Republic of the Philippines
DEPARTMENT OF SCIENCE AND TECHNOLOGY

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Subject: Requirement for Review of all health researches involving human subjects/ participants

A. Rationale

Human subjects/ participants involved in health research may be harmed or wronged or be made to face unreasonable risks. Patients by reason of their illness, gender, age, economic and social status, are particularly vulnerable to various pressures that may cloud decision-making. On the other hand, the challenges and excitement of research and discoveries may create conflicts of interest in the researcher that may be overlooked. For these reasons, there is a need for an oversight mechanism to ensure protection of the welfare and dignity of human participants in research.

B. Coverage:

All individuals, organizations, institutions who conduct research involving human persons are advised to follow these policies.

C. Policies:

1. All institutions that conduct health research are urged to establish review committees that shall be in-charge of ethical evaluation and monitoring of research involving human participants. The composition and procedures must be in compliance with the guidelines in the ***2006 National Ethical Guidelines for Health Research.***

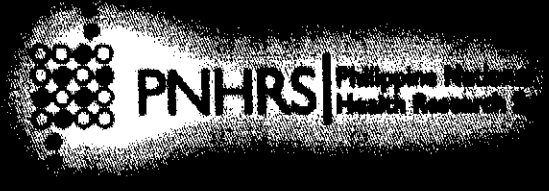
2. All research protocols for the conduct of biomedical and behavioral researches involving human subjects shall be submitted to all ethics review committee for coordination, comment, guidance and approval.

DR. ESTRELLA F. ALABASTRO
Secretary

Postal Address: 2/F, DOST Main Building, General Santos Avenue
Bicutan, Taguig, Metro Manila

Telephone Nos.: (63-2) 837-20-71 to 82
Fax No.: (63-2) 837-29-37

National Ethical Guidelines for



For inquiries, call or write

Philippine Council for Health Research and Development
Department of Science and Technology
3rd Floor, DOST Administration Bldg.
Gen. Santos Ave., Bicutan, Taguig City
Tel. Nos.: 837-75-35; 837-75-36
Fax No.: 837-29-24
E-mail: info@pchrd.dost.gov.ph (http://www.pchrd.dost.gov.ph)

Health Policy Development & Planning Bureau
Department of Health
2nd Floor, Building 3, San Lazaro Compound
Sta. Cruz, Manila
Tel. Nos.: 743-83-01 loc. 1328, 711-53-77
Fax Nos.: 781-43-62, 711-67-36
E-mail: researchethics2005@yahoo.com

FOREWORD

Advances in computing and telecommunications, coupled with the completion of the Genome Project, have forever changed the landscape of the medical and health sciences. These breakthroughs have opened the floodgates to the limitless possibilities of new technologies and of the modern scientific mind. Yet researches, no matter how impressive or noble the end, must never be allowed to prosper at the cost of the health and well-being of people, particularly the disadvantaged.

This revised edition of the National Ethical Guidelines for Health Research aims to provide the safeguards in the conduct of researches, particularly those involving human participants. It also aims to establish the needed structures for the ethical conduct of biomedical and behavioral research by setting off the scope, functions, and composition of the Philippine Health Research Ethics Board (PHREB) as a national body, as well as that of institutional ethics review committees.

The 2006 National Ethical Guidelines for Health Research likewise seeks to address the role of research and the various issues and gaps relating to research in the context of developing countries. These include ethical issues pertaining to international collaborative research funded by industrialized countries and carried out in developing countries. Such issues include difficulties in creating ethical guidelines and review processes in developing countries, the standard of care to be provided during and after clinical trials, traditional medicines, genomics and global health, benefit sharing and intellectual property, and culture and informed/misinformed consent.

Given the increasing universality of what were once region-specific health concerns, these Guidelines have also identified issues/topics that are commonly addressed by the four international ethics guidelines, namely the International Declaration on Human Genetic Data, the Council for International Organizations of Medical Sciences, UNAIDS, and the Declaration of Helsinki.

Written in simple, concise, and reader-friendly style, the 2006 National Ethical Guidelines for Health Research will hopefully encourage more studies conducted by Filipinos on local health concerns, thereby addressing the problem of under-representation of the Philippines in high-impact general medical journals, which is another key ethical issue in health research.

Estrella F. Alabastro, Ph. D.
Secretary
Department of Science and Technology

23 June, 2006

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
MANILA, PHILIPPINES
Tel Nos. (632) 743-83-01 local 1107,1111

MESSAGE

The landscape of health research has immensely changed with the explosion of new information, the ease of exchange of scientific knowledge, and information technology (IT) that allows for the quick and downloadable access of the outputs of research. There are also challenges being posed by new ethical considerations such as in balancing the need to shed light to emerging public health threats, which especially hit low-income populations against human rights not to be misused when these poor people are chosen as research subjects We must therefore adapt with the times and revolutionize ways in which we conduct local research by becoming more responsive to these scientific, technological, and social advances.

The Philippine Health Research Ethics Board (PHREB) under the Philippine National Health Research System (PNHRS) is now bringing out the updated National Ethical Guidelines for Health Research in response to these changing needs. This is indeed a welcome development for the DOH as we continuously seek better information and evidence and explore new ways, approaches, and technologies, which can enhance the performance of the entire health system. Critical reform strategies on service delivery, regulation, financing, and governance under the Fourmula 1 for Health implementation strategy shall surely benefit from these developments as we devote ourselves more to conducting researches built on a foundation of public trust, scientific integrity, and social responsibility.

While we accelerate our actions for health through speedier ways of testing new drugs, tools, strategies, and approaches in health research, we must all take care to uphold the values associated with ethical research conduct. We need to safeguard the rights of the participants, particularly those who are vulnerable or disadvantaged. The national guidelines shall ensure that more research institutions and researches from the biomedical and behavioral fields of discipline will be able to support and protect the dignity and rights of the human person as a research participant. I understand also that this initiative is pointing to one of the goals of the Philippine National Health Research System (PNHRS) - that of fostering high performing research organizations relative to technical and ethical standards.

We therefore laud the tireless efforts and admirable dedication of the members of the Ad Hoc Committee for accomplishing the revised ethical guidelines for the conduct of health research in the country.

Congratulations and more power to the Philippine National Health Research System!

FRANCISCO T. DUQUE III, M.D., M.Sc.
Secretary of Health

ACKNOWLEDGMENTS

The Ad Hoc Committee for the revision of the National Ethical Guidelines for Health Research patiently and carefully reviewed and revised the old guidelines, and formulated new ones in order to provide researchers and ethics review committees a new set of guidelines that is responsive to the needs of an evolving and growing national health research system. The committee was composed of:

Dr. Leonardo D. de Castro *(Chair)*	Professor, Department of Philosophy College of Social Science and Philosophy University of the Philippines Diliman
Dr. Sonny Matias E. Habacon	Professor, Department of Pharmacology College of Medicine Far Eastern University- Nicanor Reyes Memorial Medical Foundation
Fr. J. Cesar R. Marin, SJ	Parish Priest Mary the Queen Parish
Dr. Jaime C. Montoya	Executive Director Philippine Council for Health Research and Development Department of Science and Technology
Dr. Filipinas F. Natividad	Vice President and Director Research and Biotechnology Division St. Luke's Medical Center
Atty. Elizabeth A. Pangalangan	Professor, College of Law University of the Philippines Diliman
Dr. Marita V. T. Reyes	Professor, Department of Biochemistry and Molecular Biology College of Medicine University of the Philippines Manila
Dr. Cecilia V. Tomas	Dean, College of Medicine University of the Philippines Manila
Ms. Crispinita A. Valdez	Director, Information Management Service Department of Health

The following brought in their technical expertise to bear on the writing of specific sections of these guidelines:

Dr. Godofreda V. Dalmacion	Professor, Department of Clinical

Dr. Jacinto Blas Mantaring	Associate Professor, Department of Pediatrics College of Medicine, UP Manila
Dr. June Pagaduan-Lopez	Associate Professor, Department of Psychiatry College of Medicine, UP Manila
Dr. Isidro C. Sia	Professor, Department of Pharmacology College of Medicine, UP Manila
Prof. Elizabeth R. Ventura	Professor, Department of Social Science College of Social Science and Philosophy University of the Philippines Diliman

They also facilitated the group discussions on the guidelines during the 24th Anniversary Conference of the Philippine Council for Health Research and Development.

Imelda B. Mutuc and Guidditta L. Gelera of the Philippine Council for Health Research and Development, and Adelaida P. Mendoza of the Department of Health provided critical organizational and coordinative support in all stages of this project. The editorial assistance of Saniata P. Masulit has been invaluable.

Finally, the ultimate credit must be given to all those who actively participated and gave insightful comments and suggestions during the roundtable discussions and consultations and, thus, helped make this set of guidelines appropriate to Philippine health research.

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HOW TO USE THE GUIDELINES

This set of Guidelines is divided into two major topics: 1) the General Guidelines on ethical review of health research, and 2) the Special Guidelines on specific research areas, namely a) clinical trials on drugs, devices, and diagnostics; b) herbal medicine research; c) complementary and alternative medicine research; d) epidemiological research; e) social and behavioral research; f) research involving traumatized populations; g) HIV/AIDS research; h) research on assisted reproductive technology; and i) genetic research that includes a section on stem cell research. Guidelines on international collaborations and authorship and publications complete this new set of ethical guidelines.

In the past few years, the use of the term "human subjects" in reference to individuals involved in the research has been criticized especially by social scientist as an objectification of persons. The recommendation is to use the term "human participants". However, participation in research includes involvement in the different phases of research including identification of objectives and designing the protocol. In practice, many of health researches are conceptualized without the input of the potential "participants" and therefore, the use of the latter term is inaccurate. In this set of guidelines, therefore the terms "human subjects" and "human participants" are used interchangeably.

Three appendices are provided in these guidelines. Appendix A is a template for patient information and informed consent forms. The template lists the essential information that should be reflected in the patient information and informed consent forms. By answering each question under each heading, the proponent/s would be able to make the potential study participant understand the nature, risks, and benefits of his/her participation in the study, and thus be able to decide to participate or not. Appendix B is the standard application form for ethical evaluation of proposal that must be submitted to the ethics review committees (ERC's) together with the proposal. Appendix C lists the documents that the proponent/s should provide the Ethics Review Committee.

