 23 recommendations relating to the collection, use, storage and disposal of biological material in the context of research and an opinion document which assessed whether Genetically Modified Crops and Food (2005) represented a threat or an opportunity for Irish society.

Council thinking was informed by co-opted experts to working groups and by public consultation. In the case of the opinion on genetically modified food and crops, the Council ran an online survey and received almost 600 submissions. Our gratitude is extended to Council members, working group members and those who participated in the public consultations for their expertise and insight.

The rapid emergence of new biotechnologies has implications for all in society as they can challenge the way in which we view the environment, others and ourselves. Citizens have a central role to play in assessing the acceptability or otherwise of these new developments. In addition to publishing advisory reports and opinion documents, the Council's terms of reference also include promoting public understanding, informed discussion and education on bioethical issues. The Council fulfils this task through free public lectures, debates and seminars, as well as participation in radio and television programmes. We hope such events have assisted people in exploring their own values and have encouraged active engagement in the deliberation of issues in the areas of medicine and biotechnology.

During the first term of office, the secretariat of the Irish Council for Bioethics has grown from one to four people and this has allowed for a significant expansion in the activities of the Council. I would like to acknowledge the support, skill and commitment of my colleagues in the secretariat, which has proved vital to the work of the Council.

Going forward, the aim of the Council is to consider and advise on emerging bioethical issues as well as existing topics with special relevance to the Irish context. The second term of office will also see an expansion of the Council's outreach programme in an attempt to identify and promote dialogue on issues of interest/concern to the Irish public.

A handwritten signature in blue ink that reads "Siobhán O'Sullivan".

Dr Siobhán O'Sullivan
Scientific Director

Introduction

Bioethics is a multidisciplinary activity dealing with the ethical implications of biological research and medicine. It was born out of questions generated by the rapid medical and technological advances made in the last 30 years, such as genetic modification. The choices facing physicians, scientists and society at large are becoming increasingly difficult. Bioethics serves as a tool to make moral choices and to decide issues of public policy and the direction and control of science.

In March 1999, the Irish Government established an Inter-Departmental Group on Modern Biotechnology, in response to concerns raised in regard to genetic modification. The group was chaired by the Department of Enterprise Trade and Employment and involved representatives from the Departments of Health and Children; Agriculture and Food; Environment, Heritage and Local Government and the Food Safety Authority of Ireland. The group published a report in October 2000, which recommended that a National ethics committee be established which would consider the "ethical issues raised by biotechnology in an informed, dispassionate and independent way".

The Irish Council for Bioethics (Comhairle Bitheitice na hÉireann) was subsequently established in 2002 by the Royal Irish Academy as an independent, autonomous, non-statutory body to consider the ethical issues raised by developments in science and medicine. The Council was formally inaugurated by An Tánaiste and Minister for Health and Children (at that time Minister for Enterprise, Trade and Employment), Ms Mary Harney T.D., in January, 2003.

The Council was funded by a grant from Forfás, Ireland's national policy and advisory board for enterprise, trade, science, technology and innovation.

Terms of Reference

1. To identify and interpret the ethical questions raised by biological and medical research in order to respond to, and anticipate questions of substantive concern.
2. To investigate and report on such questions in the interests of promoting public understanding, informed discussion and education.
3. In the light of the outcome of its work, to stimulate discussion through conferences, workshops, lectures, published reports and where appropriate suggest guidelines.

Council Members

The Council's membership consisted of lawyers, philosophers, ethicists, physicians, geneticists, food scientists, biologists, microbiologists, biochemists, and journalists. Members were invited to join the Council by virtue of their personal expertise, distinction and authority and not as representatives of particular bodies or professions.



Mr Dermot Gleeson SC, Chairman
(as of December 2003)
Senior Counsel and Chairman of AIB



Dr Patrick Flanagan
Former Senior Scientific Officer,
Environmental Protection Agency



Professor Patrick Fottrell
(Chairman until September 2003)
Former President National University of
Ireland, Galway



Professor Patrick Hannon
Professor of Moral Theology,
St Patrick's College,
National University of Ireland, Maynooth



Professor Peter Whittaker, Vice Chairman
Professorial Fellow at the Centre for
Economic and Social Aspects of Genomics
(CESAGen). Institute of Environment,
Philosophy and Public Policy, Lancaster
University



Canon Kenneth Kearon
(until December 2004)
Director of the Irish School of Ecumenics,
Trinity College Dublin



Professor Patrick Cunningham
Professor of Animal Genetics,
Department of Genetics,
Trinity College Dublin



Professor Cecily Kelleher
Head of the School of Public Health
and Population Sciences,
University College Dublin



Mr Matt Dempsey
Editor and Chief Executive of the Irish
Farmers' Journal



Professor Mark Lawler
Chief Molecular Geneticist, Department
of Genetics, Trinity College Dublin and
Associate Professor of Experimental
Haematology, Trinity College Health
Sciences Centre, St. James Hospital



Dr Dolores Dooley
Lecturer, Department of Philosophy,
National University of Ireland, Cork



Professor Tony McGleenan BL
Chair in Law. School of Law,
University of Ulster



Dr Margaret Fitzgerald
(until December 2004)
Chief Specialist of Public Health,
Department of Public Health,
Eastern Regional Health Authority



Dr Peter McKenna
Consultant Obstetrician and
Gynaecologist, Rotunda Hospital,
Dublin



Ms Mary Mulvihill
Science Editor and Consultant



Professor Anne Scott
Professor of Nursing and Head of the
School of Nursing,
Dublin City University



Dr Nora O'Brien
Senior Lecturer in Nutrition,
Faculty of Food Science and Technology,
National University of Ireland, Cork



Mr Asim A. Sheikh BL
Lecturer in Legal Medicine,
Division of Legal Medicine,
University College Dublin



Professor Fergal O'Gara
Professor of Microbiology and Director
of the BIOMERIT Research Centre,
National University of Ireland, Cork



Professor Seán Strain
Professor of Human Nutrition and
Co-Director of the Centre for Molecular
Biosciences, School of Biomedical
Sciences, University of Ulster



Professor Ronan O'Regan
Professor Emeritus of Physiology and
Histology, Department of Human
Anatomy and Physiology,
University College Dublin

Secretariat



Dr Siobhán O'Sullivan
Scientific Director



Mr Paul Ivory
Researcher



Ms Emily de Grae
Researcher



Mr Pauric Dempsey (until July 2005)
Assistant Executive Secretary,
Royal Irish Academy



Dr Stephanie Dyke
Researcher

Work Programme

In selecting a work programme for the Council's first term of office individual Council members proposed issues for consideration that they felt should be addressed. In addition Government and professional bodies were entitled to refer questions and issues to the Council for consideration.

