



United Nations
Educational, Scientific and
Cultural Organization

SHS/EST/ABC/REP/08

**UNESCO ASSISTING BIOETHICS COMMITTEES PROJECT
2007**

**MALAWI NATIONAL COMMISSION FOR UNESCO
REPORT ON MEETING ON PROPOSED NATIONAL BIOETHICS
COMMITTEE FOR MALAWI**

**18 JUNE 2007
LILONGWE
MALAWI**

1. INTRODUCTION

The meeting on the proposed bioethics committee was organized as a fact finding mission for the task force on the UNESCO Assisting Bioethics Committees project. The mission was organized after Malawi, through the National Commission for UNESCO, indicated in 2006 its willingness to join the project. The Commission then organized in February 2007 a meeting in preparation for the mission. At that meeting participants came up with a concerted view that there was need to strengthen the existing research ethics committees by establishing an advisory body on bioethics.

This meeting therefore, was a follow-up to the preparatory meeting and its objectives were:
To explain to the UNESCO mission what the situation is on the ground in the area of bioethics;
To explain to the UNESCO mission what recent efforts have and are being put in place in the promotion of bioethics; and
To learn from the UNESCO mission what form can a national bioethics committee take, given the situation on the ground in Malawi.

The meeting took place on 18 June at Cresta Crossroads Hotel in Lilongwe. It was attended by 13 people (see Appendix 1).

Chair of the meeting was Dr. Charles Mwansambo who is also the chair for the National Health Sciences Research Committee (NHRC).

2. MORNING SESSION

2.1 Introductory Remarks

Mr. Francis Mkandawire, the Executive Secretary for Malawi National Commission for UNESCO made introductory remarks on the meeting. Mr. Mkandawire thanked participants for sparing their time to come and attend this very important meeting. He said the meeting had been called so that players in the bioethics field would meet the experts on Bioethics whom UNESCO identified to help Malawi set-up or synergize ethics committees. He then gave an overview of UNESCO's interest and work in bioethics:

Progress in the life sciences is giving human beings new power to improve health and control the development processes of all living species. Concerns about the social, cultural, legal and ethical implications of such progress have led to one of the most significant debates of the century: bioethics.

The UNESCO Bioethics Programme was created in 1993. Bioethics belongs to ethics of science and technology, one of the five principal priorities of UNESCO. The first major success of the Bioethics Programme occurred in 1997, when the General Conference adopted the Universal Declaration on Human Rights, the only international instrument in the field of bioethics, which was endorsed by the United Nations General Assembly in 1998.

UNESCO's ethical watch mandate justifies itself day by day and is becoming increasingly necessary in light of recent scientific developments and their far-reaching implications for society. With its standard-setting work and unique multicultural and multidisciplinary intellectual forums, the Programme has confirmed UNESCO's leading role in bioethics at the international level.

The Bioethics Programme is part of UNESCO's Division of the Ethics of Science and Technology in the Social and Human Sciences Sector. It is primarily responsible for the Secretariat of two advisory bodies: the International Bioethics Committee (IBC), composed of 36 independent experts, and the Intergovernmental Bioethics Committee (IGBC), composed of representatives of 36 Member States. These Committees cooperate to produce advice, recommendations and proposals that each submits to the Director General for consideration by UNESCO's governing bodies.

The Programme develops four main action areas:

- Intellectual forum
- Standard-setting action
- Advisory role and capacity-building
- Education and awareness raising

2.1.1 Intellectual forum

The Programme provides an intellectual forum for multidisciplinary, pluralistic and multicultural reflection on bioethics, in particular through the IBC and the IGBC and by organizing and participating in conferences, symposiums, etc.

UNESCO intends in this way to foster both national and international debate on the major ethical issues arising from recent developments in the life sciences and their applications in order to work out ethical guidelines for the international community and Member States.

2.1.2 Standard-setting action

The Programme aims to define and promote a common ethical standard-setting framework that States can use in formulating and putting into practice their own policies in the field of bioethics. The Programme's first major success in this area was the adoption of the Universal Declaration on the Human Genome and Human Rights by the General Conference in 1997. Recently, the International declaration and a modality of its implementation, was adopted unanimously and by acclamation by the General Conference at its 32nd Session, on 16 October 2003.

2.1.3 Advisory role and capacity-building

The Programme acts as an adviser to Member States wishing to promote reflection and debate on bioethics, to set up national ethics committees and to define national standards and/or legislation in the field. The Programme also contributes to national and regional capacity building by facilitating the establishment of networks of institutions and specialists concerned with bioethics, and encourages the establishment or strengthening of regional bioethics information and documentation centres.

The Programme endeavours to identify ethical issues for specific regions in an effort to define and implement appropriate strategies for the promotion and development of ethical reflection in these areas.

2.1.4 Education and awareness raising

The Programme takes part in education and awareness raising of bioethics among specialists (researchers, jurists, journalists, etc.), decision-makers, the general public and specific target groups. At university level, the UNESCO Chairs in Bioethics facilitate regional cooperation

between universities and UNESCO in bioethics education. UNESCO also identifies universities that offer bioethics education in order to foster exchanges, in particular by connecting them with the Network of Institutions for Medical Ethics Education (NIMED).

Mr. Mkandawire concluded by saying that it was against this background that Malawi saw it fit to engage the Division of Bioethics at UNESCO to explore ways of synergizing its various efforts in the area of bioethics.

2.2 Opening Remarks

The second to make opening remarks was Mr. Alick K Manda, Chief Scientific Officer, National Research Council of Malawi made remarks to officially open the meeting. He extended welcome to the UNESCO mission and went on to say that UNESCO was like a mother on issues of research. He said however not much is known about UNESCO's programme on bioethics in Malawi and was looking forward to hear more on this from the mission delegates.