A glossary of technical terms is available as a quick reference. (pp68-94)

It is important for the readers to familiarize themselves with the General Ethical Guidelines for Health Research (pp16-29) which contain the general provisions on the various elements of and considerations in

research ethics. Some elements of research ethics (e.g., informed consent) as operationally applied in specific types of research, say, genetic studies, are discussed in great detail in the guidelines for that particular type of research. These specific provisions complement those in the General Ethical Guidelines. They should not be considered as separate from the general guidelines. The subject index (pp96-100) should be able to direct the reader to all the sections where a particular item appears.

Much effort was exerted to make this guidebook easy to use by researchers, by members of the ERCs and funding agencies, by research policy makers and even by young students in health research.

For questions, please call/ email –

The Secretariat, Philippine Health Research Ethics Board (PHREB)
Philippine Council for Health Research and Development
Department of Science and Technology
General Santos Avenue, Bicutan, Taguig City
Telephone Number(s): 837-7535/36
Fax Number: 837-2924

ABBREVIATIONS

AO	-	administrative order
BFAD	-	Bureau of Food and Drugs
CAM	-	complementary and alternative medicine
CERC	-	Cluster Ethics Review Committee
CIOMS	-	Council of International Organizations of Medical Sciences
DA	-	Department of Agriculture
DNA	-	deoxyribonucleic acid
DOH	-	Department of Health
DOST	-	Department of Science and Technology
ERC	-	Ethics Review Committee
HIV/AIDS	-	human immunodeficiency virus / acquired immune deficiency syndrome
ICH	-	International Conference on Harmonization
IERC	-	institutional ethics review committee
NCCAM	-	National Center for Complementary and Alternative Medicine
NEC	-	National Ethics Committee
PALAS	-	Philippine Association for Laboratory Animal Science
PCHRD	-	Philippine Council for Health Research and Development
PHREB	-	Philippine Health Research Ethics Board
PNHRS	-	Philippine National Health Research System
POGS	-	Philippine Obstetrical and Gynecological Society
RNA	-	ribonucleic acid
SAE	-	serious adverse event
TM	-	traditional medicine
TWG	-	Technical Working Group

INTRODUCTION

> *"Research investigators should be aware of the ethical, legal, and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in the Declaration of Helsinki"* (Helsinki, 2004, 9).

Various international guidelines have been developed for the protection of human participants in research. These include the World Medical Association's Helsinki Declaration of 1964 (revised and amended in 1975, 1983, 1989, 1996, and 2000), the WHO Council of International Organizations of Medical Sciences (CIOMS) 2002, and the International Conference on Harmonization Good Clinical Practice Guidelines (1996). Nevertheless, national and local guidelines still need to be developed so that research ethics can be embedded in the local practices as well as national laws and regulations while taking into consideration the country's culture and traditions, and existing research infrastructures.

In 1984, the National Ethics Committee (NEC) was organized by the Philippine Council for Health Research and Development (PCHRD) under Special Order No. 84-053 of then Executive Director, Dr. Alberto G. Romualdez, Jr. The following year, the NEC put together the first set of guidelines for the conduct of biomedical research in the country. These guidelines subsequently underwent revisions in 1996 and 2000 to address various developments in health research including multicenter clinical trials, genetic research, and organ transplantation research.

In 2003, the Department of Science and Technology (DOST) and the Department of Health (DOH) signed a Memorandum of Understanding to establish the Philippine National Health Research System (PNHRS) that envisions "a vibrant, dynamic, and responsible health research community working for the attainment of national and global health goals." The PNHRS endeavors "to create and sustain an enabling environment for health research through evidence-informed health and health-related policies and actions." A Technical Working Group (TWG) on Ethics was one of six groups constituted to firm up the PNHRS programs and strategies. The constitution of the TWG on Ethics emphasized the

research system. This Ethics Group later proposed the establishment of the Philippine Health Research Ethics Board (PHREB) and the revision of the national guidelines on biomedical/behavioral research, among its several recommendations.

The PHREB evolved from the TWG on Ethics and was formally constituted on March 17, 2006. It is mandated "to ensure that all phases of health research shall adhere to universal ethical principles that value the protection and promotion of the dignity of health research participants." The membership of the board is multidisciplinary, multisectoral, and reflective of the close collaboration between DOH and DOST.

A task force composed of representatives from the National Ethics Committee and from the Technical Working Group on Ethics worked on and prepared a draft revision of the National Ethical Guidelines for Health Research. This was critiqued in roundtable discussions with stakeholders before it was formally presented to a wider audience during the 24th Anniversary of the Philippine Council for Health Research and Development on March 17, 2006.

The 2006 version of the National Health Research Ethical Guidelines aims to put global health research norms in the context of Philippine values and realities. It embodies the adherence of Philippine health researchers to ethical principles to protect human life and the dignity of the human person.

Just like the earlier editions, these guidelines are meant to promote, and not to stifle, good and ethical scientific research. After all, advancement of the frontiers of knowledge brings hope for the good life, even for survival. But rules, codified as they are, are only rules on paper. In the final analysis, all individuals concerned with health research must resolve for themselves the omnipresent conflict between present peril or risk and future benefits of the study at hand.

Philippine Health Research Ethics Board
2006

ETHICS REVIEW AUTHORITIES

Introduction

Advancement in science and technology in the '70s has made biomedical research involving human participants a necessity in order to determine the efficacy and safety of such new discoveries. Ethical issues involving the rights, safety, and protection of research participants emerged and these brought about the formulation of international guidelines in addition to the Nuremberg Code of 1949 and the Helsinki Declaration of 1964. As a national response, the Philippines established the National Ethics Committee (NEC) in 1984 through Special Order No. 84-053 issued by Dr. Alberto G. Romualdez, Jr., then Executive Director of the Philippine Council for Health Research and Development (PCHRD).

The NEC was created to ensure that all health research and development proposals conformed with ethical standards. It also promoted the establishment of ethics review committees in various localities and institutions.

In 2003, the Philippine National Health Research System (PNHRS) led to the creation of the Philippine Health Research Ethics Board (PHREB), a national policymaking body on health research ethics. In the different regions, policymaking boards shall also be established as Regional Health Research Ethics Boards.

The Philippine Health Research Ethics Board (PHREB)

Composition

The Philippine Health Research Ethics Board has 13 members, including two ex-officio members: the Department of Science and Technology (DOST)-PCHRD Executive Director, and the Department of Health (DOH) Research Ethics Committee Chair. Except for the ex-officio members, appointments shall be for a term of three years (initially, however, five were appointed for three years, and six members for two years). The members represent a balance of background, gender, and disciplines (e.g., health research,

philosophy, law, academe, medicine, public health/ epidemiology, theology, social science, allied health sciences, people's organizations, and the youth). The Chair and Co-Chair have two-year terms.

Functions

PHREB shall have the following functions:

1. Formulate/Update guidelines for the ethical conduct of human health research;
2. Develop guidelines for the establishment and management of ethics review committees and standardization of research ethics review;
3. Monitor and evaluate the performance of institutional ethics review committees in accordance with procedures outlined in a prior agreement;
4. Promote the establishment of functional and effective ethics review committees;
5. Provide advice and make recommendations to the PNHRS Governing Council and other appropriate entities (including the Bureau of Food and Drugs [BFAD]) regarding programs, policies, and regulations as they relate to ethical issues in human health research;
6. Initiate and contribute to discourse and discussions of ethical issues in human health research; and
7. Network with relevant local, national, and international organizations.

Regional Research Ethics Boards

Composition

The regional research ethics boards will be constituted by the PNHRS Governing Council and will have a multidisciplinary, multisectoral, gender- and age-balanced membership that reflects the cultural and social milieu obtaining in the region they are in. They will be under the supervision of PHREB.

Functions

The regional research ethics boards will be established in key regions to act as a regional research ethics review policy-making authority. Their functions will, therefore, be similar to that of PHREB with the region as their area of responsibility.

Ethics Review Committees (ERCs)

The Ethics Review Committees include the Cluster Ethics Review Committees, the Institutional Ethics Review Committees and the erstwhile National Ethics Committee. The latter has for several years conducted initial review for researches done in institutions without a functional research ethics review committee.

Cluster Ethics Review Committees (CERCs)

Several institutions may form a common ethics review committee if it is not feasible to form their own committees.

The management of CERCs and its areas of responsibility should be covered by a memorandum of agreement among the involved institutions.

The CERC's functions shall be similar to that of an institutional ethics review committee.

The Institutional Ethics Review Committees (IERCs)

Philippine institutions that engage in biomedical and behavioral research

independent, competent, and timely review of the ethics of proposed studies. The main purpose of the IERC is to help "safeguard the dignity, rights, safety, and well-being of all actual or potential human participants" (WHO Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000). To this end, it is important that "in its composition, procedures, and decision-making, the IERC shall be independent of political, institutional, professional, and market influences" (WHO Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000).

The IERC should consider both the scientific and ethical aspects of the proposed research even when the IERC is distinct from the technical review committee (Council for International Organizations of Medical Sciences).

Data from a recent survey of local institutions conducted by the Philippine National Health Research System Technical Working Group on Ethics (2003-04) show that only 50 percent of these institutions have an IERC (Reyes, 2004). Of the 80 reported IERCs in the country, almost half (36) are in the National Capital Region. Lack of training in research ethics was cited as a major flaw of many IERCs. The efforts of DOST-PCHRD, DOH, and University of the Philippines Fogarty Group in organizing intensive training courses in research ethics may answer the need for capacity building in this field.

Standardization of ethics review is an area of concern that the IERC should address. In this regard, the IERC may use as references the WHO Operational Guidelines for Ethics Committees that Review Biomedical Research (2000), and the 2006 General Ethical Guidelines for Health Research (pp16-29). However, it should develop a manual of standard operating procedures.

Composition

1. The membership of the institutional ethics review committee should be multidisciplinary and multisectoral, including the relevant expertise, e.g., medicine and research, theology, social or behavioral science, law, philosophy, environmental science, and public health. It is recommended that the IERC should include a person without disciplinal constraints who will

community. At least one member should be independent of the institution or research site. The IERC should have at least five members and should consider age and gender distribution.

2. In addition to the committee members, there should be adequate support staff for carrying out the IERC's responsibilities.

Appointment

3. The officers and members of the IERC shall be officially appointed by the administrative head of the institution.

4. The appointing official shall indicate their functions, terms of office, scope of work, conditions of appointment, and compensation, if any.

5. Procedures for renewal of appointment, resignation, replacement; grounds for disqualification; and procedures in regard to conflict of interest due to financial gains shall be included in the manual of standard operating procedures.