The issues examined by the Irish Council for Bioethics were decided upon based on a number of factors, such as public interest and concern, relevance to Ireland and in particular whether the Council could make a unique contribution to the discussion of an issue. Three working groups were established by the Council to address the following issues; Research Ethics Committees, Human Biological Material, and Genetically Modified Organisms. Working groups were chaired by a member of the Council and were comprised of a combination of Council members and externally co-opted individuals who were selected on the basis of their expertise in the issue under consideration. The composition of the working groups, therefore, ensured that a broad range of views and disciplines were represented, which encouraged an informed and balanced discussion of each issue.

The working groups, in regular liaison with the Council each drafted a report, in the form of guidance, recommendations or opinion, which was submitted to the Council for consideration and approval before publication. The Council operated on a consensus basis, however, there was a facility to record minority views should the need have arisen.

Research Ethics Committees

The working group on Research Ethics Committees was established in December 2002 to review in depth, the operational procedures of research ethics committees (RECs) in Ireland. The group chaired by Professor Cecily Kelleher met on eight occasions between October 2002 and February 2005.

In October 2002 the working group undertook a national survey of RECs. A letter was sent to Universities, Institutes of Technology and Hospitals inviting them to submit details of the existence or otherwise of research ethics committees in their institutions and the rules of procedure for any such committees.

The survey showed that there were, in 2002, 52 institutional ethics committees in Ireland attached to hospitals and/or Health Boards, third level institutions and a variety of organisations.

They were generally established on an ad-hoc basis, most operating independently of one another with little or no harmonisation of documentation or standard operating procedures.

As well as publishing a guidance booklet for RECs the working group established a REC Extranet, in order to stimulate cooperation between RECs and serve as a source of information on EU directives and developments in ethical issues. The working group also hosted a full-day national research ethics committee meeting in March 2004 (see National Research Ethics Committees in Symposia section).

Terms of Reference

1. To review in depth, the existing practices of Ethics Committees in the Republic of Ireland, with particular reference to Research Ethics Committees
2. To identify best practice in the area internationally and across the island of Ireland
3. To produce guidance on the composition and operation of Research Ethics Committees and to suggest a national structure for such organisations in the Republic of Ireland
4. To report to Council on all aspects of the deliberations and conclusions of the working group on Research Ethics Committees

Operational Procedures for Research Ethics Committees: Guidance 2004

On 14th September 2004, the Irish Council for Bioethics launched its first publication entitled *Operational Procedures for Research Ethics Committees: Guidance 2004*, which provided guidance on how to establish and operate RECs. The booklet was based on requirements for ethical review established in international guidelines and provided advice on general standards and principles that should be considered by RECs when reviewing research proposals. Previously, Ireland lacked comprehensive guidance in this area. Mr Ivor Callelly T.D., Minister of State, Department of Health and Children launched the booklet and stated that he was sure that the document would “prove to be a very valuable contribution to the conduct of clinical trials in this country.”

At the launch of *Operational Procedures for Research Ethics Committees: Guidance 2004*, Professor Cecily Kelleher (Chair of the working group) said that the Council was “hopeful that the guidance contained in this document will facilitate research ethics committees in conducting an independent, comprehensive ethical review of research proposals, which will serve researchers and the public alike”.

The guidelines were compiled following a consultation with various stakeholders including the Department of Health and Children, the major research funding agencies in the State and took cognisance of the European Clinical Trials Directive 2001/20/EC.

The Council is hopeful that this guidance will facilitate and support efficient and effective ethical review of research proposals.

Operational Procedures for Research Ethics Committees: Guidance 2004 is available in hardcopy by contacting the secretariat or can be downloaded from the Council's website www.bioethics.ie.

Working Group Members

Professor Cecily Kelleher, Chairperson
School of Public Health and Population Sciences, University College Dublin

Dr Margaret Fitzgerald (until December 2004)
Department of Public Health, Eastern Regional Health Authority

Mr Dermot Gleeson SC (until December 2003)
Senior Counsel and Chairman of AIB

Canon Kenneth Kearon (until December 2004)
Irish School of Ecumenics, Trinity College Dublin

Mr Dan Lynch
Secretary, Research Ethics Committee of Adelaide and Meath Hospital, Dublin Incorporating the National Children's Hospital

Dr Peter McKenna (as of December 2004)
Department of Obstetrics and Gynaecology, Rotunda Hospital, Dublin

Dr Siobhán O'Sullivan
Irish Council for Bioethics

Professor Anne Scott
School of Nursing, Dublin City University

Human Biological Material

The working group on Human Biological Material was established in October 2002 to examine the ethical issues relating to the collection, use, storage and disposal of human biological material. The group chaired by Professor Mark Lawler until July 2004 and subsequently by Mr Asim A. Sheikh BL from July 2004 onwards met on a total of ten occasions between October 2002 and June 2005.

Mr Asim A Sheikh
BL (Chair, working
group), An Tánaiste
Mary Harney T.D.,
Minister for Health
and Children and
Mr Dermot Gleeson
SC (Chair ICB) at
the HBM launch
2005.

To assist their deliberations the working group on Human Biological Materials engaged in a public consultation exercise entitled "The Question of Biological Material for Research" in July 2003. Advertisements were placed in the national press and Dr Siobhán O'Sullivan (Scientific Director) also made a series of presentations in print and broadcast media. All interested parties were asked to make written submissions (via post or email). An information sheet was prepared, highlighting some of the key questions to be tackled. The working group received over one hundred submissions from both the general public and professional organisations. An analysis of the results was included as an appendix to the final report.

Terms of Reference

1. To identify and report on the specific scientific and medical research uses made of human biological material
2. To identify ethical and legal questions arising from the collection, use, storage and disposal of human biological material

3. To evaluate the public's perception of human biological material and to inform the public in relation to the current and potential benefits and difficulties arising from the use of such research material
4. To produce a set of recommendations with respect to the collection, use, storage and disposal of biological materials for researchers and those individuals/institutions evaluating research

Human Biological Material: Recommendations for Collection, Use and Storage in Research 2005

On 29th June 2005, the Council published a report entitled, Human Biological Material: Recommendations for Collection, Use and Storage in Research 2005. An Tánaiste Ms Mary Harney T.D., Minister for Health and Children launched the report saying that she welcomed its publication adding that her Department was currently looking at transposing an EU Directive on Human Tissue into Irish law. Informed consent is a key element in the ethical conduct of research involving human biological samples and forms the basis of the report.