2.3 Introductory Remarks on Assisting Bioethics Committees (ABC) Project

Mr. Henk Ten Have, Chief of UNESCO Division of Ethics of Science and Technology explained why the UNESCO delegation was in Malawi. He said that Malawi had indicated interest to be included in the project on assisting bioethics committees that UNESCO had introduced to member states as a follow up to the adoption of Universal Declaration on Bioethics and Human Rights. He said that the Declaration encourages member states to establish bioethics committees. He said some countries especially in the west already have bioethics infrastructure in place. This is why UNESCO was asked to take the lead role by inclusion of developing countries to establish or strengthen these committees. UNESCO initiated three projects for this: the first project seeks to build six databases; the second project seeks to provide ethics education and the third project is the one titled "Assisting Bioethics Committees" (ABC) which seeks to assist bioethics committees in developing countries for two years. He also emphasized the importance of:

- identifying the best approach to starting a committee,
- training committee members in working methods and operational procedures, including legal issues;
- addressing the needs of particular committees and of creating a network of existing committees, so that they can get feedback from each other, exchange policy documents between each other and establish partnerships.

He informed participants that the project has targeted two groups of countries, one from English speaking countries and the other from French speaking countries. The seven French speaking countries are Togo, Vietnam, Gabon, Madagascar, Senegal, Mali and Benin. Of these Togo has inaugurated its bioethics committee. Malawi is one of six countries in English speaking countries that have joined the "Assisting Bioethics Committees" (ABC) project. The other countries are Ghana, Jamaica, Kenya, South Africa and Swaziland. Of these Ghana will inaugurate its committee this year.

2.4 Presentation on National Research Council of Malawi

The presentation was made by Mr. Alick Manda. He gave an account of the mandate of the council secretariat, its affiliated technical committees, the council's functions and programmes.

2.4.1 Mandate

The council was established in 1974. It does not do research itself. It has a Governing Council which is chaired by Office of the President and Cabinet. Its membership is drawn from academia, parastatals and the private sector. The council secretariat is headed by a director and below him are technical committees in relevant areas including agricultural science, research projects, national health sciences, science competition, genetic resources and biotechnology, legal and patenting.

2.4.2 Functions

Functions of the council include:

- promoting and coordinating research,
- developing and implementing programmes for research
- promoting applications of research results and
- strengthening national and international collaboration

2.4.3 Programmes

Some of the programmes that the council is running are:

- Research Grant scheme- for awarding of research grants to local researchers;
- Water research fund for Southern Africa
- National Biotechnology programme
- Secondary School Science Competition
- TWAS Prize for Young Scientists in Malawi
- Mainstreaming HIV and AIDS
- Malawi sustainable development network programme

2.4.4 Publications

The National Research Council of Malawi has and continues to develop several publications including:

- Directory of research projects in Malawi

2.4.5 Challenges

Mr. Manda also cited some of the problems affecting the council:

- Limited funding
- Limited human resources
- Lack of monitoring and evaluation of projects funded or approved by the council

2.5 Presentation on National Health Sciences Research Ethics Committee

This presentation was made by the chair of the meeting who was also the chair for the committee Dr. Charles Mwansambo. The presentation gave an account of the history, mandate of the committee and the challenges it was facing.

2.5.1 Historical background

The committee began as a unit established in 1988 in the Ministry of Health. In September 1993 following the resolution by the Governing Council the National Health Sciences Research Committee was officially established as one of the technical committees of the National Research Council of Malawi. It is serviced by the Research Unit in the Ministry. In April 1997 the National Health Services Research Committee delegated some of its powers to the College of Medicine Research and Ethics Committee (COMREC).

2.5.2 Mandate

The National Health Sciences Research Committee has the responsibility of reviewing and approving all health related research proposals in Malawi. Research proposals from faculty members and students of the College of Medicine and Kamuzu College of Nursing are reviewed and approved by the COMREC with exception of all research proposals of national interest.

2.5.3 Functions

According to its constitution the functions of the NHSRC are to:

- 1) advise the Ministry on all scientific and ethical aspects of research matters pertaining to the Health Sciences
- 2) review and approve all research proposals with health science content from prospective researchers whatever their discipline. *However research from the College Of Medicine and Kamuzu College of Nursing and their collaborators shall be reviewed by COMREC and shall be referred to the NHSRC only if national interests are at stake.*
- 3) offer guidance in relation to each research proposal, on the balance between the use of laboratories and expertise outside the country, and the import of techniques and equipment (including personnel) into the country. All research specimens and materials shall not be exported without permission from the NHSRC.
- 4) review and clear on behalf of the Ministry all materials intended for publication within and outside Malawi except where these have already been cleared by an authorized committee such as College of Medicine Research Committee.
- 5) encourage and make recommendations to the Ministry contacts among research scientists of varying capabilities and or/about attachments to advanced research centers, within and outside Malawi, for the purpose of upgrading the available research manpower and skills.

2.5.4 Goal

The goal of the NHSRC is therefore:

- To ensure that research with human subjects is conducted in ways that minimize risk of harm to subjects and balances the risks with anticipated benefits

2.5.5 Membership

The membership of the NHSRC consists of:

- National Research Council
- Ministry Of Health: Headquarters, Central Hospitals, CHSU
- Christian Health Association of Malawi
- National AIDS Commission
- CSR

- NMCM
- Research Institutions
- Community Representatives

2.5.6 Meetings

The Committee meets for business at least six times per fiscal year, with additional meetings held at the Chairman's discretion. Decisions at the meetings are made by consensus.

2.5.7 Research Fees

The NHSRC charges 10% of the budget of any proposed research work as stated in the proposal by the researcher payable to the NHSRC. This is to support the designated research collaborating/ affiliating institution as overhead expenditure, and also to support the Secretariat in its functions.

2.5.8 Challenges

The NHSRC faces a number of challenges including:

- Low staffing levels in the secretariat
- Underfunding - as allocated by the Ministry of Health
- Reluctance of some scientists to contribute to the development of research capacity in Malawi
- A number of international guidelines to abide by: Declaration of Helsinki; CIOMS (The Committee for International Relations of Medical Sciences); Nuremberg
- Research investigators are NOT aware (or pretending not to be aware) of the ethical, legal and regulatory requirements of conducting research in Malawi.
- Exportation of biological specimens for analysis abroad that could potentially be done locally if there was the will to invest
- Unauthorised research.