6. Prior to serving as a regular member, each member of the IERC shall sign a disclosure document which states that he/she has no conflict of interest (e.g., financial interests in a pharmaceutical company) as a reviewer, and a confidentiality agreement.

7. The appointing official should consider "a fixed rotation system for members that allows for continuity, the development and maintenance of expertise within the committee, and the regular input of fresh ideas and approaches" (WHO Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000).

External

8. The committee shall establish a list of external

regarding ethical, scientific, psychological or social aspects of researches for review.

9. In deliberations on research involving special subject groups or concerns (e.g., HIV/AIDS, the physically challenged), best efforts must be exerted to include participation of advocates.

Functions and Responsibilities

10. The IERC is responsible for "acting in the full interest of potential research participants and affected communities, taking into account the interests and needs of the researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws" (WHO Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000). In the Philippines, the regulatory agencies include PNHRS-PHREB, DOH-BFAD, and the National Committee on Biosafety.

11. The IERC's functions are as follows:

    a. To evaluate the conduct of research in their institutions in accordance with international and national guidelines; local laws; standards of professional conduct and practice; and community mores, values, and needs;
    b. To promote research integrity by identifying and resolving conflicts of interest;
    c. To establish appropriate mechanisms in all stages of the research in order to:
        1) ensure the safety, protect the rights, and promote the welfare and well-being of human participants,
        2) provide counsel to human participants, including proponents and researchers,
        3) ensure prompt reporting of changes in the protocol and unanticipated problems,
        4) ensure the proper documentation of and adherence to the confidentiality rule and

        5) monitor the progress of ongoing research.

    d. To report to the institutional or national authorities any matter that affects the conduct and ethics of research which in its view may affect the rights and safety of research participants;

    e. To keep a systematic and organized record of all proposals reviewed, including actions taken and other pertinent information; and

    f. To submit an annual report to the Philippine Health Research Ethics Board c/o DOST-PCHRD.

    The IERC annual report shall contain the following:

        1) The composition of the IERC, including a short curriculum vitae (name of the person, educational attainment, most recent ethics training/seminars attended), and term of office of each member

        2) Members of the IERC secretariat, office/ email addresses, and contact numbers

        3) Number of meetings held during the year, including the date and venue

        4) Number of researches reviewed by the IERC during the year categorized as follows:

            - Researches approved without changes
            - Researches for which the IERC required modifications or revisions before approval
            - Researches disapproved

5) Such other information as may be required by PHREB

Meetings and deliberations

12. The IERC shall regularly meet as a committee on a schedule that is determined based on the research cycle of the institution. There shall be a provision for holding special meetings to consider urgent matters as decided by the chairperson.

13. More than half the members shall constitute a quorum, which should include one with expertise in a non-scientific area and at least one member who is independent of the institution or research site.

14. Deliberations of the IERC shall be characterized by transparency and collegiality. A member who is involved in whatever capacity in the study/ project under consideration should so inform the committee and his/her further participation in the deliberations must be determined accordingly.

15. As much as possible, decisions shall be made by consensus.

Training and continuing education of ethics committee members

16. Members of the IERC shall undergo continuing training on the ethics and science of biomedical research. Initial training must be required of new members. Continuing educational activities must be held at least once a year. These may be linked with those of other ethics committees within the province or region.

THE RESEARCH ETHICS REVIEW PROCESS

All proposals for the conduct of biomedical and behavioral researches involving human subjects shall be clearly formulated in a research protocol to be submitted to an ethics review committee (ERC) for consideration, comment, guidance, and approval.

The review must be transparent, timely, and reasonable. Each ethics review committee shall indicate a time frame for completing the review process, and provide the proponent initial feedback within four weeks after receipt of the complete documents.

Required documents

1. The research investigator/proponent shall be required to submit the following documents:

   a. Application for review;

   b. Research protocol that includes the title of the proposal, background of the study, rationale, objectives, research design, inclusion and exclusion criteria, and safety information. (For general guidelines on the research protocol, refer to the General Ethical Guidelines for Health Research on pp16-29);

   c. Written information to be provided the participants, which shall include the objectives and significance of the research; the nature of their participation; their rights, privileges, and obligations; the risks involved; and benefits, including payment of trial-related expenses;

   d. Written informed consent in English, together with the translation in Filipino or any dialect understandable to the participants (see Informed Consent in the General Ethical Guidelines for Health Research. For a template on informed consent see Appendix A);

   e. Safety information (e.g., safety precautions,

adverse events, contact telephone numbers);

f. Procedure for participant recruitment, including advertisements;

g. A section on ethical considerations (e.g., anticipated risks and why they are outweighed by potential benefits, how the risks will be minimized, how confidentiality of data and privacy of participants are going to be protected);

h. Investigators' qualifications (e.g., curriculum vitae). If a conflict of interest exists, the investigator shall formally disclose this; and

i. Information regarding funding, sponsors, institutional affiliations, other potential conflict of interest, and compensation for the subjects.

Review procedure

2. The ERC should have a standard operating process that should be made available to the researchers and stakeholders. It is advisable for the ethics review committee to have a standard application form (Appendix B).

3. The ERC Chairperson shall schedule a research review meeting reasonably within four weeks after submission of the required documents.

4. ERC members shall be provided with a copy of the documents to be reviewed well ahead of the meeting to give them sufficient time to study the documents and ready their comments.

5. The quorum shall be set and attendance of members recorded. The rule on quorum shall not only specify numbers but shall also require a balanced composition (e.g., gender, expertise).

6. The minutes of the meeting, including actions taken, shall be properly documented. Minutes and other records shall be properly secured at least three years after the completion of the study or as required by the official agencies or institutions.

7. The ERC may invite the investigator/proponent to clarify certain issues. The latter shall leave the room immediately after the clarification has been made.

Action on proposals

8. The ERC shall inform the investigator/proponent in writing of the committee's action. The ERC's action may be one of the following:

   a. Approval
   b. Conditional approval with modifications
   c. Disapproval

9. The ERC shall include in its letter to the investigator the a) title of the proposal reviewed (revision/amendment, date, version number); b) name and title of applicant; c) documents reviewed; d) name of review site; e) date and place of decision; and f) the name of the ERC making the decision.

10. In case of **approval**, the ERC shall inform the investigator in writing of the ERC's requirements for approved researches that must be complied with during the conduct of the research. These include the following:

    a. Report of serious and/or unexpected adverse event/s (SAEs) related to the conduct of the research within a timeframe required by the ERC (e.g., 24 or 48 hours after occurrence).

    b. Report of SAEs from other study sites or

In case of SAEs, a justification for why the research should continue.

c. Any major changes, deviations or amendments to the approved protocol. These shall need another approval by the ERC.

d. Any revision in the informed consent form.

e. Progress report at least once a year or as requested by the ERC.

f. Notice of termination of the research before its anticipated completion date, and the reason for it.

11. In case of **conditional approval with modifications**, the ERC shall clearly describe the required modifications.

12. In case of **disapproval**, the ERC shall clearly state its objections and the reason/s for disapproval. The ERC may include its recommendations for improvement.

Approval for reconsideration

13. In case of an unfavorable decision, the investigator may make oral or written representation to the ERC for reconsideration.

Withdrawal of prior approval

14. Prior approval may be withdrawn for the following reasons:

a. Serious or adverse events directly or indirectly attributed to the research

b. Breach of previously agreed-upon conduct of the research

Completion of the research

15. Upon completion of the research, the investigator shall inform the ERC in writing that the study has been completed, and shall furnish the committee a copy of the final report.

GENERAL ETHICAL GUIDELINES FOR HEALTH RESEARCH

Introduction

For the purposes of these guidelines, an activity is deemed to be "research" if it aims to develop or contribute to generalizable knowledge (including theories, principles, relationships, or any accumulation of information using scientific methods, observation, and inference).

These general guidelines shall govern all health researches involving human subjects. Additionally, special guidelines on clinical trials (pp30-37), herbal medicine research (pp38-41), complementary and alternative medicine research (pp42-44), epidemiological research (pp45-47), social and behavioral research (pp48-49), research involving traumatized populations (pp50-52), HIV/AIDS research (pp53-54), research on assisted reproductive technology (pp55-56), and genetic research (pp57-63), international/collaborative research (pp64-65), have been formulated because of special concerns that have been identified by practitioners.

Health research involving human subjects includes research on identifiable human material or identifiable data (Principle 1 – Declaration of Helsinki, 2004).

Considerations related to the well-being of the human subject should take precedence over the interests of science and society (Principle 1 – Declaration of Helsinki, 2004).

It is the duty of the researcher to protect the life, health, privacy, and dignity of the human subjects, and to safeguard scientific integrity.

I. Elements of Research Ethics

Informed consent

1. For all biomedical research involving humans, the investigator must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is incapable of giving informed consent, the permission of a legally authorized

Waiver of informed consent is to be regarded as uncommon and exceptional, and must in all cases be approved by an ethics review committee (Guideline 4 – Council for International Organizations of Medical Sciences [CIOMS], 2002).

2. The investigator shall provide the following information to the potential subject, using language that can be understood:

   a. That the individual is invited to participate in the research, the reasons for considering the individual suitable for the study, and that participation is voluntary;

   b. That the individual is free to refuse to participate and is free to withdraw from the research at any time without penalty or loss of benefits to which he/she is entitled;

   c. The purpose of the research, the procedures to be carried out by the investigator and the subject, and an explanation of how the research differs from routine medical care;

   d. For controlled trials, an explanation of features of the research design (e.g., randomization, double blinding), and that the subject will not be told of the assigned treatment until the study has been completed and the blind has been broken;

   e. The expected duration of the individual's participation (including number and duration of visits to the research center and the total time involved) and the possibility of early termination of the trial or of the individual's participation in it;

   f. Any foreseeable risks, pain or discomfort, or

associated with participation in the research, (in both the control and experimental group), including risks to the health or well-being of a subject's spouse or partner;

g. The direct benefits, if any, expected to result to subjects from participating in the research;

h. Whether money or other forms of material goods will be provided in return for the individual's participation and, if so, the kind and amount;

i. That the subjects have the right of access to data on demand even if these data lack immediate clinical utility (unless the ethics review committee has approved temporary or permanent non-disclosure of data, in which case the subject should be informed and given the reasons for such non-disclosure);

j. That after the completion of the study the subject will be informed (if he/she so desires) of any findings related to his/her health status;

k. The expected benefits of the research to the community or to society at large, or contribution to scientific knowledge;

l. Whether, when, and how, any products or interventions proven by the research to be safe and effective will be made available to the subjects after they have completed their participation in the research, and whether they will be expected to pay for them;

m. Any currently available alternative interventions or courses of treatment;

n. The provisions that will be made to ensure

confidentiality of records in which the subjects are identified;

o. The limits, legal or other, to the investigator's ability to safeguard confidentiality, and the possible consequences of breaches of confidentiality;

p. The sponsors of the research, the institutional affiliation of the investigators, and the nature and sources of funding for the research;

q. The possible research uses, direct or secondary, of the subject's medical records; and the possible future use and final disposition of biological specimens;

r. If the specimens collected will not be destroyed, where, how, and for how long they are going to be stored;

s. That the subjects have the right to decide about such future use, continued storage, or destruction of collected specimens;

t. Whether commercial products may be developed from biological specimens, and whether the participant will receive monetary or other benefits from the development of such products;

u. Whether the investigator is serving only as an investigator or as both investigator and the subject's physician;

v. The extent of the investigator's responsibility to provide medical services to the participant;

w. That treatment will be provided free of charge for specified types of research-related injury

research, the nature and duration of such care, the name of the organization or individual that will provide the treatment, and whether there is any uncertainty regarding funding of such treatment;

x. In what way, and by what organization the subject or the subject's family or dependents will be compensated for disability or death resulting from such injury (or, when indicated, that there are no plans to provide such compensation);

y. That an ethics review committee has approved or cleared the research protocol (Guideline 5 – CIOMS, 2002).

3. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed (Principle 22 – Declaration of Helsinki, 2004).

4. Caution must be exercised in obtaining informed consent for a research project if the subject is in a dependent relationship with the investigator (e.g., as a patient) to ensure that the consent is not given under duress. The ethics review committee may stipulate that the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of the relationship (Principle 23 –Declaration of Helsinki, 2004).

5. The participation of children in research requires extra protection, as children cannot volunteer to participate in a research study in the same way as an adult can. While they cannot give informed

obtaining consent by being asked for their assent to participate. When appropriate, both a child's assent and the parent's or guardian's permission should be obtained prior to enrolling a child in a research study.

6. In obtaining informed consent, sponsors and investigators have a duty-to:

a. avoid deception, undue influence, or intimidation;

b. seek consent only after ascertaining that the prospective subject has adequate understanding of the relevant facts and the consequences of participation, and has had sufficient opportunity to consider whether to participate;

c. as a general rule, obtain from each prospective subject a signed form as evidence of informed consent; investigators shall justify any exceptions to this general rule and obtain the approval of the ethics review committee;

d. renew the informed consent of each subject if there are any significant changes in the conditions or procedures of the research, or if new information becomes available that could affect the willingness of subjects to continue to participate;

e. renew the informed consent of each subject in long-term studies at pre-determined intervals even if there are no changes in the design or objectives of the research (Guideline 6 - CIOMS, 2002).

Risks, benefits, and safety

7. Health research is only justified if there is a reasonable likelihood that the populations in which

the research results (Principle 19 – Declaration of Helsinki, 2004).

8. Every health research project involving human subjects should be preceded by a careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others (Principle 16 – Declaration of Helsinki, 2004).

9. Every precaution should be taken to minimize the negative impact of the study on the subject's physical and mental integrity (Principle 21 – Declaration of Helsinki, 2004).

10. There must be an assurance of reasonable availability of a research product within the local market.

Community care

11. The conclusion or termination of the research activity should not preclude the possibility of administering extended community care. This should be especially considered in researches involving depressed communities, ethnic groups or in international collaborative protocols (Bhutta, 2000).

Privacy and confidentiality

12. Every precaution should be taken to respect the privacy of the participant and the confidentiality of the participant's information.

Disclosure of research results

13. Disclosure of research results to subjects should occur only when *all* of the following apply:

    a. the findings are scientifically valid and confirmed;

    b. the findings have significant implications for the subject's health concerns; and

    c. the course of action to ameliorate or treat these concerns is readily available when research results are disclosed to its subjects. Appropriate medical advice or referral should be provided.

Standard of care

14. The particular needs of the economically and medically disadvantaged must be recognized in determining the standard of care that must be provided them as research subjects.

15. The benefits, risks, burdens, and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, or therapeutic methods. Placebo, or no treatment, may be used in studies where no proven prophylactic, diagnostic, or therapeutic method exists (Principle 29 – Declaration of Helsinki, 2004).

Compensation for research subjects

16. Compensation given to subjects for lost earnings, travel costs, and other expenses incurred in taking part in a study; free medical services; and compensation for the inconvenience and time spent by those who do not have direct benefit from the research should not be so large, or the medical services so extensive as to induce the prospective subjects to consent to participate in the research against their better judgment (Guideline 7 – CIOMS, 2002).

Subject groups that require special consideration

17. Some populations require special protection because of characteristics or situations that render them vulnerable. Vulnerable groups should not be included in research unless a) such research is necessary to promote the health of the population represented, and b) such research cannot be performed on legally competent persons.

18. Before undertaking research involving children,

a. the research cannot be carried out equally well in adults;

b. the purpose of the research is to obtain knowledge relevant to the health needs of children;

c. a parent or legal representative of each child (0-18 years old) has given permission The following order of authority is suggested:

Parents
Surviving Parent
Grandparents
Surviving Grandparents
Oldest sibling over 21 years old
Actual custodian

d. the assent of each child has been obtained to the extent of the child's capabilities; and

e. a child's refusal to participate or continue in the research is respected (Guideline 14 – CIOMS, 2002).

19. Before undertaking any research involving individuals who, by reason of mental or behavioral disorders, are not capable of adequately giving an informed consent, the investigator shall ensure that:

a. the research cannot be carried out equally well on persons whose capacity to give informed consent is not impaired;

b. the purpose of the research is to obtain knowledge relevant to the particular health needs of persons with mental or behavioral disorders;

c. the consent of each subject has been obtained

d. in cases where prospective subjects lack the capacity to consent, permission is obtained from a responsible family member or a legally authorized representative in accordance with applicable laws (Guideline 15 – CIOMS, 2002).

20. Investigators, sponsors, or ethics review committees shall not arbitrarily exclude women of reproductive age from biomedical research. The potential for becoming pregnant during a study shall not, in itself, be used as a reason for precluding or limiting women's participation in research.

21. The following should be considered in enrolling women who may become pregnant during research:

a. A thorough discussion of risks to the pregnant woman and to her fetus is a prerequisite for the woman's ability to make rational decision to enroll in a clinical study.

b. A pregnancy test shall be done and access to effective contraceptive methods ensured before the research commences if participation in the research might be hazardous to a fetus or a woman if she becomes pregnant. Where such access is not possible for legal or religious reasons, investigators shall not recruit for such possibly hazardous research women who might become pregnant (Guideline 16 – CIOMS, 2002).

c. Investigators and ethics review committees shall ensure that prospective subjects who are pregnant are adequately informed about the risks and benefits to themselves, their pregnancy, the fetus and their subsequent

d. Research in this population should be performed only if it is relevant to the particular health needs of a pregnant woman or her fetus, or of pregnant women in general and, when appropriate, if it is supported by reliable evidence from animal experiments, particularly as to risks of teratogenicity and mutagenicity (Guideline 17 –CIOMS, 2002).

22. Competent advice and assistance shall be provided to subjects who, by virtue of social, economic, political or medical disadvantages, are liable to give consent under duress or without the benefit of adequate information.

Absence of direct benefit

23. When there is ethical and scientific justification to conduct research with individuals capable of giving informed consent, the risk from research interventions that do not hold out the prospect of direct benefit for the individual subject should be no more likely and no greater than the risk attached to routine medical or psychological examination of such persons. Slight or minor increases above such risk may be permitted when there is an overriding scientific or medical rationale for such increases and when an ethics review committee has approved them (Guideline 9 – CIOMS, 2002).

II. Ensuring Quality Research

Role of the ethics review committee (ERC)

24. The ERC shall:

a. Review the scientific merit and ethical acceptability of any research involving human participants;

b. Conduct further reviews as necessary in the course of the research as well as monitor the study's progress (Guideline 2 – CIOMS, 2002);

c. Research approved by a foreign ERC for implementation in the Philippines shall also be subjected to ethics review.

Ensure that the ethical standards applied are no less stringent than they would be if the research were to be carried out in the country of the sponsoring agency;

d. Ensure that the proposed research is responsive to the health needs and priorities of the Philippines and meets the requisite ethical standards (Guideline 3 - CIOMS, 2002);

e. Issue the ethical clearance required for the implementation of any research it has reviewed and approved; and

f. Review amendments/changes in the protocol of researches that have been previously approved.

Research protocol

25. The research protocol should adequately address the four ethical principles: respect for persons, beneficence, non-maleficence, and justice. And should be sufficiently detailed to serve as documentation of the study. It should -

a. justify the need for the study, i.e., why the study should be conducted given the current state of knowledge;

b. demonstrate the appropriateness of the proposed methods for testing the stated hypothesis;

c. demonstrate the feasibility of doing the study as proposed, i.e., that the study can be completed successfully in the specified time and with the available resources;

26. The purpose of the study, the design, the population, the methods of data collection, and the planned analyses shall be described in the protocol.

27. All procedures, whether invasive or not, should be satisfactorily described in detail.

28. The protocol should provide information on how the welfare of the participants shall be protected.

29. It is also advisable to include in the protocol the agreements on the time schedule, publication of research findings, and authorship (see Guidelines on Authorship and Publication, pp66-67).

Qualifications of investigators

30. Persons engaged in health research involving human subjects should be scientifically qualified. The investigator must have the ability and skills to conduct the proposed study and the knowledge of the literature on the subject of interest.

Protection of the environment and biosafety

31. In the conduct of biomedical or behavioral research, appropriate caution shall be exercised to avoid harm or damage to the environment (Principle 12 – Declaration of Helsinki, 2004).

In the use of biological and hazardous materials including those that involved genetic modification and manipulation of microorganisms and of animal and plant tissue cells.

Welfare of animals

32. In regard to the use of animals for research, investigators shall abide by RA No. 8485 - Animal Welfare Act of 1998 and its Implementing Rules and Regulations [DA Administrative Order No. 40 series of 1998 and the Code of Practice for the Care and Use of Laboratory Animals in the Philippines, 2nd edition, 2002 developed by the Philippine Association for Laboratory Animal

III. Other Considerations

The National Unified Health Research Agenda

33. In general, researches should adhere to the national unified health research agenda that must be firmly grounded through a process of priority setting (Margetts, Arab, Nelson, & Kok, 1999).