Other important issues discussed in the document include confidentiality and privacy, the commercialisation of human biological material, intellectual property rights, patenting and the storage and disposal of biological material. The report contains twenty-three recommendations with regard to these areas.

At the launch of *Human Biological Material: Recommendations for Collection, Use and Storage in Research 2005*, Mr Asim A. Sheikh BL (Chair of the working group) said “this report will assist in the formulation of good practice guidelines and in the continuing debate and discussion of this important subject that is so vital to medical research and also to better healthcare.” He also said that the report “contributes to the formulation

of a better relationship between researchers and those who get involved in research by promoting a clear exchange of information between the parties”.

The Council hopes that the report will assist in the formulation of an ethical framework for those actively involved in the use of human biological materials in research and encourage further discussion and debate of the complex issues surrounding the use of human biological samples in research.

Human Biological Material: Recommendations for Collection, Use and Storage in Research 2005 is available in hardcopy by contacting the secretariat or can be downloaded from the Council’s website www.bioethics.ie.

Working Group Members

**Mr Asim A. Sheikh BL, Chairperson
(as of July 2004)**

Division of Legal Medicine,
University College Dublin

**Professor Mark Lawler
(Chairperson until July 2004)**

Department of Genetics, Trinity College Dublin
and Trinity College Health Sciences Centre,
St. James Hospital

Professor Patrick Cunningham

Department of Genetics,
Trinity College Dublin

Dr Dolores Dooley

Department of Philosophy, National University of
Ireland, Cork

Dr Brian Farrell

Dublin City Coroner, Coroners’ Society of Ireland

Dr Patrick Flanagan

Formerly, Environmental Protection Agency

Professor Andrew Green

National Centre for Medical Genetics, Our Lady’s
Hospital for Sick Children, Crumlin, Dublin

Dr Peter McKenna

Department of Obstetrics and Gynaecology,
Rotunda Hospital, Dublin

Mr Matt Moran

Irish BioIndustry Association

Ms Mary Mulvihill

Science Editor and Consultant

Dr Seán O’Briain

Faculty of Pathology, Royal College of
Physicians of Ireland

Ms Mary Duffy (until December 2003)

Patient Focus

Ms Sheila O’Connor (as of July 2004)

Patient Focus

Professor Ronan O’Regan

Department of Human Anatomy and Physiology,
University College Dublin

Dr Siobhán O’Sullivan

Irish Council for Bioethics

Dr David Smith

Department of General Practice, Royal College
of Surgeons in Ireland

Professor Robert Stout

Research and Development for the Northern
Ireland Health and Personal Social Services

Genetically Modified Organisms

In response to a request from the Food Safety Authority of Ireland a working group on genetically modified organisms (GMOs) was established in 2002. The working group considered the ethical issues raised by developments in genetic modification in the medical, industrial, and agricultural arenas, with particular reference to the Irish setting. It also examined the ethical consequences of adopting GM crop and food technology in Ireland. The group, chaired by Professor Peter Whittaker, met on eight occasions between November 2002 and September 2005.

In October 2003 a public consultation was undertaken. Advertisements were placed in National and regional newspapers inviting people to fill in a questionnaire, which could be submitted online or by post. Dr Siobhán O'Sullivan (Scientific Director) publicised the consultation through print and broadcast media. The working group received a total of 560 submissions. An analysis of the results was included as an appendix to the final report.

Terms of Reference

1. To discuss the ethical issues surrounding GMOs in general and also with particular reference to the Irish context
2. To co-opt appropriate others to the working group as deemed necessary
3. To seek the views of the general public on the ethical issues surrounding GMOs
4. To prepare a draft report for submission to the Irish Council for Bioethics

Genetically Modified Crops and Food: Threat or Opportunity for Ireland? Opinion

On the 28th November 2005 the Council launched its report Genetically Modified Crops and Food: Threat or Opportunity for Ireland? Opinion.

The report examined the ethical consequences the introduction of GM crops and food in Ireland would have for consumers and farmers, as well as the implications of cultivating GM crops for the environment and citizens in developing nations.

At the launch of Genetically Modified Crops and Food: Threat or Opportunity for Ireland? Opinion, Professor Peter Whittaker (Chair, GMO working group) stated that while the working group did not view the genetic modification of plants as morally objectionable in itself "ethical considerations demand that new applications of genetics should be based on sound science with generally acceptable objectives, and progressed in a cautious but not fearful manner".

The Irish Council for Bioethics hopes the report will clarify the main scientific and ethical considerations involved in the GMO debate, thereby encouraging constructive discussion on this contentious issue.

Genetically Modified Crops and Food: Threat or Opportunity for Ireland? Opinion is available in hardcopy by contacting the secretariat or can be downloaded from the Council's website www.bioethics.ie.

Working Group Members

Professor Peter Whittaker, Chairman

Centre for Economic and Social Aspects of Genomics (CESAGen). Institute of Environment, Philosophy and Public Policy, Lancaster University

Dr James Burke

Teagasc

Mr Matt Dempsey

Irish Farmers' Journal

Dr Patrick Flanagan

Formerly, Environmental Protection Agency

Professor Patrick Hannon

St Patrick's College, National University of Ireland, Maynooth

Dr Jonathan Hughes

Centre for Professional Ethics, Keele University, UK

Dr Richard Hull

Centre of Bioethical Research and Analysis (COBRA), Department of Philosophy, National University of Ireland, Galway

Professor Tony McGleenan

School of Law, University of Ulster

Dr Tom McLoughlin

Environmental Protection Agency

Dr Nora O'Brien

Faculty of Food Science, Food Technology, and Nutrition, National University of Ireland, Cork

Professor Fergal O'Gara

Microbiology Department, National University of Ireland, Cork

Dr Patrick O'Mahony

Food Safety Authority of Ireland

Dr Siobhán O'Sullivan

Irish Council for Bioethics

Professor Seán Strain

Centre for Molecular Biosciences, University of Ulster

Mr Dermot Gleeson S.C. (Chair, ICB) and Prof. Peter Whittaker (Chair, GMO working group)



Symposia

Genetics and Disability

The Irish Council for Bioethics sponsored a symposium entitled "Genetics and Disability", which was held at NUI Galway from 10th-12th March 2004. The symposium was organised by the Philosophy Department's Centre of Bioethical Research and Analysis (COBRA) and included presentations from renowned speakers in the fields of ethics and philosophy.