2.5.9 Discussions

At the end of each presentation there was discussion which took the form of a question and answer session.

Asked what the NHSRC's workload was like, Dr. Mwasambo explained that it was quite huge and difficult especially considering that the committee is not compensated. Asked further what the proportion of local to international research applications was he said that 75% of applications were from international researchers. However, international researchers are required to have national collaborators.

2.6 The Role of the Centre for Bioethics in Eastern and Southern Africa (CEBESA)

Mr. Mike Kachedwa, Fellow in Bioethics at Malawi College of Medicine made this presentation to highlight the various activities of CEBESA in the area of Bioethics, including, Teaching of Bioethics, Research being conducted in the area of Bioethics and other related activities.

2.6.1 The history of the Centre for Bioethics

The Centre for Bioethics in Eastern and Southern Africa is based at the College of Medicine. The College of Medicine was opened in 1991. The College Research and Ethics Committee (COMREC) was formed in 1996 to review, approve and monitor research. The COMREC created the position of Bioethicist in April 2001 in response to growing demand for training and competence in the area of Bioethics

Consequently, a Bioethicist was hired and entrusted with the task of laying groundwork for the establishment of a full-fledged Bioethics Research Unit in the department of Community health. On 28th May 2001, the Malawi Bioethics Research Unit (MABIRU) was founded. MABIRU was renamed Centre for Bioethics in Eastern and Southern Africa with effect from 30 May 2006 in order to reflect the regional nature of its new activities which now included a Fogarty funded programme for training in Research Ethics.

2.6.2 Activities of CEBESA

CEBESA falls under the Department of Community Health at College of Medicine and is mainly involved in the following activities:

- Teaching of Bioethics to all undergraduate students in all programmes in COM
- Teaching of Bioethics to Postgraduate students in the MPH programme
- Training Fogarty Fellows from Eastern and Southern Africa in International Research Ethics as part of the University of Malawi College of Medicine and Michigan State University Fogarty Training Programme
- Providing training to ethics committee members and researchers on Research Ethics, Clinical Trial monitoring and Good Clinical Practice.
- Conducting research on various topics in the area of Bioethics.
- Advising various stakeholders including Government, Research Ethics Committees (RECs), hospitals, researchers, health practitioners, students, members of the public and others on issues related to Bioethics, Research Ethics and Good Clinical Practice (GCP)

2.6.4 Vision of CEBESA

CEBESA wishes to be a centre of excellence in Bioethics in Africa and to do this it seeks:

- To offer relevant bioethics training at both undergraduate and post graduate levels
- To provide internet based research ethics & IRB distance learning for Malawi and Africa
- To train, promote and conduct research in Bioethics in Africa
- To promote bioethics publication in Malawi and Africa.
- To coordinate cross border research collaboration in the area of Bioethics.

2.6.5 Centre for Bioethics Staff

Mr. Kachedwa informed participants that currently the center has the following staff:

- **PROF Joseph Mfutso Bengo PhD**
Professor of Bioethics and Director of CEBESA
- **Paul Ndebele PhD candidate Uni. Of KwaZulu Natal, MSc, BSc**
Deputy Director of the Bioethics Unit as well as an Honorary Lecturer
- **Matilda Mkunthi, PhD Candidate Keele Uni, MA**
Graduate research Officer
- **Francis Masiye B.A. Phil. Hons**
Research Officer
- **Vincent Jumbe, B.A. Hons**
Research Officer

- **Fellows**
 - Veronica Maluwa
 - Mike Kachedwa
 - Rose Mwangi
 - Edward Chigwedere

2.6.6 Major Achievements in the Area of Bioethics

Mr. Kachedwa summarised the achievements of the centre as follows:

- A biomedical ethics curriculum was developed for undergraduates.
- College of Medicine is one of the few medical School in Africa to introduce a compulsory Biomedical Ethics curriculum which covers all five years of training
- There are 12 several Bioethics modules which are taught as electives in the Master of Public Health programme.
- Several Publications in local and international medical journals on bioethics
- Promotion of Bioethics research among medical students
- Won several grants in the area of Bioethics
- Staff have been involved in several international, regional and national workshops, conferences and other initiatives aimed at promoting Bioethics.

2.6.7 Teaching of Bioethics at Undergraduate Level

Bioethics is taught to all undergraduate students from Year 1 to Year 5 as follows:

- **Year 1 Aim:** To provide a basic introduction to the subject of Bioethics and a critical appreciation of the various Bioethics theories and principles.
- **Year 2 Aim :** To provide some skills for addressing moral dilemmas in science and medicine using the Bioethical principles.
- **Year 3 Aim :**To provide an understanding of the basic principles of health law as well as an appreciation of the various pieces of medical laws and professional ethics.
- **Year 4 Aim :** To introduces students to ethical issues that arise in the conduct of research with human beings.
- **Year 5 Aim:** To prepare students for practice by looking at various issues such as current or proposed policies or pieces of legislation and current health problems.

2.6.8 Teaching methods

Bioethics is taught at COM through:

- lectures,
- group discussions,
- case analysis
- case development,
- debates,
- film and video presentations,
- directed reading and research,
- direct observation,
- review and other relevant methods.

2.6.9 Teaching of Bioethics at Postgraduate Level

CEBESA currently involved in the teaching of 12 modules in Masters in Public Health (MPH). Modules are open to occasional students and even professionals involved in relevant

areas such as research or as members of ethics committees. The postgraduate modules are aimed at equipping participants with some detailed understanding of ethical issues as well as some skills for addressing dilemmas. Some of the modules taught are:

- Bioethics theories, principles, guidelines and African Bioethics
- Research Ethics and Integrity
- Ethical review of health research and IRB Management
- International Research Ethics
- Informed consent and research with vulnerable populations
- Public Health Law
- Special and current topics in Bioethics
- Health, Ethics and Human rights
- Good clinical practice (GCP)
- Clinical Trial Monitoring

2.6.10 Fogarty International Research Ethics Training Programme for Eastern & Southern Africa

This programme is run jointly by University of Malawi College of Medicine and Michigan State University (MSU). The goal of the 15-month program is to enable individuals with outstanding research or scholarly potential to develop a sustainable research and teaching program in the field of international research ethics. Students spend 4 months at MSU and 11 Months at College of Medicine. Students receive an Advanced Certificate in Research Ethics or MPH with specialty in Bioethics.