34. Government-sponsored health researches should conform with the National Unified Health Research Agenda.

Community participation

35. A larger and more difficult challenge is to involve the communities themselves in the research questions and to link the research to their own development. Such a participatory process with the community is a continuum that includes community consultation in protocol development, appropriate information disclosure and informed consent, protection of condidentiality and right of dissent, and community involvement in the conduct of research (Wejer & Emmanuel, 2000).

Externally-sponsored collaborative research

36. In externally sponsored collaborative research, sponsors and investigators have an ethical obligation to ensure that biomedical research projects for which they are responsible shall contribute effectively to capacity building which may include, but is not limited to the following activities:

    a. Designing and conducting biomedical research

    b. Strengthening research capacity to develop technologies appropriate to healthcare and biomedical research training of research and healthcare staff

    c. Educating the community from which research subjects will be drawn (Guideline 20 – CIOMS,

ETHICAL GUIDELINES FOR CLINICAL TRIALS ON DRUGS, DEVICES, AND DIAGNOSTICS

Introduction

A clinical trial is a scientifically designed experiment that evaluates the safety and efficacy of a treatment. There are four phases of clinical trials

Phase I study refers to the first introduction of a drug into humans. Normal volunteer subjects are usually studied to determine the levels of drugs at which toxicity is observed. Such studies are followed by dose-ranging studies in patients for safety and, in some cases, early evidence of effectiveness.

Phase II investigation consists of controlled clinical trials designed to demonstrate efficacy and relative safety. Normally, these are performed on a limited number of closely monitored patients.

Phase III trial is performed after a reasonable probability of a drug's effectiveness has been established. This type of trial is intended to gather additional evidence of effectiveness for specific indications and more precise definition of drug-related adverse effects. This phase includes both controlled and uncontrolled studies.

Phase IV trial is conducted after the national drug registration authority (i.e. BFAD) has approved a drug for distribution or marketing. This trial may include research designed to explore a specific pharmacological effect, establish the incidence of adverse reactions, or determine the effects of a long-term drug administration. It may also be designed to evaluate a drug in a population (such as children or the elderly) not studied adequately in the pre-marketing phases, or to establish a new clinical indication for a drug. Such research is to be distinguished from marketing research, sales promotion studies, and routine post-marketing surveillance for adverse drug reactions in that these categories ordinarily need not be reviewed by ethics review committees.

The four conventional phases in clinical drug development present different ethical issues. Careful consideration should be noted and addressed in each phase as indicated in the International Conference

Clinical Practice, General Consideration for Clinical Trials (E8).

General guidelines	1. All research involving human subjects should be conducted in accordance with the ethical principles provided for in the General Ethical Guidelines for Health Research on pp16-29.
	2. All clinical trials must have scientific and social value and, therefore, shall be adequately justified.
	3. The various phases of the pharmaceutical trial present different ethical issues that should be keenly looked into by the institutional ethics review committee (IERC). These issues include product toxicities in Phase I, use of placebo in Phases II and III, and professional integrity and conflict of interest in post-marketing activities in Phase IV.
Clinical equipoise	4. Investigator/s involved in clinical trials shall be governed by clinical equipoise. A state of clinical equipoise means that on the basis of available data, a condition of genuine uncertainty on the part of the clinical investigator/s and/or a community of medical experts exists regarding the comparative therapeutic merits of each arm in a trial. Thus they would be content to have their patients/clients pursue any of the treatment strategies being tested since none of them has been clearly established as preferable.
Enlistment period	5. The investigators/ should have adequate time to enlist the necessary number of participants to, and conduct the trial.
Adequacy of staff and facilities	6. The investigator/s should have adequate and fully informed staff, and adequate facilities to accurately and carefully undertake the trial.
Compliance with regulatory	7. A clinical research shall comply with the necessary regulatory requirements for the conduct of the

regulations on the approval and conduct of clinical trials issued by the Department of Health - Bureau of Food and Drugs (DOH-BFAD) in Administrative Order 47-A dated August 30, 2001.

The investigator/s and sponsor shall be responsible for complying with each of the applicable regulatory requirements of BFAD.

8. Investigational and comparator products, whether produced locally or abroad, should be prepared in accordance with the principles of good manufacturing practice, of assured quality, fully described, appropriately packaged and stored, and acceptably safe. All pre-clinical studies or available non-clinical and clinical information about the product shall be made available for review.

9. Good laboratory practices shall be strictly observed when a clinical trial requires laboratory assay.

Agreement with sponsor

10. The investigator/s shall establish with the sponsor an agreement on the protocol, standard operating procedures, monitoring, and auditing of the trial and allocation of trial-related responsibilities including publication and authorship.

Protocol

11. The protocol shall at least contain the following:

    a. General information about the trial such as investigator/s, sponsor/s, monitor/s, other qualified medical expert/s, diagnostic laboratories, and research institutions involved.

    b. Background information regarding the product under investigation, relevant current research findings and references to such information and data, potential risks and benefits, reasons for the indicated route of administration, dosage, periods of treatment, population to

compliance with good clinical practice, and regulatory requirements.

c. Objectives and purpose.

d. Trial design, which substantially determines the scientific integrity of the trial and reliability of the data, and which shall include the following:

    1) Description of the type of design and trial plan (double-blind, placebo controlled, parallel design) and diagram of procedures and stages
    2) Primary and secondary endpoints to be measured
    3) Measures to minimize or avoid bias, such as randomization and blinding
    4) Trial treatments and investigation product's dosage, packaging, labeling, and storage
    5) Estimated duration of subjects' participation in the trial
    6) Discontinuation rules for the subjects and the trial
    7) Treatment randomization codes maintenance and rules on breaking the code
    8) Procedures for accountability for product being investigated, placebos, and comparators
    9) Other sources of data

e. Selection and withdrawal of participants, which include inclusion, exclusion, and withdrawal criteria

f. Informed consent

g. Subjects' therapy or treatment, and monitoring

h. Efficacy parameters, methods, and timing

i. Safety parameters, methods, timing, and procedures for recording and reporting as well as monitoring adverse reactions

j. Plan for data and statistical analysis

k. Statement regarding direct access to trial data and documents for monitoring, audits, institutional ethics committee reviews, and regulatory inspections

l. Ethical considerations

m. Data management and record keeping

n. Financing and insurance

o. Publication plans and procedures

p. Clinical trial participants' information sheet/ brochure

12. Any amendment/s to the protocol should be resubmitted to the IERC and BFAD.

Use of placebo

13. Use of placebo is generally not acceptable when there are standard treatments available to a patient population. Thus, a placebo control may be used only when –

a. Standard therapy is unavailable
b. Existing treatment is of unproven efficacy, or possesses unacceptable side-effects
c. The placebo itself is an effective therapy
d. The disease has little adverse effect on the patient
e. Testing an add-on treatment to a standard therapy when all subjects get all treatments

f. The patient has provided informed rejection or refusal of standard therapy for a minor condition for which the patient refuses treatment, and when such refusal for therapy will not lead to unjustified affliction or irreparable damage or harm

Informed consent

14. Refer to section on Informed Consent in the General Ethical Guidelines for Health Research (pp16-29).

Therapy versus research

15. The difference between therapy and research shall be upheld throughout a clinical trial. The investigator/s shall ensure that participants comprehend and keep in mind that in a clinical trial, the drug is experimental and that its benefits are currently being proven.

Research on medical devices, diagnostic procedures and preventive measures

16. Clinical trials of medical devices, diagnostic procedures, and preventive measures, including vaccines, raise similar ethical concerns especially on free and informed consent, and potential conflict of interest.

a. Trials of critical medical devices such as implants which may present a potential serious risk to health, safety or welfare of the subject shall not be conducted on healthy volunteers. The current safety data on the medical device shall be gathered and the risks posed by the device considered and evaluated. Safety procedures in the introduction of such medical device in the patient shall be followed. The patient information sheet shall contain information on procedures to be adopted should the patient decide to withdraw from the trial. Medical devices that are not used regularly have less risk- potential than those used regularly. Likewise, devices used outside the body have less risk than those used inside

b. In the case of contraceptive implant trials, adequate monitoring for removal of the implant shall be done when the trial is over or the subject has withdrawn from the trial. Children born as a result of failure of the contraceptive being investigated shall be followed up for any abnormalities and properly reported to monitoring authorities.

c. For vaccine trials using active or live attenuated microorganisms, the subject may be exposed to the specific infection for which the vaccine is being tested. As such, the vaccinated subject shall be informed accordingly and properly cared for.

d. Clinical trials involving diagnostic agents using radioactive materials and X-ray should not necessarily expose subjects to more radiation than normal and shall be undertaken on patients undergoing the procedure for diagnostic or therapeutic purposes. Radiation limits for the use of such materials and X-rays shall be within the medically acceptable limits. Measures to safeguard research subjects and others who may be exposed to radiation shall be taken. Adequate provisions for detecting pregnancies to avoid risks of exposure to the embryo shall be given. Subjects shall also be provided information on possible genetic damage to their offspring.

Publication of clinical trial results

17. Clinical trial results shall be communicated in a timely fashion and published regardless of results or findings. Findings shall be brought into the public domain and generally made known through scientific and other publications.

18. Preliminary reports that raise false hopes and expectations of product safety, efficacy, and

19. The plan for publication and the actual publication of trial results shall not expose the identity of the participants or their family and community, or imperil their privacy or confidentiality as individuals, family, or community. As necessary, a clear consent to publication shall be obtained not only at the start of the trial but also at its completion.

ETHICAL GUIDELINES FOR HERBAL RESEARCH

Introduction

The use of herbal remedies can provide a practical and inexpensive way of alleviating illness in countries like the Philippines that is rich in natural resources and has a fecund pool of indigenous healing practices.

Philippine Republic Act No. 8423, the Traditional and Alternative Medicine Act of 1997 declared the policy of the state "to improve the quality and delivery of health care services to the Filipino people through the development of traditional and alternative health care and its integration into the national health care delivery system." This law aims to 1) encourage scientific research on and develop traditional and alternative health care systems that have direct impact on public health care; and 2) promote and advocate the use of traditional, alternative, preventive, and curative health care modalities that have been proven safe, effective, cost-effective, and consistent with government standards of medical practice.

These legislated objectives have generated research activities on herbal remedies or preparations to evaluate their safety and effectiveness. Necessarily, these researches involve human participants for which ethics review is mandated.