The symposium considered a wide range of topics related to genetics and disability and included discussions on child welfare, disability and embryo selection, the eradication of disability, the provision of information about disability during pregnancy, disability and society and the pros and cons of selecting for or against disability.

Both students and staff of many disciplines, including philosophy, medicine, biomedical engineering and social sciences, politicians and other interest groups, attended the lectures. In addition, a number of presentations given during this symposium were opened to the public.

The Council was delighted to be involved in the "Genetics and Disability" symposium, which attracted significant media attention.

National Research Ethics Committees

On 23rd March 2004 the Irish Council for Bioethics hosted the National Research Ethics Committee meeting in Dublin.

The aim of this meeting was two-fold: firstly, to seek the views and experience of ethics committee members on how best to achieve an optimal framework for the operation of RECs generally and secondly, to discuss the practical implications of transposing the EU Clinical Trials Directive into Irish law.

The meeting was attended by members and administrators of RECs from various institutions and organisations and representatives from the Department of Health and Children. Topics discussed included: the current structure and composition of RECs in Ireland; the principles of ethical conduct; recruitment of REC members; review processes; archiving documentation and the monitoring of RECs. During discussions an overwhelming majority of attendees called for the establishment of a coherent national framework for RECs and there was overwhelming support for a formalised structure for the training of REC members.

The meeting proved extremely beneficial to the Council's deliberations in this area and was welcomed by REC members and policy makers alike.

Ethics of Eating

The Council, in co-operation with the Royal Irish Academy's National Committee for Nutritional Sciences organised a conference on 24th March 2004 entitled "The Ethics of Eating". The Council was delighted that so many speakers from diverse backgrounds accepted the invitation to address an audience including academics, policy makers and members of the public.

The aim of the conference was to provide information and to stimulate discussion and debate in the area of ethics and food production, promotion and consumption. The major topics discussed during this one-day conference included: obesity, the balance between state intervention and personal choice in relation to health promotion, genetically modified (GM) crops and their potential impact on health and the environment and the ethical and political issues surrounding world hunger.

"The Ethics of Eating" provided a valuable insight into many of the ethical issues concerning food. In particular the discussion of GM crops and their impact on society and the environment proved extremely useful to the Council's working group which was at that time considering this issue.

Stem Cells - Possibilities and Pitfalls

On 9th December 2003 the Irish Council for Bioethics held a morning symposium entitled "Stem Cells - Possibilities and Pitfalls". The symposium consisted of presentations from three speakers who are leaders in their respective fields: Professor Angelo Vescovi, Director, Stem Cell Institute, Milan; Professor Ruth Chadwick, Institute for Environment, Philosophy and Public Policy, Lancaster University and Professor Alexander Capron, Director of Ethics and Health WHO and member of President Clinton's National Bioethics Advisory Council. Dr Siobhán O'Sullivan (Scientific Director) opened the session with an "Introduction to Stem Cells". The Honourable Mr Justice Francis Murphy, former Supreme Court judge, moderated the symposium.

The primary aim of the meeting was to present an analysis of the principal scientific and ethical issues surrounding stem cell research to an invited audience of politicians and civil servants. The symposium covered issues such as cutting edge research and the future potential of stem cells, the politics of stem cell research and the ethical considerations arising from such research.

"Stem Cells-Possibilities and Pitfalls" presented an occasion for analysis, serious comment and a free exchange of views.

Forensic DNA Databases: Balancing Criminal Investigation with Civil Rights

The Council invited three distinguished speakers to address an audience of politicians, civil servants, members of an Garda Síochána and other stakeholders at a symposium entitled "Forensic DNA Databases: Balancing Criminal Investigation with Civil Rights". They were: Mr Martin Fairley, Head, DNA Section, Strathclyde Police Authority; Mr Ray Byrne, Director of Research, Law Reform Commission and Ms Aisling Reidy, Director, Irish Council for Civil Liberties. Dr Sheila Willis, the director of the National Forensic Science Laboratory, moderated the symposium, which was held on 3rd November 2005.

The primary aim of the symposium was to provide information and encourage analysis of the principal scientific, legal and ethical issues surrounding the collection, use and retention of forensic DNA samples and profiles. Dr Siobhán O'Sullivan (Scientific Director) provided a brief overview of the various types of forensic DNA databases currently in operation in other countries and some of the main benefits and risks associated with the use of such databases.

The establishment of a forensic DNA database is being presented as a potential criminal investigation tool to combat serious crime in Ireland. Numerous ethical questions arise with respect to individual rights and to how genetic data will be protected from unauthorised intrusion.

The Council hopes that the information provided will enhance discussions regarding the establishment of a forensic DNA database in Ireland.

Conferences and Meetings

An increasing number of countries have created official bodies to provide advice to their executives and legislative branches and to the general public regarding bioethical issues. Since its establishment the Irish Council for Bioethics has worked to forge links with its international counterparts and has attended meetings and conferences in Europe and further afield. The Council feels that becoming part of international networks is an essential element of its work as it offers an opportunity for Councils to learn from one another's experience and expertise.

European Forum of National Ethics Councils (NEC)

The Forum of National Ethics Councils (NEC Forum) is an independent platform for the exchange of information, experience and best practice on issues of common interest in the fields of ethics and science. The establishment of such a forum was suggested at a European Union (EU) sponsored meeting held in Denmark in December 2002. It was decided that the NEC Forum should follow the method of "open coordination" and its meetings should be hosted by alternating National Ethics Councils. Since its initiation, the Forum has developed an important network among national bioethics councils.

June 2003

Dr Siobhán O'Sullivan represented the Irish Council for Bioethics at the inaugural NEC forum in Athens, on 24th June 2003. This meeting consisted of a discussion of the challenges facing NECs in Accession States. A session was devoted to the methods used by various NECs for the provision of public information. The meeting closed with the establishment of a provisional agenda for future meetings. It was decided that the NEC forum would take place twice a year under the auspices of the EU presidency.