2.6.11 MPH Degree with Specialty in Bioethics

The College of Medicine offers a Master of Public Health degree with specialty in Bioethics. The programme was specifically initiated as a part of the University of Malawi / Michigan State University Fogarty Training Programme. Students are required to complete all the six (6) Core courses of the MPH Programme that is being offered in the Division of Community Health within the College of Medicine plus (6) Bioethics module credits as part of the 16 elective modules and dissertation in the area of Bioethics.

2.6.12 Research

The Centre for Bioethics is currently conducting a study titled Anthropological and Bioethics study of Clinical Research in Malawi. The study was made possible through a grant awarded by Wellcome Trust. The project is being conducted in three phases over three years (2004-7):

- **Phase 1:** Anthropological and Cultural Study (complete)
- **Phase 2:** Bioethics Sub-Study of Clinical Research (Complete)
- **Phase 3:** Applied and Comparative Ethics

2.6.13 Grants

The center has received grants from a variety of partners. These include the following:

- 2004-2008 Fogarty Research Ethics Training Grant worth US\$740,000
- 2004-2007 Wellcome Trust Bio-Ethics Research Grant of £140,000 UK Pounds
- 2007-2009 EDCTP Building and Strengthening National Capacities in Ethical Review and Clinical Trial Monitoring in Malawi worth €98,123.00
- 2007-2008 EDCTP strengthening of Ethics Committees in Malawi worth €50,000

2.6.14 Publications

The centre has produced more than 40 publications in the area of Bioethics as well as several books and book chapters focus on issues of relevance to Africa as a way of contributing to the limited African literature.

2.7. Proposal for strengthening Bioethics in Malawi

This proposal which was presented by Mr. Mike Kachedwa covers several components including; establishment of National Bioethics Advisory Committee, promoting discussion of topics in the area of Bioethics through Seminars and debates, establishment of a UNESCO Bioethics Chair, holding of a National stakeholders meeting and support for Research in Bioethics

The background to the proposal is that;

- Currently no National Bioethics Committee
- Most bioethics activities are based in the College of Medicine
- Current focus is on research Ethics and Medical Ethics
- There is no body to look at the ethics of science in its broad sense

The proposal therefore, proposes support to initiate various activities aimed at strengthening Bioethics in Malawi.

The proposed National Bioethics Advisory Committee is to be housed in National Research Council of Malawi (NRCM). It will be made up of representatives from:

Government departments:

- Industry and Commerce, Science and Technology, Education, Health, Environment
- NGOs
- Research Ethics Committees
- Religious groups
- University of Malawi
- And others

The proposal details the requirements for setting up the Bioethics Advisory Committee:

- Secretarial support (including fulltime coordinator and secretary)
- Budget to cover
 - Meeting costs
 - Travel and allowances for members
 - 1 Vehicle, fuel and maintenance
 - Setup office and office equipment
 - Stationery
 - Publication of reports
 - Communication and postage

The proposal envisages a National stakeholders meeting

- To include all interested stakeholders in Malawi
- To discuss the new developments
- To nominate members etc

It further envisages the organization of seminars and debates for the promotion of discussions in the area of Bioethics. The seminars would be held in Colleges, Universities and Schools while the debates would be on radio and Television.

The proposed UNESCO Bioethics Chair is to be based in the College of Medicine within the Centre for Bioethics. It is to be a member of National Bioethics Advisory Committee

The proposal further invites support in Research in Bioethics through small grants to undergraduate and postgraduate students in all universities. The grants will be extended to researchers to look into selected topic (s).

2.7.1 Discussions

Mr. Ten Have commented that it was interesting to have an African perspective on bioethics as CEBESA was thinking. He then asked what three challenges would need to be addressed if Malawi were to set-up a National Bioethics Committee.

Mr. Kachedwa responded that the first challenge would be issues of consent by the participant in the case of research on human subjects. The second challenge according to him would be removal of vulnerability, again, of human subjects. The third would be how to disentangle the therapeutic from the non-therapeutic issues of health research.

Mr. Kachedwa further said that the NBC would have to have a distinctly different mandate to the already existing committees.

Responding to the question whether CEBESA provides forum for public debate and whether there is another body that deals with this Mr. Kachedwa said that CEBESA had been planning to organize in the near future public debates on specific ethical topics funds permitting.

Asked how relevant CEBESA's advice had been to the NHSRC, Mr. Kachedwa said that NHSRC's response had been positive and he gave the example of the advice that CEBESA gave to the NHSRC concerning standardization of the memoranda of understanding between foreign based researchers and local collaborators which had been approved.

Dr. Vasantha brought up the issue concerning the separation of animal research and other scientific research ethics. She explained that animal health ethics is particularly interested in the protection of animals. After some discussions it was apparent that members generally agreed that the ultimate goal of any health science research is to protect humans.

Dr. Mwasambo explained that there was a proposal to separate purely ethical issues from a biasness towards science. He said however, the stakeholders who met on this issue agreed to maintain the status quo until the appropriate time. The stakeholders had agreed in principle of the need for this separation but noted that the volume of research taking place did not warrant the separation at the time.

Dr. Kutyla emphasized that it was now time to separate ethics from science issues.