Advocates of herbal medicine are convinced that herbal products can be used without subjecting them to the same rigorous scientific evaluation (e.g., requirement for pre-clinical trials) required in Western medicine. It is argued that the current universal scientific procedures and standards are not applicable to remedies with a long history of use in and have been accepted by communities.

This set of ethical guidelines will not dwell on the aforementioned issues surrounding herbal research. In this regard, these ethical guidelines were formulated with the Traditional and Alternative Medicine Act as its political framework and Good Clinical Practice for its scientific underpinning.

These guidelines shall serve as parameters in the conduct of research on herbal remedies based on universally accepted ethical principles such as respect for persons, beneficence, and justice. Thus, it is expected

and rights of all human participants in research. Aside from this substantive type of ethical requirement, ethically sound research must satisfy a number of important procedural requirements of which the most important is a prior review by an independent and competent ethics review committee. The latter requirement is what these ethical guidelines will attempt to describe.

General guidelines

1. All research involving human subjects should be conducted in accordance with the ethical principles provided for in the General Ethical Guidelines for Health Research on pp16-29.

2. There must be proof of long history of use of the herbal plant/remedy to be tested. An exhaustive literature search on prior studies must introduce the research proposal. Any documents supporting its putative actions and traditional use in the community must be incorporated in the research proposal.

3. The original herbal preparations and manner of use by people in the community must be similar to that intended in the proposed research.

4. Once an active principle is identified from the herbal preparation and there are intentions to synthesize it for research and eventual commercial purposes, any studies thereafter need to be reviewed based on the International Conference on Harmonization Good Clinical Practice Guidelines and Good Manufacturing Practice guidelines.

5. Although efficacy of herbal preparations is a major objective of herbal researches, adverse reactions such as side effects, tolerance profile, and interaction with other administered preparations should always be part of herbal research.

6. Research in herbal remedies should include standardization of the preparation and identification

studied and assessed are the same.

7. In the absence of a standard for the test preparation, the geographic area, maturity of collection of the plant, and the method of its preparation must be clearly described.

8. Priority should be given to clinical trials that are responsive to the country's health/economic needs.

Special guidelines

Informed consent

9. Uncertainty regarding product adulteration, interactions between herbal remedies and other entities, minimal toxicity data, and incomplete prior dose finding must be clearly disclosed to all concerned, particularly in the informed consent process (WHO Operational Guidance: Information needed to support clinical trials of herbal products, 2005).

Recruitment of volunteers

10. When normal volunteers are recruited, participants must preferably come from the community where the herbal preparations are frequently used.

Participation of traditional healers

11. Cultural settings and expectations must be considered in the review of the proposal and this may require inviting a traditional healer or a known scholar of herbal medicines in the ethics review board.

Research design

12. Placebo-controlled trials may be accommodated in consonance with the guidelines on the use of placebo as indicated in Ethical Guidelines for Clinical Trials on Drugs, Devices, and Diagnostics - 13b, 13d, and 13f.

13. Effectiveness of herbal preparations may not only be measured with improvements in health or

disease-related variables. It may also be measured in terms of overall health and well-being.

Transport of materials

14. No indigenous materials used in the research may be transported outside the country unless the source (represented by the community leader, government agency or institution) of the material and the recipient sign a material transfer agreement.

15. Researchers must comply with the transfer agreement if plant products or herbal preparations will be tested outside the country.

Benefit sharing

16. Where possible, the community from where the medicine originates should be consulted during the course of the research, and the results and benefits of the research should be shared with this community (WHO Operational Guidance: Information needed to support clinical trials of herbal products, 2005).

17. A memorandum of agreement regarding benefit sharing and patenting conditions especially for indigenous plant products must be set as early as the planning stage of the research.

Commercialization of herbal preparations

18. Researchers must include provisions for conditions when the herbal preparations may likely be commercialized. They should be guided by existing laws and regulations of the Philippine Intellectual Property Rights Office.

ETHICAL GUIDELINES FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE RESEARCH

Introduction

Worldwide, there is a continuing popular interest in and utilization of complementary and alternative medicine (CAM). In the Philippines, promotion of the utilization of CAM is embodied in Republic Act No. 8423, the Traditional and Alternative Medicine Act of 1997 which declared that the state shall "improve the quality and delivery of health care services to the Filipino people through the development of traditional and alternative health care and its integration into the national health care delivery system."

The World Health Organization and national health authorities have looked to CAM as a welcome wellspring of accessible, cost-effective, and beneficial alternative to the expensive conventional methods of treatment. Scientists, however, call for the application of the rigors of scientific investigation before specific CAM modalities could be promoted for widespread use.

Complementary and alternative medicine is defined as a group of diverse medical and health care systems, practices, and products that is not presently considered to be part of conventional medicine. Complementary medicine is used together with conventional medicine, while alternative medicine is used in place of conventional medicine (NCCAM, 2006). As opposed to CAM, traditional medicine (TM) is defined as the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to a particular culture, whether explicable or not, used in the maintenance of health, and in the prevention, diagnosis, improvement, or treatment of illnesses. However, the term complementary/alternative/non-conventional medicine is used interchangeably with traditional medicine in some countries (WHO, 2000). It will also be so used in this guidelines.

CAM therapies include (NCCAM):

1. Biologically-based therapies such as dietary supplements, herbal products, animal products, and aromatherapy;

2. Manipulative body-based methods such as massage, acupressure, chiropractic, and osteopathic manipulation;

3. Mind-body interventions such as meditation, prayer, mental healing, art or music therapy;

4. Energy therapies such as *qi gong*, *reiki*, therapeutic touch, pranic healing, electromagnetic fields methods; and

5. Other methods used in alternative medical systems such as in medical traditions that developed in the West (e.g., naturopathy and homeopathy), and in Oriental traditional medicine (e.g., *ayurveda*, *unani*, and traditional Chinese medicine).

While some scientific evidence exists regarding some CAM therapies, for most there are key questions that have yet to be answered through well-designed scientific studies—questions such as whether these therapies are safe and whether they work for the diseases or medical conditions for which they are used.

General guidelines

1. All research involving human subjects should be conducted in accordance with the ethical principles provided for in the General Ethical Guidelines for Health Research on pp16-29.

Specific guidelines

Participation of traditional medicine expert

2. The technical review committee should include an expert in the specific traditional medicine modality being considered in the research protocol.

Study design

3. In contrast to conventional medicine, CAM modalities focus on beneficial effects (e.g., quality of life) rather than efficacy. In this context, study designs other than randomized controlled trials may be acceptable.

4. Blinding could be difficult to achieve in the application of certain CAM modalities, in which case the research protocol should provide mechanisms for blinding the clinical outcome evaluator.

Rescue medication	5. The protocol must identify and describe the rescue medication which should be available to the study participants who may require such an intervention.

ETHICAL GUIDELINES FOR EPIDEMIOLOGIC RESEARCH

Introduction

Epidemiology is the study of the determinants of the incidence of diseases in public health. A related study, clinical epidemiology, deals with the prevention, diagnosis, risk factor analysis, causation, and treatment of diseases. Epidemiological research aims at studying determinants of health and disease in human populations in order to improve people's opportunities for making choices.

A major segment of epidemiologic research involves collection of data from individuals which may or may not require procedural interventions. Although researchers may claim that epidemiologic research such as observational studies often do not involve interventions that may cause discomfort to eligible individuals, these studies still require the individual's time and attention and may encroach on the individual's right to privacy and confidentiality. There are also social risks that need to be considered. Most people who take part in public health epidemiological research gain no personal benefit and often may not have a disease that needs treatment.

Considering the nature of observational epidemiologic studies, the principles that govern consent procedures need not be as strict as those for experimental study designs. However, when the investigator proposes selective disclosure of information, the ethics committee must review the protocol and decide on its adequacy.

Ethics committees and other appropriate authorities should set the conditions for the use of genetic and other biological materials collected in epidemiologic researches.

These guidelines are for consideration of ethics committees for the protection of participants in epidemiologic research involving humans, focusing primarily on non- experimental studies. Its main difference from other researches is in the nature and extent of the informed consent process.

General	1. All research involving human subjects should be

principles provided for in the General Ethical Guidelines for Health Research on pp16-29.

Specific guidelines

Informed consent

2. For case-control and cohort studies, non-disclosure of all the study objectives may be permissible if full disclosure of the study hypothesis could bias the investigation.

3. Consent may not be required for collection of information in the public domain. Public domain information may include common general data such as address, marital status, educational attainment, and number of children among others.

   It should be realized that communities differ in their definition of what type of information about citizens is regarded as public.

4. Data regarding income, personal habits, preferences, personal opinions, political and religious inclinations, among others, may be considered confidential and will require consent prior to collection.

5. Collection of data by questionable means, such as deception, should not be condoned.

6. Data gathered for administrative purposes (as long as the information is not sensitive) do not require consent and may be waived if getting consent is considered impractical or too expensive.

7. Review of medical records may be done without requiring consent if anonymity can be maintained and if information sought is considered non-sensitive (Gordis and Gold, 1980).

8. The appropriate permission for storing biological

individuals. If the samples are to be used for research not covered by the original consent, an ethics committee should decide whether renewed consent is needed or if the analyses may be done on anonymized samples. Details regarding the collection and storage of biological material are covered in the document on ethical guidelines for genetics research.

9. A person of authority may be allowed to give consent for collection of data among children and other individuals who are temporarily or permanently unable to give informed consent by themselves, provided that the research does not involve more than minimal risks to the participants.

10. If the information is obtained by means of a questionnaire, and adequate information has been given to the research subject, there is no need for a written informed consent, since answering the questionnaire implies consent.

11. There are alternative methods of obtaining informed consent (e.g., verbal consent). These are covered by the document on Ethical Guidelines for Social and Behavioral Research (pp48-49).

Privacy and confidentiality

12. Working with personal data is a privilege that calls for a high degree of data protection, especially in situations where data are used without personal consent. A working standard for data protection that secures as little risk of disclosure as possible should be developed.

Information shared with participants

13. Important findings from the research should be made available to all the participants in a suitable form.

Compensation for participants

14. Compensation commensurate to the time given and effort exerted by participation is encouraged

ETHICAL GUIDELINES FOR SOCIAL AND BEHAVIORAL RESEARCH

Introduction

Social and behavioral research necessarily involves individuals, groups, organizations or societies, and for a great part are conducted in the field. There are several perspectives that one may bring to bear on such research: positivist, interpretive, or critical (see Glossary, pp.88-89). Regardless of the preferred perspective of an individual researcher, social and behavioral research involves the basic dilemma of balancing the pursuit of valid knowledge and concerns for the participants' rights for privacy as well as preserving their integrity, dignity, and autonomy.