December 2003

Dr Siobhán O'Sullivan and Mr Pauric Dempsey attended the second NEC Forum in Rome, on 19th December 2003 on behalf of the Council. The meeting considered a number of ethical issues arising from the development of nanotechnology and its increased use in medicine. Delegates discussed the need for the establishment of ethical protocols and the instigation of public awareness campaigns on this issue.

There followed an examination of the ethical issues involved in biobanking including how to guarantee confidentiality and the protection of personal data stored in national and international biobanks.

June 2004

National Ethics Council (NEC) Forum hosted by ICB in June 2004



Under the auspices of the Irish Presidency of the EU, the Irish Council for Bioethics hosted the third NEC Forum in Dublin on 11th June 2004. The meeting was opened by an address by An Tánaiste, Ms Mary Harney T.D. Minister Harney commended the NEC as a valuable initiative for the exchange of views and best practice on ethical issues.

The meeting consisted of discussions on a number of issues such as the fusion of human and animal cells in the development of human-animal chimeras; stem cell research; cloning and xenotransplantation. The Council was delighted to have distinguished researcher Professor András Dinnyés (Animal Biology Agricultural Biotechnology Centre, Hungary) to explain his work in the human-animal chimera area.

The meeting also included a breakout group session where delegates considered the operational aspects of NECs including the different methods by which national ethics committees generate opinion documents, the process by which topics are selected and the optimal approaches in informing and engaging the general public in bioethical issues.

December 2004

Ms Emily de Grae represented the Council at the fourth NEC Forum in Amsterdam on December 21st-22nd 2004. The first day of the forum involved a joint meeting of the European Group on Ethics in Science and New Technologies (EGE) and NEC Forum members on the use of information communications technology (ICT) devices in humans. The day concluded with a discussion of the relationship between the NEC Forum and the EGE, which advocated the need for continued cooperation and communication between the two groups.

At the NEC forum itself, delegates discussed the ethical aspects of cost utility analysis in public healthcare policy. Delegates also considered the relationship between local and national ethics committees in the different Member States. There was also a session devoted to breakout group discussions of the working activities of NECs, which examined topics such how to deal with the press; whether councils should aim for unanimity or at presenting a diversity of opinions and how to be proactive in addressing relevant policy or research issues.

May 2005

Dr Siobhán O'Sullivan and Ms Emily de Grae attended the fifth NEC Forum, in Luxembourg on 24th May 2005 on behalf of the Council. Forum delegates discussed the scientific and ethical aspects of stem cell research and the ethics of organ transplantation, which highlighted the shortage of transplantable organs compared to their demand in the EU and the need for increased efforts at a national level to improve donor numbers including the creation of artificial organs and replacement organs via stem cell therapy and gene therapy.

Research on animals in basic and applied research was also considered with special reference to genetically modified animals. This was followed by a session dealing with education in bioethics, which outlined different ways to raise the awareness of ethics and science with different stakeholders in society.

November 2005

Dr Siobhán O'Sullivan represented the Council at the sixth NEC Forum in London on 18th November 2005. The meeting focused on public health and delegates discussed the need for balance between Government interventions and life style choices, as well as social disparities and resource allocation.

The afternoon session of the forum considered forensic databases, biometrics and the use of personal information and was chaired by Dr Siobhán O'Sullivan (Scientific Director). There was a discussion of the UK National DNA Database and of the current debate in the UK surrounding the ethics of sampling the data held in the database and the storage of the data itself.

European Group on Ethics in Science and New Technologies (EGE)

The Irish Council for Bioethics was delighted to host a meeting with the European Group on Ethics in Science and New Technologies (EGE) under the auspices of the Irish Presidency of the EU on May 18th 2004. The EGE is an independent, pluralist body that directly advises the European Commission on ethics in science.

The meeting consisted of a discussion of the working practices and composition of both the Council and the EGE. The EGE outlined its most current document, Opinion (19) on the Ethical Aspects of Umbilical Cord Blood Banking. The Irish Council for Bioethics reported to the EGE on the work of the Human Biological Materials working group. The process of public consultation was also discussed.

The meeting proved an extremely beneficial exercise for the two groups and both the Irish Council for Bioethics and the EGE agreed on the importance of joint meetings in the context of fostering professional links in a diverse European society.

European Conference of National Ethics Committees (COMETH)

The European Conference of National Ethics Committees (COMETH) was established in 1992 in Madrid where its first meeting took place and has since met biennially. It has become an international forum for the reflection and exchange of thoughts on moral, legal, medical, social and economic questions and dilemmas arising from progress in biotechnology and biomedicine. Over the years COMETH's significance in the area of bioethics has been increasingly acknowledged and established at a regional as well as at a European level. The Council of Europe recognises the important contribution of the conference and therefore endorses its aims and activities.

December 2003

Ms Emily de Grae represented the Council at the seventh COMETH meeting entitled "New Ethical Challenges: Bioethics Education and Biobanks", which was held in Strasbourg, on 1st-2nd December 2003.

The National Ethics Committee Programme considered the method of bioethics education for second level students in various Member States. The programme also incorporated a session discussing opinion documents published by National Ethics Committees, which included topics such as embryonic stem cell research; genetic diagnosis before and during pregnancy; the Estonian Genome Project and the ethical problems posed by collections of biological material and associated data. During the second day of the conference delegates considered in depth the subject of research on stored tissue and heard presentations on issues such as legislation and commercialisation.

April 2005

Dr Siobhán O'Sullivan represented the Council at the eighth COMETH conference entitled "Meeting the Challenges of Changing Societies", which took place in Dubrovnik, on 25th-26th April 2005.

During the National Ethics Committee Programme delegates reviewed a selection of recent opinion documents. Topics covered included surrogacy; informed consent in genetic research; assisted reproduction and pre-implantation genetic diagnosis. The conference also included discussions on the Convention on Human Rights and Biomedicine and the ethical implications of an ageing society, age discrimination, mental health and advance directives.

Global Summit of National Bioethics Commissions

The Global Summit of National Bioethics Commissions aims to facilitate international dialogue in bioethics. These meetings provide an opportunity to share ideas and plans and to explore issues of common interest from a global perspective. Dr Siobhán O'Sullivan attended the two most recent Global Summits.