3. AFTERNOON SESSION

3.1 ABC Project and Way Forward

The afternoon session started with Mr. Henk Ten Have drawing conclusions from the morning session, suggesting the way forward and giving further information on the ABC project:

1. It was clear for the various presentations that already there were experts on bioethics on the ground compared to other countries participating in the ABC project.
2. There was a general agreement among participants of the need of a Bioethics committee. A NBC would therefore combine the expertise in science and bioethics because the UNESCO idea of a NBC is not to remove the structures already existing. However a NBC can go beyond the expertise on science and health. One of the functions of a NBC is to advise government on what needs to be done and legislations required.
3. There was a general agreement among participants of the need for a broader perspective on bioethics than health research. Therefore, the other function of a NBC is to involve the public in bioethics debate for awareness of their rights.
4. UNESCO has a small purse which can only suffice as seed money which can be used to generate more funds through extra-budgetary sources. UNESCO's main role is to motivate, instigate and initiate. Hence, in addition to the seed money UNESCO can also facilitate the following:

- Training on how to run a NBC
- Provision of documentation to NBCs
- Opportunity for the NBC members to network with similar
- Twining of NBCs
- Training of students in bioethics in other countries

3.2 Presentation on Bioethics Committees in the United Kingdom

Mr. Harald Schmidt, Assistant Director Nuffield Council on Bioethics, United Kingdom made this presentation in which he identified 6 categories of ethics bodies in the UK.

3.2.1 Independent advisory committees

3.2.1.1 Nuffield Council on Bioethics

Established in 1991 the Nuffield Council on Bioethics is an independent body that examines ethical questions raised by advances in biology and medicine. It contributes to policy making and stimulates debate. It is funded by the Nuffield Foundation, the Medical Research Council and the Wellcome Trust.

i. Terms of Reference

The Council's terms of reference are:

- 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
- 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

- In the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate



ii. Membership

The Council has around 16-18 members, each with a relevant field of expertise, including science, medicine, philosophy and law. It appoints its own members independently. Vacancies are advertised openly, Membership Panel makes recommendations about applicants to the Council. Members receive no remuneration. The Council meets 4 times per year in private.

iii. Outputs

A Working Party of the Council consisting of 10-14 members examines a particular topic and produces a report after every 10 meetings over 18 months-2 years. A short guide accompanies each report – to make more accessible to a wider audience. Recent topics include: research involving animals, critical care decisions in fetal and neonatal medicine, genetics and human behaviour, public health, forensic use of bio-information, health-related research in developing countries. Reaching Out to Young People subgroup, is involved in educational projects

3.2.1.2 Scottish Council on Human Bioethics

Established in 1997 the Scottish Council on Human Bioethics is an independent charitable organisation, funded by individual supporters. Its mandate is to:

- Collect and evaluate evidence and information relating to ethical issues to inform public debate.
- Engage and advise legislators, professionals and others.
- Respond to media interest
- Encourage Scottish society to engage in ethical discussion of topics in medicine and biology

The Council's directors include doctors, lawyers, psychologists, ethicists and other professionals

3.2.2 Governmental Advisory Committees

3.2.2.1 Human Genetics Commission (HGC)

Established in 1999 the HGC is a non-statutory governmental body created as part of the regulatory and advisory framework for human genetics. It supports the needs of the Government in this area.

i. Terms of reference

The HGC's terms of reference include:

- To analyse current and potential developments in human genetics and advise ministers on:
 - impact on human health and healthcare
 - social, ethical, legal and economic implications
- To advise on strategic priorities such as genetic services and research
- To consult public and stakeholders and encourage debate
- To advise on the effectiveness of existing guidance
- To consider specific issues as requested by ministers

ii. Membership

The HGC's 18 members consist of experts in clinical and research genetics, consumer affairs, ethics, law, media, primary care, those with experience in genetic conditions and lay members. Members are appointed on merit by the National Health Services Appointments Commission following open call for applications. Representatives of the four UK Chief Medical Officers also participate with observer status

The main meetings of the Council are held in public 4 times per year while working groups meet separately. During the meetings members are paid £150 per day plus expenses.

iii. Outputs

The HGC has produced various publications, including four major reports, newsletters and policy documents. Topics covered in these publications include reproductive technologies and genetic profiling of the newborn

The HGC has organised public involvement activities including: consultations, open meetings, citizens' jury and consultative panel events

3.2.2.3 Agriculture and Environment Biotechnology Commission (AEBC)

Established June 2000, the AEBC ceased operation in April 2005, due to internal wrangles.

The Commission had held 5 main meetings per year in public. Its main function was to provide the UK Government and devolved administrations with advice on developments in biotechnology and their implications for agriculture and the environment. Its membership included experts in consumer affairs, farmers, academics and lawyers. The AEBC produced reports on GM crops, animals and biotechnology.

3.2.2.4 Advisory Committee on Releases to the Environment (ACRE)

Established in 1993, the ACRE is a statutory advisory committee appointed under section 124 of the Environmental Protection Act 1990

3.2.2.6 Terms of reference

The ACRE's terms of reference include:

- Advising ministers of the UK Government and devolved administrations of Scotland, Wales and Northern Ireland, the Health and Safety Commission/Executive and other bodies as appropriate on:

- whether consent to release or market GMOs should be issued and any conditions which should be attached to consents
- the limitations and conditions of consents issued to release or market GMOs, this covers post-release monitoring and provision to make amendments to consents
- fees and charges relating to the cost of issuing consents and in respect of maintaining inspection and enforcement regimes
- the making of regulations under Part VI of the EPA 1990 and the deliberate release directive
- the evaluation of new GM research findings
- any science-based GM matter
- research needs in the area of risk assessment of GMOs
- releases into the environment of non-indigenous animals and plants

i. Membership

ACRE membership consists of various areas of expertise, including ecology, molecular biology, plant biology, and farming and agriculture. Currently it has 14 members. It holds 6-8 meetings per year in private plus some open meetings to gather evidence. All appointments are made by the Secretary of State for Environment, Food and Rural Affairs (Defra), in conjunction with Ministers in the Devolved Administrations. Appointments are on basis of technical and scientific expertise. They do not represent any particular stakeholder interests such as the biotechnology industry or environmental pressure groups. Members are paid during the meeting remuneration of £162 per day.

ii. Outputs

The ACRE publishes Annual Reports, advice to Ministers, and some other background materials including:

- “Managing the Footprint of Agriculture: Towards a Comparative Assessment of Risks and Benefits for Novel Agricultural Systems”
- “Gene Flow from Genetically Modified Crops - Background Paper”

3.2.3 Regulatory authorities

3.2.3.1 Human Tissue Authority (HTA)

Established in 2005 the HTA is a statutory body - set up under the Human Tissue Act (2004), which covers England, Wales and Northern Ireland while in Scotland – the Human Tissue (Scotland) Act 2006. The HTA performs certain tasks on behalf of the Scottish Executive (approval of living donation and licensing of establishments for storing tissue for human application). Therefore, the HTA is an executive non-departmental public body accountable to the Department of Health.