The guidelines below are consistent with existing ones on research on human subjects but are made more specific for social research.

General guidelines

1. All research involving human subjects should be conducted in accordance with the ethical principles provided for in the General Ethical Guidelines for Health Research on pp16-29.

Special guidelines

Informed consent

2. Informed consent shall be obtained, with the possible exception of research involving archival work, participant observation, and observation in public places. The researcher shall inform his/her participants as to the nature of the research and obtain verbal or written consent. Verbal consent must be attested to in the absence of a written consent. Coercion in any form may not be used to force individuals to participate. If participants are minors, consent of the parent/guardian must be obtained. Assent of the minor must also be obtained, properly documented, and attested to by an impartial witness of legal age.

Privacy and confidentiality

3. The researcher shall respect the respondent's right to privacy and preserve the confidentiality of

render the participants anonymous to those not directly involved in the research.

4. The researcher shall not release information that permits linking specific individuals to specific information. In cases where information pertaining to groups or specific communities exposes them to possible harm or abuse, the researcher shall refrain from identifying such groups or communities unless required by law.

Access to services or benefits

5. In carrying out experimental or quasi-experimental designs in field research, access to services or benefits provided to the experimental group shall also be provided to the control group.

6. In the case of field research, the participants may be given information about the study through feedback sessions or other means, with the possible exception of the intervention being the benefit itself.

7. Where the research may cause emotional and psychological stress to the study participants, there shall be provisions for care and counseling.

Withholding information

8. The researcher should avoid deception. In exceptional cases where the withholding of information may be justified by the integrity of the research design and the importance of the objectives, debriefing must be performed. However, in no instance should the withholding of information result into irreversible harm.

ETHICAL GUIDELINES FOR THE CONDUCT OF RESEARCH ON POPULATIONS TRAUMATIZED IN EMERGENCIES AND DISASTERS

Introduction

Traumatized populations live in communities that have experienced extreme forms of life- threatening stress due to natural calamities or human atrocities such as armed conflict, political repression as well as criminal and domestic violence. The severe stress on these populations may have lingering physical, social, and psychological consequences, including chronic poverty, deprivation of basic needs, violation of basic rights, vulnerability, and a profound sense of hopelessness and disempowerment.

Research involving traumatized populations must be guided by principles applicable to the practice of humanitarian assistance in general and work with vulnerable groups in particular. Of relevance are universal humanitarian imperatives of alleviating human suffering, preserving human dignity as well as protecting and respecting human rights regardless of race, creed, nationality or political belief. More specifically, work with traumatized populations must place special attention on the unique needs and special concerns of survivors, including those of specific cultural, racial, and ethnic group members, so that services and opportunities are appropriate and acceptable to these individuals (where feasible and appropriate to the study question). Issues of possible repeat traumatization and potential risks (e.g., stigmatization and reprisals) for the study population should likewise be fully addressed.

These guidelines address the following issues: the potential for harm resulting from the research process and its sociopolitical implications, the potential for the exploitation of subjects, conflicts of researchers' interest with that of the community being studied, the recruitment of participants and obtaining of valid informed consent, ensuring gender and cultural sensitivity, and the need for research to contribute to the healing and re-empowerment of the traumatized community.

General guidelines

1. All research involving human subjects should be conducted in accordance with the ethical principles provided for in the General Ethical

2. In deliberations on research involving traumatized populations, a community advocate or representative must be present.

3. In the course of research, the psychosocial needs of the community must be taken into account.

4. The different roles of the researchers, caregivers, and volunteer workers must always be clarified and the potential conflicts of interest identified.

5. The ethics review committee must put in place a monitoring mechanism to ensure that the above guidelines are followed.

Special guidelines

Research protocol

6. The research proposal must explain how its objectives relate to the priorities of the community.

7. The research methodology must ensure that the research process will not impede the healing or recovery of the community. It must contribute to the process of designing intervention programs.

8. The protocol must include provisions for aftercare, including closure activities and a proper referral mechanism to deal with the health needs of participants and members of the research team.

9. Researchers must demonstrate familiarity with the community's situation and their cultural beliefs and practices.

   a. The research team must include a local community counterpart.
   b. The research team must describe a preliminary community mapping/scoping exercise to ensure familiarity with the situation

resources which will support the faithful implementation of the project.

c. The research team must demonstrate the ability to anticipate adverse reactions and facilitate appropriate interventions.

10. The researchers have the responsibility to identify the specific vulnerabilities of the research population and the mechanisms that are being put in place to address them.

Recruitment and informed consent

11. The researchers must consult the community and secure its permission before approaching individuals for their informed consent.

12. The research team must identify factors that serve as a barrier to the freedom of individual members of the subject population to give consent, and provide effective mechanisms to address them.

Community participation

13. The study design must demonstrate the principles of participatory research and describe the involvement of the community participants in research planning, design, conduct, analysis, validation/feedback, and utilization.

Non-disclosure of information

14. The withholding or non-disclosure of pertinent information must be justified in the context of protecting the participants from specific harm or risks and must be done according to the ethical guidelines for social science research (pp48-49), and with the approval of the ethics review committee.

NATIONAL ETHICAL GUIDELINES FOR HEALTH RESEARCH

ETHICAL GUIDELINES FOR HIV/AIDS RESEARCH

Introduction

HIV/AIDS research encompasses a wide range of health research that includes basic research on the infectious agent and its effect on individuals, clinical trials on vaccines and other therapeutic protocols, and investigations on the psychosociocultural aspect of HIV/AIDS. The basic principles of research ethics shall, therefore, apply in all these activities as they apply to other health research activities. However, institutional research ethics committees, researchers, and funding agencies should pay special attention to the issues of justice and respect for groups and individuals affected by HIV/AIDS as their condition gives them distinct vulnerabilities because of the cultural sensitivity of reproductive health issues.

For a more detailed discussion of ethical issues, the reader is referred to the *Ethical Guidelines in AIDS Investigations in the Philippines* published by the Philippine National AIDS Council and the AIDS Society of the Philippines, and the Philippine AIDS Prevention and Control Act of 1998.

General guidelines

1. All research involving human subjects should be conducted in accordance with the ethical principles provided for in the General Ethical Guidelines for Health Research on pp16-29.

Special guidelines

Identification consent

2. The recruitment process shall be sensitive to the social implications of being identified as a potential HIV/AIDS case or of belonging to a high-risk group. Specific mechanisms to protect the privacy of individuals shall be described and put in place.

3. Special attention shall be given to the possible sensitive nature of the information to be extracted from the research participants and, if applicable, the necessity of undergoing an HIV test. It is also important to determine the participant's willingness

reportability, and the implication on his/her sexual activities if found positive.

The participant must also be informed that he/she is free to withdraw from the study anytime.

Pre- and post-test counseling

4. Pre- and post-test counseling by well-trained, culture- and gender-sensitive research personnel shall be put in place as part of the research protocol.

Standard of care

5. In an interventional study, the control group shall receive the standard of care accepted by the larger community. It is unethical to subject the control group of affected individuals to placebo treatment or be withdrawn from the current mode of treatment before the start of the study.

Research benefits

6. Special effort shall be exerted to make the beneficial findings of the research project accessible and available to participants under reasonable circumstances.

Use of research data and publication of reports

7. Special care shall be taken in the public use of research data and the publication of reports so that participant groups are not further stigmatized or become blameworthy targets. Reports shall be carefully examined for gender and culture bias.

ETHICAL GUIDELINES FOR RESEARCH ON ASSISTED REPRODUCTIVE TECHNOLOGY

Introduction

Research in assisted reproductive technology includes studies to improve ovulatory rates, ejaculatory efficiency, embryo viability, fertilization success, and uterine hospitability. It may also involve studies on the psychosociocultural aspects of reproductive technology. Research in the reproductive health field in general is studded with gender issues.

In general, assisted reproductive technology is ethically complex. This is because the research participants, in contrast to other health researches, include two individuals (i.e., the source of the ovum and the source of the sperm) and the fertilized egg in various stages of development, whose status as a moral agent has religious and ethical implications. This means that the ethical principles enunciated for health research in general must be equitably and equally applied to the research participants with special consideration for gender and religious issues.

The Philippine Obstetrical and Gynecological Society (POGS) and the Philippine Society of Reproductive Endocrinology and Infertility have set requirements that must be satisfied by medical hospitals, clinics, centers, and/or other facilities that conduct assisted reproductive techniques/technologies and related research. Additionally, it is emphasized that clinical and biological research involving assisted reproductive technology shall be carried out under the supervision of a qualified practitioner who has acquired adequate and up-to-date training in, and is sensitive to the technical aspects of using technology for assisted reproduction.

General guidelines

1. All research involving human subjects should be conducted in accordance with the ethical principles provided for in the General Ethical Guidelines for Health Research on pp16-29.

Specific guidelines

Research on gametes, human zygotes

2. The use of gametes in fertility research shall be subject to ethical review with special attention to the harm and risks involved in the collection of

3. The intentional creation of human zygotes, embryos or fetuses for study, research, and experimentation or for commercial and industrial purposes is unacceptable (POGS, 1995).

4. Research may be conducted on a human embryo only for the purpose of improving that particular embryo's chances of being born alive and healthy.

5. The sale of human zygotes is unacceptable.

Research participants

6. Special effort shall be exerted to ascertain the emotional stability and maturity of research subjects. Gender-sensitive counseling shall be made available and offered as an adjunct service to research participants.

Informed consent

7. It shall be the responsibility of the attending physician to ensure that consent of research subjects is given freely and on the basis of adequate information and that potential conflict of interest is resolved. The investigator must be sensitive to the coercive and unfair pressure on women to bear children.

Privacy and confidentiality

8. Researchers shall uphold the dignity of participants and protect their privacy by putting in place adequate mechanisms for upholding the confidentiality especially of the circumstances of conception of children born out of assisted reproductive technology.

Embryos from in vitro fertilization

9. Embryos formed by in vitro fertilization shall be given respect commensurate to their status (POGS,1995). Extreme care shall be exercised in the handling of human embryos.

10. Arrangements regarding unused embryos, sperms, and ova shall be agreed upon by the investigator and the source/s prior to the research.