November 2002

The fourth Global Summit of National Bioethics Commissions took place in Brazil on 3rd-4th November 2002. The participants from 27 nations discussed a wide range of issues, which arose in their national deliberations. In addition to a plenary discussion of the ethics and policy options surrounding human stem cell research, breakout sessions were held on the use of biological samples for research, pharmacogenetics, the patenting of DNA, cell and DNA databases and the role of the media. A communiqué was produced which set out the conclusions from the meeting.

November 2004

The fifth Global Summit of National Bioethics Commissions took place in Canberra on 7th-9th November 2004. The issues discussed included; intellectual property rights and patenting; advance directives; living organ transplantation; and stem cell research. A number of workshops were held in order to discuss in depth issues pertaining to indigenous health and health research; protection of research participants; stem cell research; sponsored pharmaceutical research; and end of life choices.

Outreach Work

The Irish Council for Bioethics recognises the importance of engaging the public in the discussion of bioethical issues and strives to achieve this on a continual basis. The Council has hosted public lectures and debates and has established a teaching programme for transition year students as well giving lectures to third level students and various organisations. Members of the Council and the secretariat regularly gave interviews to media and submitted articles to journals and magazines. The Council also set up a website www.bioethics.ie.

Public Events


Annual Public Lecture 2004

The Nobel Laureate, Professor Sir John Sulston, whose research group was responsible for sequencing a third of the human genome presented the Irish Council for Bioethics' inaugural annual public lecture. The lecture entitled "The Common Thread: Society and the Human Genome" was held on 12th February 2004 in Dublin City University.

Professor Sulston spoke about how the Genome Project came to pass and what possibilities it offered for the advancement of science and medicine. He explained his determination to make his discoveries freely available to other researchers stating that patenting "impedes research and innovation, throttles ethical decision-making, widens the gap between rich and poor and contributes to global insecurity".

Professor Sulston is praised as a key figure in the race to discover the entire human genetic blueprint. His insistence that each element of the genome be published free and in full ensured that scientists around the world would be able to share in these important discoveries. Therefore the Council was delighted and honoured that Professor Sulston accepted the invitation to give the inaugural lecture.





**Irish Council for Bioethics
Second Annual Lecture**

The Irish Council for Bioethics held its Second Annual Lecture on the 11th May 2005.

Organs for Sale? - Regulation of a Market for Human Organ Donation.

Annual Public Lecture 2005

The Council invited eminent academics, Professor John Harris (University of Manchester) and Professor Paul Schotsmans (University of Leuven, Belgium) to present the second annual public lecture entitled "Organs for Sale? - Regulation of a Market for Human Organ Donation". The lecture, which took the form of a debate, was held on 11th May 2005 in the Royal College of Surgeons in Ireland. Mr Maurice Nelligan, former heart transplant surgeon, chaired the discussion.

Should a live organ donor programme be implemented in Ireland? More controversially should people receive financial incentives to donate their organs? These were the issues considered by the two speakers. There is currently a severe global shortage in the number of donor organs available for transplantation. While both speakers agreed that the problem should be addressed urgently, they proposed different solutions. Professor Harris spoke in favour of a regulated open commercial market in donor organs. He also supported a system where bodies of the dead should become public property so they can be used to make up for the growing shortage of transplant organs. Professor Schotsmans outlined the argument against commercialisation on the basis that it would denigrate the absolute value of the individual.

However, he advocated presumed consent, which has increased the rate of donation in countries where it is general practice.

The audience engaged in a vigorous debate of the issues and while questions were raised as to Ireland's readiness to embrace commercialisation or presumed consent, there was overwhelming consensus that dialogue and debate are essential.

Euthanasia Debate

The Irish Council for Bioethics organised a debate in conjunction with UCD's Medical and Literary and Historical (L&H) Societies. The motion of the debate, which took place on 20th October 2004, was "That this house would legalise euthanasia". The event, which was chaired by Professor Denis Cusack (Division of Legal Medicine, UCD) was a great success and was very well attended.

The Council and the UCD societies secured extremely high calibre speakers including proponents; Mr Rob Jonquiere (Right to Die, Netherlands); Mr Ludwig Minelli (Dignitas, Switzerland) and opponents; Professor William Binchy (TCD); Dr Regina McQuillan (St. Francis Hospice, Raheny); Dr John Scally (TCD); and Dr Eoin Tiernan (St. Vincent's University Hospital).

Following a robust discussion of the arguments for and against legalising euthanasia in Ireland, the motion was voted down by a significant majority.

Public Attitudes to Bioethics

In August 2005 the Irish Council for Bioethics undertook a nationwide survey to determine the level of understanding, awareness and interest in bioethics amongst the general public. TNS MRBI was commissioned to conduct the survey entitled "Public Attitudes Towards Bioethics". A number of bioethical issues were assessed in detail including: organ donation, stem cell research, patenting, IVF, forensic DNA databases and end of life issues.

The survey comprised structured, face-to-face questionnaire-based interviews with 500 adults aged 18 years and over. The sample was quota controlled in terms of gender within age and region with overall socio-economic controls also incorporated.

The survey provided an extremely valuable insight into the opinions and concerns of a cross-section of Irish society. It also highlighted which information sources would be best suited to engaging the different sections of society in the discussion of bioethical issues.

"Public Attitudes Towards Bioethics" showed that public interest, knowledge and opinion was greater in the more practical or commonplace areas of bioethics i.e. those more likely to impact people, or those with high media coverage, such as organ donation, the use of DNA in solving crime, prolonging the life of premature babies and end of life issues (e.g. euthanasia and assisted suicide). The challenge for the Council will be in educating the public in less well known areas such as patenting human life, biobanking, genetic selection and gene therapy.

Bioethics Teaching Project

"Bioethics for Beginners" was a teaching project undertaken by Dr Siobhán O'Sullivan (Scientific Director) and Mr Paul Ivory (Researcher) during September and October 2005 in a Dublin community school. The project was specifically targeted to transition year students and comprised five full-day visits to the school with approximately 30 students involved in each visit.

The teaching project was developed with multiple objectives in mind: to help the students see the relevance of biology and its associated technologies in their lives; to help them recognise the moral and ethical issues associated with advances and developments in biological and medical research; to stimulate their sense of responsibility as members of society and to encourage them to become more analytical through the use of case studies and discussion.

Each workshop consisted of an introduction to the subject of bioethics, providing some background information regarding the role and importance of bioethics in society today. The students reviewed and analysed six hypothetical case studies, each of which highlighted various bioethical issues, such as genetically modified crops, assisted suicide and genetic testing. The final session of the workshop involved a role-play situation. Students were divided into groups to act as research ethics committees to review research proposals.