“The HTA’s strategic aim is to create a regulatory system for the removal, storage use and disposal of human tissue and organs that is clear, consistent and proportionate and in which professionals, patients, families and members of the public have confidence.”

i. Membership

The HTA has a Chair and 16 members with variety of medical, scientific, legal, administrative and political backgrounds. The Chair and 6 members have no past professional interest in the area of human tissue. 8 members are professionals drawn from groups most

directly affected by the HT Act. Welsh Assembly Government and the Northern Ireland Office each nominate one member. Members are appointed by the Secretary of State for Health (via the Offices of the Commissioner for Public Appointments) by open competition. The HTA holds 4 meetings per year in private and 1 annual public meeting. Remuneration of members is agreed with the Secretary of State for Health (this was £0-5000 per annum in 2005/6). The Chair receives increased remuneration.

ii. Outputs

The HTA has issued Codes of Practice and other practical advice about the Human Tissue Act to ensure best practice is adhered to in this sector.

The HTA has also provided advice and information to the Secretary of State for Health and the public about relevant issues.

3.2.3.2 Human Fertilisation and Embryology Authority (HFEA)

Established in 1991 the HFEA is a statutory body set up under the Human Fertilisation and Embryology Act (1990). It is a non-departmental Government body, accountable to the Department of Health. It has an Ethics and Law Committee. There are plans to merge HFEA and the HTA into the Regulatory Authority for Tissues and Embryos (RATE) by 2009. The HFEA holds 9 meetings per year in private, plus 1 annual public meeting. It also holds other public events.

i. Terms of Reference

The terms of reference for HFEA include:

- Licensing and monitoring all clinics or centres carrying out fertility treatment such as IVF, donor insemination and human embryo research to ensure that the principles of the HFE Act are upheld
- Regulating the storage of sperm, eggs and embryos

ii. Membership

The HFEA has 18 members with a range of expertise, including medicine, law, religion, philosophy and those involved with infertility interest groups. The Chair, Deputy Chair and at least half of the HFEA members are neither doctors nor scientists involved in human embryo research or providing infertility treatment. Members are appointed by UK Health Ministers in accordance with the guidance from the Commissioner for Public Appointments (the 'Nolan' Guidelines). Members get a remuneration of £176 as daily allowance as of 2005. Joint chair of both HTA and HFEA - remuneration £60,000 per annum (3 days per week).

iii. Outputs

The HFEA expects to:

- Produce information materials for patients, donors and clinics about fertility treatments and the issues they raise.
- Create, update and enforce a Code of Practice which gives clear operational guidelines to fertility clinics.
- Keep a register of patients and the result of treatments they received, the details of any donor involved and the children who are born.
- Publish facts and figures on infertility and fertility treatments

3.2.3.3 HFEA Ethics and Law Committee

The HFEA Ethic and Law Committee is a subcommittee of the Authority which comprises Authority members and co-opted members. The Committee Considers the ethical, social and legal aspects of the Authority's work. At any time it has at least 5 members. However, currently the Committee has 11 members who 4-5 meetings per year in private.

3.2.4 Research ethics: humans

3.2.4.1 National Research Ethics Service (NRES)

The NRES superseded the Central Office for Research Ethics Committees (COREC) in April 2007. Head Office of NHS REC is in England; a directorate within the National Patient Safety Agency (a Special Health Authority). It works with similar committees in Scotland, Wales, Northern Ireland. The exact arrangements in this working relationship are under review.

i. Functions

The functions of the NRES Head Office are:

- To coordinate the development of operational systems for RECs
- To advise the Department of Health on operation of the NRES in England
- To train REC members in England
- To liaise with colleagues in NI, Scotland and Wales
- To develop, implement and maintain operating procedures and standards for RECs that will be consistent across the UK
- To provide advice to the Department of Health on transposing the European Clinical Trials Directive in the UK

ii. NRES Head Office Membership

The Head Office of NRES has 18 advisers on strategy, ethics, quality assurance, policy, training and corporate affairs

3.2.5 Research ethics: animals

3.2.5.1 Animal Procedures Committee (APC)

The APC is an advisory, non-departmental public body. It advises the Secretary of State on matters concerned with Animals (Scientific Procedures) Act 1986. It gives regard both to legitimate requirements of science and industry and to the protection of animals. It also reviews certain applications for 'substantial' procedures and primate use. The PAC reports annually to the Secretary of State and Parliament.

i. Membership

Membership rules are determined under the Animals (Scientific Procedures) Act 1986. The Act provides that the APC must have 12 or more members plus the Chairman. Two thirds or more of members must be medical practitioners/veterinary surgeons, or qualified in a relevant biological subject. One member must be barrister, solicitor or advocate. Half or more of the

members must not have held a licence under the Act during the previous 6 years. Interests of animal welfare should be represented. Membership usually includes an academic philosopher. Duration of membership is four years with one re-appointment. The Chairman is remunerated while members are paid expenses only. The Committee holds five to six meetings per year in private.

ii. Output

The APC aims to offer independent, expert and balanced advice to the Home Secretary. It reviews all applications for licences involving:

- use of wild-caught primates
- use of cats, dogs, horses or primates in procedures of ‘substantial’ severity
- ‘substantial’ severity involving (a) xenotransplantation of whole organs or (b) chronic pain models or (c) study of the central nervous system
- applications of any kind raising novel or contentious issues, or giving rise to serious societal concerns

APC produces advisory reports on aspects of animal welfare and experimentation

3.2.6 Other committees

3.2.6.1 British Medical Association Medical Ethics Committee (BMA)

This is a health professionals association committee (HPA) which debates issues of principle in medical ethics, medical law and ethical matters concerning the relationship between the medical profession, the public and the state. It has 18 members consisting of doctors, philosophers, lawyers, theologians and lay people. The committee meets four times per year in private. The BMA receives funds from members (doctors).

3.2.6.2 Genetics and Insurance Committee (GAIC)

This is a non-statutory advisory non-departmental public body with UK-wide remit. It is financially sponsored by Department of Health. It has eight members of various expertises. It meets three to four times per year in private and occasionally holds public meetings.

i. Terms of Reference

The terms of reference of GAIC are:

- to evaluate genetic tests and their relevance to insurance
- to report to Health, Treasury, and Department of Trade and Industry Ministers on proposals from insurers and compliance by the industry with GAIC recommendations
- to provide independent oversight of how insurers are using genetic tests

3.2.6.3 Gene Therapy Advisory Committee (GTAC)

GTAC is a UK research ethics committee for clinical research involving gene therapy. It has 18 members consisting of lawyers, researchers, patient advocates and medical ethicists. It meets three to four times per year in private and occasionally holds public meetings. GTAC is sponsored financially by the Department of Health.

i. Terms of Reference

The functions of GTAC are:

- to consider and advise on the acceptability of proposals for gene therapy research on human subjects, on ethical grounds, taking account of the scientific merits of the proposals and the potential benefits and risks
- to provide advice to United Kingdom Health Ministers on developments in gene therapy research and their implications

3.3 The Situation of Bioethics in India

Dr. Vasantha made a quick and brief summary of the situation in India:

- India is a vast country
- A lot of research is going on in India and it is not easy to regulate it
- India has animal research policy and animal research committee in place
- The Medical Council of India regulates all medical research
- Academic trials in India are not regulated
- India has a Biosafety Committee
- A Biomedical Protection Bill will be passed soon
- Independent ethics committees are just starting to come up now
- The National Bioethics Committee was formed under the Department of Biotechnology

4. THE WAY FORWARD

After some discussions participants agreed on the following as the way forward:

1. The National Research Council will prepare draft terms of reference for a National Bioethics Committee as well as draft constitution. The UNESCO mission provided the steps on how to establish a national bioethics committee (Appendix 4) a sample of the draft constitution (Appendix 3)
2. The National Research Council will then marry the terms of reference with the proposal for establishment of the National Bioethics Advisory Committee prepared by CEBESA
3. The National Research Council in collaboration with the National Commission for UNESCO organize a consultation forum where all stakeholders will be involved to discuss the consolidated proposal for the National Advisory Committee
4. The National Commission for UNESCO will then inform UNESCO of the consensus reached at the consultation meeting.

5. CLOSING REMARKS

Mr. Henk Ten Have thanked participants for the interest they showed in the ABC project. He then urged them to follow through the agreed process to realize the goal of establishing the NBC. He said Malawi must come up with a structure that is most suited to its situation and then inform UNESCO about the decision.

Mr. Manda made the closing remarks in which he pointed out that there was a consensus among participants on the need for a National Bioethics Committee and that the next step would be to develop the terms of reference and the constitution. After this a wide consultation will be organized through the National Commission for UNESCO. Mr. Manda thanked

UNESCO for the ABC project initiative. He then thanked participants for attending the meeting in spite of their busy schedules.

APPENDICES

APPENDIX 1 PROGRAMME OF MEETING ON THE STRENGTHENING OF BIOETHICS COMMITTEE IN MALAWI – 18 JUNE 2007, LILONGWE

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APPENDIX 2: ABC PROJECT OUTLINE

ABC PROJECT “ASSISTING BIOETHICS COMMITTEES”

10 October 2006

OVERALL OBJECTIVE: Fully operational and adequately functioning national bioethics committees in 12 Member States

I. Introduction

The need to reflect on the moral dimension of advances in science and technology, as well as the desire to enhance the public's health has, in many areas of the world, led to the establishment of various forms of Bioethics Committees. For example the French *Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé* (CCNE) and the United States President's Council on Bioethics serve as platforms for providing guidance and advice to policy makers and governments in their States at the national level. Establishing bioethics committees may thus be a first step for States to create platforms and bodies for ethical debate, analysis and policy development.

Within the Programme and Budget for 2006-2007 (33 C/5), support to the establishment of ethics and bioethics committees at all levels (national, regional, local) as well as assistance to existing committees are essential elements of the **capacity-building action** of UNESCO in the field of bioethics. Moreover, national bioethics committees can be an effective platform from which to implement UNESCO's Declarations in bioethics – the Universal Declaration on the Human Genome and Human Rights (1997), the International Declaration on Human Genetic Data (2003) and the recently adopted Universal Declaration on Bioethics and Human Rights (2005).

II. Description

The Project ABC “Assisting Bioethics Committee” is a three years project aiming at reinforcing the bioethics infrastructure in 12 Member States through the establishment of national bioethics committees, and, once they are established, through the enhancement of the functioning of committees.

Exchange of experience, facilities, resources and expertise at international level can be helpful in creating a more extensive and stable bioethics infrastructure in Member States. At the same time, the establishment and functioning of bioethics committees need to be closely adapted to the needs of a country taking into account the culture, history and traditions of this country.

The project consists in the setting-up of two taskforces of experts – one English-speaking and one French-speaking – with practical experience in ethics committees from 12 countries. They will assist 6 English-speaking and 6 French-speaking Member States in need of bioethics committees at national level.

The project will follow three phases:

- (1) provide practical recommendations in order to establish national bioethics committees in 12 Member States;
- (2) support national bioethics committees, once established, in developing appropriate working methods and operational procedures; and

- (3) improve the functioning of bioethics committees, once operational, through evaluation and training.

III. Objectives and expected outcomes

OBJECTIVE 1

Creation of a national bioethics committee in 12 Member States: to advise Member States, through the establishment of national bioethics committees, on how to reinforce their bioethical infrastructure.

OBJECTIVE 2

Enhancement of the functioning of the committees established: to assist national bioethics committees, once established, in developing appropriate working methods and operational procedures.

OBJECTIVE 3

Training of members of established committees: to improve the functioning of national bioethics committees, once operational, through an analysis of the strengths and weaknesses of the bioethics infrastructure in participating countries, and an evaluation of the work of committees, and appropriate training of committee members.