On the basis of this initial pilot series and the overwhelmingly positive feedback received from students, the Council wishes to expand the bioethics teaching project nationwide. The project could be developed to incorporate a bioethics educational pack for schools and training days for teachers.

Presentations and Lectures

Since its establishment in 2002, the Irish Council for Bioethics has been active in teaching bioethics to third level students at both undergraduate and postgraduate level. It has also endeavoured to address stakeholders and other interested parties in relation to bioethical issues. This education

programme has proved extremely successful and has been well received. A chronology of this programme is given below.

Date	Institute	Speaker	Title
December 2005	St Vincent's Hospital, Fairview	Dr Siobhán O'Sullivan	Clinical Trials Directive: Implications for Research Ethics Committees
November 2005	Department of Legal Medicine, UCD	Dr Siobhán O'Sullivan	Medical Research Present and Future: Good Practice
July 2005	Beaumont Hospital	Ms Emily de Grae	Clinical Trials on Medicinal Products for Human Use
March 2005	Medico-Legal Society of Ireland	Dr Siobhán O'Sullivan	The Ethics of Stem Cell Research
December 2004	Faculty of Law, NUI Galway	Dr Siobhán O'Sullivan	Commercialisation of Human Tissue
May 2004	Dublin Institute of Technology	Dr Siobhán O'Sullivan	Research Ethics: Challenges and Dilemmas
May 2004	The Rotunda Hospital, Dublin	Dr Siobhán O'Sullivan	Human Biological Material: International Best Practice
March 2004	Irish Council for Bioethics, National Ethics Committee Meeting	Dr Siobhán O'Sullivan	Research Ethics Committees: Best International Practice
March 2004	UCD Women Graduates	Dr Siobhán O'Sullivan	Irish Council for Bioethics: What is Our Role
April 2004	Department of Biological Sciences, DIT	Dr Siobhán O'Sullivan	Principles of Ethical Research
March 2004	University College Cork, Public Lecture	Dr Siobhán O'Sullivan	Stem Cells, Past, Present and Future
March 2004	Faculty of Law, NUI Galway	Dr Siobhán O'Sullivan	National and International Bioethics Codes

March 2004	Department of Public Health	Dr Siobhán O'Sullivan	Ethics and Public Health
December 2003	Irish Council for Bioethics, Stem Cell Symposium	Dr Siobhán O'Sullivan	Introduction to Stem Cells
November 2003	The Academy of Medical Laboratory Sciences	Dr Siobhán O'Sullivan	Legal and Ethical Considerations in Designing Studies for Evidence Based Research
October 2003	National Institute for Cellular Biotechnology (NICB), DCU	Dr Siobhán O'Sullivan	Research Ethics Committees, What the Investigator Needs to Know
October 2003	Royal College of Surgeons in Ireland (RCSI)	Dr Siobhán O'Sullivan	Bioethics and Pharmacogenetics
August 2003	Irish Business and Employers Confederation (IBEC)	Dr Siobhán O'Sullivan	An Introduction to the Work of the Irish Council for Bioethics
May 2003	NUI Galway	Dr Siobhán O'Sullivan	Ethics Regulations and Implication for Researchers

Communciations and Media

Since its establishment in 2002, the Irish Council for Bioethics has been very active in promoting awareness and understanding of issues of bioethical importance amongst academia, industry and the general public through various media. A detailed chronology of this outreach work is given below.

Media Coverage T.V.

Date	Institute	Speaker	Title
November 2005	RTÉ 1, Six One News	Dr Siobhán O'Sullivan and Prof. Peter Whittaker	Launch of the ICB* report "GM Opinion Document"
June 2005	TV3 News	Dr Siobhán O'Sullivan	Launch of the ICB report "Human Biological Material"
June 2005	RTÉ 1, Nine o'clock News	Ms Emma O'Kelly	Launch of the ICB report "Human Biological Material"
May 2005	Ireland AM, TV 3	Dr Siobhán O'Sullivan	Stem Cell Research
May 2005	The Big Bite, RTÉ 1	Dr Siobhán O'Sullivan	Ageing
December 2003	Prime Time, RTÉ 1	Dr Siobhán O'Sullivan	Stem Cell Research
December 2003	RTÉ News	Dr Siobhán O'Sullivan	Special Report, Careers in Science
September 2003	Scope, RTÉ	Dr Siobhán O'Sullivan	Cloning
May 2003	One News, RTÉ	Mr Asim A. Sheikh BL	Stem Cell Research

*ICB = Irish Council for Bioethics

Media Coverage Radio

Date	Institute	Speaker	Title
December 2005	Quantum Leap, RTÉ 1	Dr Siobhán O'Sullivan	Preview of Ethical Issues in 2006
November 2005	Five Seven Live, RTÉ 1	Dr Siobhán O'Sullivan	Results of MRBI Poll on Public Attitudes to Bioethical Issues
October 2005	Quantum Leap, RTÉ 1	Dr Siobhán O'Sullivan	Stem Cell Research
May 2005	Today with Pat Kenny, RTÉ 1	Dr Siobhán O'Sullivan	Organs for Sale? - Regulation of a Market for Human Organ Donation (Promotion for 2nd Annual Public Lecture of ICB)
July 2004	The Right Hook, George Hook, Newstalk 106	Ms Emily de Grae	Designer Babies
June 2004	Summer Days with Tom McGuirk, RTÉ 1	Dr Siobhán O'Sullivan	Appointment of Chief Scientific Advisor
May 2004	BBC World Service	Dr Siobhán O'Sullivan	Funding of Stem Cell Research
November 2003	Today with Pat Kenny, RTÉ 1	Dr Siobhán O'Sullivan	Stem Cell Research
October 2003	The Right Hook, George Hook, Newstalk 106	Dr Siobhán O'Sullivan	Genetically Modified Foods
July 2003	Today with Pat Kenny, RTÉ 1 hosted by Leo Enright	Dr Siobhán O'Sullivan	Human Biological Material for Research