IV. Modalities of work

MEANS: The core of the project is the setting up of two task forces – one English-speaking, the other French-speaking. Each task force will be composed of around 6 experts from UNESCO Member States with long-time experience in bioethics committee work. They will work closely together with policy-makers and colleagues from countries that have indicated an intention to establish a national bioethics committee.

PROCESS: The project will follow three stages:

- First year: setting-up of two task forces of experts

During a plenary start-off meeting, the experts will develop common strategies for the exchange of expertise and support provided to Member States. Meetings will be organised in 6 English-speaking and 6 French-speaking countries that have previously indicated an intention to establish a national bioethics committee, and would bring together the relevant task force of experts and policy-makers in the country concerned. The meeting will provide practical recommendations for the actual decision-making process leading to the establishment of a national bioethics committee.

⇒ Outcome 1: **Establishment of national bioethics committee in 6 English-speaking countries and 6 French-speaking countries**

- Second year: meeting of task forces with newly established bioethics committees

Once national bioethics committees have been established, both task forces of experts will meet with the newly appointed members of the bioethics committees in order to discuss appropriate working methods and operational procedures. Meetings in each of the countries will enable the new committees to work in an adequate way. Additional support will be provided through resources such as model forms, literature and internet consultations. The experts of both task forces will also meet in plenary to have an intermediary evaluation of the progress and provisional results of the project.

⇒ Outcome 2: **Development of appropriate working methods and operational procedures**

- Third year: assessment of the work capacities of the newly established bioethics committees and training of their members

Another round of meetings in the 12 countries will take place between the experts of the relevant task force and the members of the national bioethics committees. Together they will assess the weak points and the strong points of the work of the committee so far, and evaluate the reasons of success or failure. The committee members will also participate in training activities in order to enhance capacities in ethical analysis, research review and policy advice. Finally, a plenary meeting will take place with all experts of both task forces as well as all members of the bioethics committees of the participating 12 countries in order to exchange experiences, to improve the functioning of the committees, and to create an international network for future cooperation.

⇒ Outcome 3: **Evaluation and improvement of the work of the newly established bioethics committees and creation of a network for future cooperation**

BASIC MATERIAL:

- The Universal Declaration on Bioethics and Human Rights (2005) - Article 19 on Ethics Committees
- Publication of the Division of Ethics of Science and Technology: Guidebook N°1 “Establishing Bioethics Committees”; Guidebook N°2 “Bioethics Committees at Work: Procedures and Policies”. These guidebooks provide practical information and will constitute a useful resource to support the consultation activities of the task forces.

V. Duration of the project

3 years

VI. Donors

The potential donors are the following:

Belgium

Canada

France

Germany

Iceland

India

Italy

Lebanon

Netherlands

Norway

Saudi Arabia

Switzerland

United Kingdom of Great Britain and Northern Ireland

United States of America

VII. Partners Proposal

TASK FORCES OF EXPERTS

In the first phase, when the project will start in the first two countries, a limited number of experts will be involved. This number will gradually be expanded when also the number of recipient countries will expand.

- **Task force 1** – with experts from:
 - India
 - Netherlands
 - Saudi Arabia
 - United Kingdom
 - Democratic Republic of Congo
 - Mexico
 - France

PARTICIPATING COUNTRIES IN NEED OF CREATION OF NATIONAL BIOETHICS COMMITTEES

In the first phase of the project, the activities will start in two countries (Malawi and Madagascar). After the starting phase is over, another group of two countries will be involved (Ghana and Jamaica).

- **Group 1 – English-speaking**
 - Ghana
 - Jamaica
 - Kenya
 - Malawi
 - South Africa
 - Swaziland

- **Group 2 – French-speaking**
 - Benin
 - Gabon
 - Madagascar
 - Mali
 - Senegal
 - Togo
 - Vietnam

Annex I – Work plan

ANNEXE I – WORK PLAN

Year 1: Establishing bioethics committees

- Setting up of task force 1
- Task force meeting: strategy meeting with all task forces experts
- Country meetings: conference in each participating country with task force experts and relevant policy makers

Year 2: Working methods and operational procedures

- Country meetings: conference in each participating country with task force of experts and members of established bioethics committees
- Task force meeting: intermediary evaluation meeting with all task forces experts

Year 3: Evaluation and training

- Country meetings: conference in each participating country with task force of experts and members of established bioethics committees
- Plenary meeting: plenary meeting of all members of established bioethics committees of all participating countries and creation of networks

APPENDIX 3: OUTLINE OF THE CONSTITUTION OF A NATIONAL BIOETHICS COMMITTEE

STATUTES (draft)

Art.1

The National Bioethics Committee of Malawi has been created byon 2007

Art.2 Membership

2.1. The Committee shall consist of members

2.2. The members will represent the following organizations and institutions:

.....
.....

2.3. The members are appointed by One of the members shall be appointed as chairperson

2.4. The members and chairperson are appointed for a term of years. Reappointment may take place once.

APPENDIX 4:

HOW TO ESTABLISH A BIOETHICS COMMITTEE?

Checklist of subsequent steps

1. Determine the level
- 2.

- a. National
- b. Regional
- c. Local

3. Determine the form of committee, depending on the goal

- | | | |
|----------------------------|--------|-----|
| a. Policy | —————→ | PMA |
| b. Research | —————→ | REC |
| c. Professional guidelines | ————→ | HPA |
| d. Case consultation | ————→ | HEC |

4. Make statutes
5. Select chairperson
6. Select members
7. Determine the legal framework
8. Determine the budget
9. Decide whether meetings will be open or closed
10. Determine to whom the chairperson is responsible
11. Determine work procedures

- a. Frequency of meetings
- b. Formal reports of the meetings

- i. Minutes
- ii. Decisions
- iii.

- c. Distribution of reports
- d. Provision of documents
- e. Preparation of meetings

12. Establish the secretariat

13. Provide ethics education to members

- a. Determine the need for training of members
- b. Establish a training programme for members