Media Coverage Print

Date	Institute	Speaker	Title
December 2005	Medico-Legal Journal of Ireland	Dr Siobhán O'Sullivan	Stem Cell Research: Science, Ethics and Regulation
December 2005	Metro	Prof. Peter Whittaker	Launch of ICB GM Opinion Document
November 2005	Irish Times	Dr Siobhán O'Sullivan	MRBI Poll on Public Attitudes to Bioethical Issues
September 2005	Irish Medical News	Dr Siobhán O'Sullivan	New system mooted to prevent "ethics shopping"
July 2005	Medico-Legal Journal of Ireland	Mr Paul Ivory	Organs for Sale? - Regulation of a Market for Human Organ Donation (Report on 2nd Annual Public Lecture of ICB)
June 2005	Irish Medical News	Mr Asim A. Sheikh BL	Launch of ICB report "Human Biological Material"
June 2005	Irish Examiner	Dr Siobhán O'Sullivan	Launch of ICB report "Human Biological Material"
June 2005	Irish Times	Dr Siobhán O'Sullivan	Launch of ICB report "Human Biological Material"
May 2005	Science Spin Magazine	Ms Emily de Grae	Forensic DNA databases: Ethical Issues
May 2005	Irish Times Health Supplement	Editorial	Organs for Sale? - Regulation of a Market for Human Organ Donation. 2nd Annual Lecture
January 2005	Irish Medical News	Ms Emily de Grae	Ethical Eye: Biomedical Research (Book Review)
October 2004	Irish Times Health Supplement	Dr Marie Murray	UCD Euthanasia Debate
June 2004	Medico-Legal Journal of Ireland	Ms Emily de Grae	The Common Thread: Society and the Human Genome (Report on Inaugural Public Lecture)
January 2004	Irish Times	Mr Dick Ahlstrom	"Hear the Nobel Laureate Who Mapped Human DNA" (Promotion for Inaugural Public Lecture)
August 2003	Irish Times	Prof. Peter Whittaker	Stem Cell Research
July 2003	Irish Times	Prof. Peter Whittaker	Gene Therapy
Summer 2003	Science Spin Magazine	Dr Siobhán O'Sullivan	Stem Cells Hope or Hype

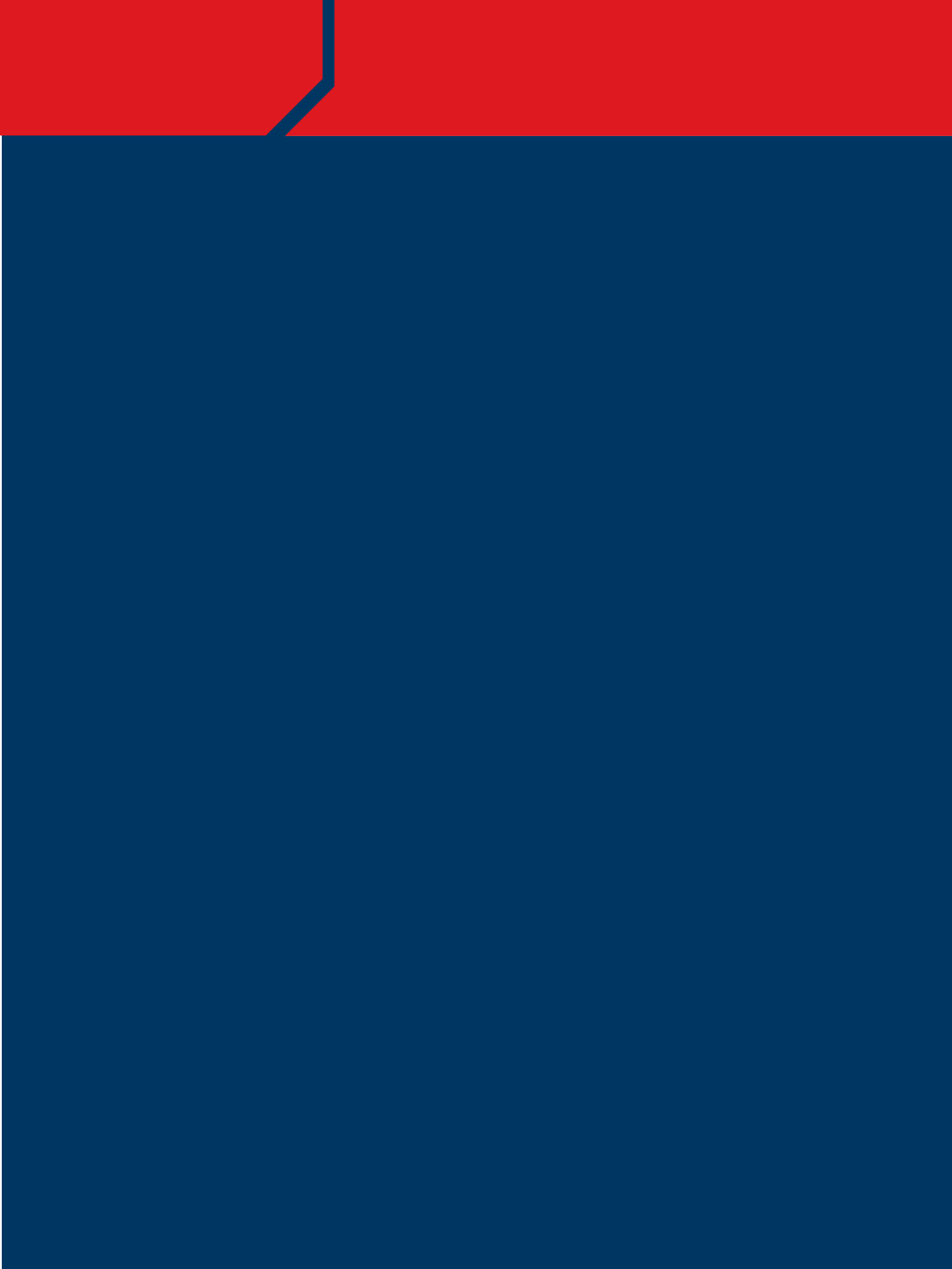
The Website

The Irish Council for Bioethics' website (www.bioethics.ie) was launched in 2003 and has proved to be an essential tool for the dissemination of information. The site provided information on public events, public consultations, and the Council's work programme and included a provision for downloading Council reports.

In 2004 the Council's website received 4,421 visitors; in 2005 the number of visitors to the site increased to 13,262. In order to ensure that the website remains a valuable resource for the public and academics, the Council is updating it to include international bioethics news, voting polls and a discussion forum. This updated website will go live in April 2006.

www.bioethics.ie







THE IRISH COUNCIL FOR

BIOETHICS

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