ETHICAL GUIDELINES FOR GENETIC RESEARCH WITH A SECTION ON STEM CELL RESEARCH

Introduction

A person's current and future health is the interaction of many factors, including environment, lifestyle, and genes. Genes are the biochemical instructions for the development and growth of individuals. When a gene is altered, it may cause or contribute to a disease. Genes themselves do not cause disease, but alterations in the normal gene sequence may lead to a disease.

The presence of a "disease allele" usually leads to an increased predisposition or susceptibility for developing a disease, with no certainty that disease will actually happen. There are various reasons for genetic testing: diagnosis, carrier testing, prenatal testing, predictive testing, susceptibility, predisposition or risk testing, genetic screening, and research testing. This raises a new set of issues, particularly on how this information is interpreted by those who might be affected in the future. Even for some single-gene diseases, not everyone with the gene develops the disease. This variability in gene expression further complicates multifactorial inheritance. Many counselors find it difficult to explain the uncertainty associated with genetic testing.

Human genetic research aims to identify genes associated with health and disease, and elucidate their functions. The ultimate goal is to use the knowledge gained through research to discover ways of better diagnosis and treatment. The main types of genetic research are: cloning human genes, family studies, linkage analysis, DNA sequencing and association studies, pharmacogenetics, behavioral genetics, population-based genetics, and stem cell research. Genetic information may be obtained in several ways. One of the most important ways is from a family medical history, which is a kind of genetic test that are commonly used by good doctors. Genetic information is also available from clinical examination, and testing of DNA, RNA, proteins, or cellular metabolites that indicate gene activity.

Human stem cell research holds enormous potential for contributing to an understanding of fundamental human biology, leading to the possibility of novel treatments and, ultimately, cures for many diseases for which

and informed about ethical and policy issues raised by stem cell research and its applications. Informed public discussions of these issues should be based on an understanding of the science associated with stem cell research and should involve a broad cross-section of society. Special efforts should be made to promote equitable access to the benefits of stem cell research. Intellectual property regulations for stem cell research should set conditions that do not restrict basic research or encumber future product development.

The ethical considerations in reviewing genetic research are no different from those that arise when reviewing other types of research. However, in addition to those that apply to all research involving humans, there are ethical issues unique to genetic research. These arise from the nature of genes and genetic information which, though personal, are also shared with other family members and with unrelated individuals in the population.

These guidelines shall be used by research institutions, scientists, pharmaceutical companies, health researchers, and institutional review boards for the ethical pursuit of genetic research so that the expected benefits in the improvement of health and healthcare will be attained.

General guidelines

1. All research involving human subjects should be conducted in accordance with the ethical principles provided for in the General Ethical Guidelines for Health Research on pp16-29.

2. Given the familial nature of genetic research, confidentiality, privacy, and security are important considerations in the ethics review of a genetic study.

Specific guidelines

Collection of samples from humans

3. Human biological samples for genetic research include samples that can serve as DNA, RNA, and protein sources: solid tissues, biopsies, aspirates, scrapings, and body fluids such as blood, saliva, ocular fluids, and excretions. Samples may be collected, processed, used and

   a. Diagnosis and healthcare, including screening and predictive testing
   b. Medical and other scientific research (i.e., epidemiological, prognostication, population-based genetic studies, anthropological or archeological studies)
   c. Forensic medicine, in which case, use of samples shall be in accordance with domestic laws and consistent with laws on human rights
   d. Development of drugs, biomedical devices, molecular diagnostics, and medical technologies
   e. Others as dictated by local and/or international interests, or in the event of global health and technology trends, or other reasons of public interest

Informed consent

4. Prior, voluntary, informed, and expressed consent, without inducement by financial or personal gain, should be obtained for the collection of biological samples, human genetic and proteomic data, and for their subsequent processing, use, and storage.

5. Informed consent shall be required for all research protocols that propose the use of any kind of human tissue sample for genetic research.

6. Potential research subjects should be adequately informed about what will happen to any genetic material or information obtained as part of the study.

7. Subjects should be recruited as individuals in their own right rather than as a family group, and should consent as individuals.

8. In cases where identities of groups or communities may be linked with genetic traits under study, informed consent for the whole group may be obtained from an elected or recognized leader who will be responsible for making decisions on

9. Informed consent shall not be required for those protocols for genetic research that use anonymous samples or samples that have no identifiers. Any sample that can be linked to an individual through an identifier, or through any person or institution that has the capability to link the sample with its source, is not to be considered anonymous.

10. Stored biological samples collected for purposes other than those stated in No. 3 above may be used to produce human genetic or proteomic data with the prior, free, informed, and express consent of the person concerned.

11. In case informed consent is withdrawn, the samples and data should be irretrievably unlinked from their source. This will be accomplished by the destruction of all identifiers.

Informed consent of vulnerable groups

12. Genetic studies involving indigenous groups shall be guided by domestic and international regulations on respect for human rights and privacy, and protection from exploitation.

Genetic counseling and disclosure

13. The informed consent shall include statements on the disclosure and sharing of the results and findings of the study, i.e., to whom should the information be revealed, etc.

14. Genetic counseling (pre- and post-test) shall be provided when there is a need to disclose the findings of the genetic study.

Privacy, confidentiality, and security

15. Researchers must ensure the confidentiality and privacy of stored genetic information or research results relating to identified or potentially identifiable participants in accordance with domestic and international laws on human rights. Researchers should also ensure that safeguards

16. Disclosure of genetic information is sometimes impossible to avoid. Such information should be dealt with sensitively, and the possibility that such a disclosure may occur should be considered in the initial process of seeking consent.

17. There is potential harm to participants arising from the use of genetic information, including stigmatization or unfair discrimination. Researchers should take special care to protect the privacy and confidentiality of this information.

18. Identifying genetic information must not be released to others, including family members, without the written consent of the individual to whom the information relates, or a person or institution which may legally provide consent for that person.

19. The patient's right to privacy (researcher's duty for confidentiality) continues after the patient's death so that confidential information may be revealed after death only with proper legal authority. The only exception is the right to disclose information to a family member if there is a clear and urgent need to provide information to avoid a serious health risk.

Handling of biological specimens

20. Genetic research often involves the storage of DNA or other biological samples in "tissue" or "sample" collections. In some cases, samples can be anonymized so that the donors cannot be identified. This raises problems in cases where the information from research might be of value to the individuals or families. Most genetic research studies will require linking of DNA samples to health records, family pedigrees, and individual results.

21. Handling and preservation of biological samples shall be in accordance with standard scientific

22. Disposal of stored biological specimens shall be in accordance with standards for handling biohazardous and infectious materials.

23. Transport, transfer, and disposal of all stored biological samples shall be properly documented and filed.

24. Retention time for stored biological samples shall be determined by the respective institution.

25. All specimens in a tissue bank must be accompanied by a copy of the consent agreement signed by the donor.

26. No specimen shall be removed from a tissue bank for research purposes without an approved research protocol.

27. A researcher must not transfer genetic material or related information to another research group, unless

    a. The researcher and the other research group are collaborating on research which has been approved by their respective institutional ethics review committee
    b. The genetic material and information are provided in a form that ensures that participants cannot be identified

Ethical considerations in stem cell research

28. Securing stem cells for research, whether from children, adults or naturally aborted fetuses, must be done under conditions of the most rigorous integrity for several reasons:

    - To protect the interests of the donors
    - To reassure the public that important boundaries are not being overstepped
    - To enable those who are ethically uncomfortable with elements of this research to participate to the greatest extent possible
    - To ensure the highest quality of research and outcomes

29. Obtaining adult stem cells and hematopoietic stem cells presents no ethical problems. Whether from adults or from children, protection of donors is the same as in research on human subjects where adequate protection and regulation exist.

30. Research with aborted fetuses and pre-implantation embryos is highly controversial and may be unacceptable to several sectors of society. Thus, where the research benefits may be obtained using adult and cord blood stem cells, the use of these acceptable alternative sources is strongly recommended.

31. Patients and researchers should be able to avoid participating in stem cell use if the cells were derived in a way they consider unethical.

32. Documentation of the original source of the stem cells should be made readily available to researchers and potential recipients of stem cell-based therapies.

ETHICAL GUIDELINES FOR INTERNATIONAL COLLABORATIVE RESEARCHES

Introduction

Health research is a public good whose burdens and benefits should be shared equally by all the concerned populations (Torres-Edejer, 1999). However, North-South research collaboration is currently plagued by differing interpretations of ethical standards of doing research in developing countries. Should new treatments be compared against Western standards of care or against local existing standards? Can communities benefit from research they have taken part in when they may not be able to afford the new interventions they have helped prove efficacious? How can researchers and institutions in developing countries be strengthened through international collaboration (Lansang and Crawley, 2000)?

One other major issue is that of inequitable funding, with only 10 percent of global research funding going to diseases which make up 90 percent of the global burden. For this, three guideposts - Think action - Think local - Think long term - can be used (Torres-Edejer, 1999).

Scientific advances are not the only yardstick to measure success of North-South research collaboration: the choice of identified priorities as areas of work, the sustainability of the studied interventions outside the research setting, and the investment in local research capacity are becoming equally important as indicators of success (Torres-Edejer, 1999).

In order to support health research in developing countries that is both relevant and meaningful, the focus must be on developing health research that promotes health equity and developing local capacity in bioethics (Bhutta, 2000).

To achieve the goals of effective collaborative health researches between North and South, the following guidelines must be given utmost consideration (Swiss Commission for Research Partnership with Developing Countries, 1998):

1. Decide on the objectives together;

3. Share information and develop networks;
4. Share responsibility;
5. Create transparency;
6. Monitor and evaluate the collaboration;
7. Disseminate the results;
8. Apply the results;
9. Share the profits equitably;
10. Increase research capacity; and
11. Build on achievements.

Finally, the above considerations should result into a clear agreement on the conduct of collaborative research including data management and research outputs (e.g., storage and utilization of data, publication strategy, dispute settlement, nature of benefits and their distribution) (South African Medical Research Council, 2005).

General guidelines

1. All research involving human subjects should be conducted in accordance with the ethical principles provided for in the General Ethical Guidelines for Health Research on pp16-29.

Special guidelines

2. Research approved for implementation by an ethics review committee (ERC) in a foreign country must also be subjected to ethics review in the country of implementation. When the research is intended for implementation in several communities, the ERC that has jurisdiction over a particular community has the right to conduct its own review before giving approval for the research to be carried out.

3. There shall be clear agreements on all aspects of the research. These include intellectual property sharing, management of the research process, division of responsibilities, finances, spreading of benefits and burdens and other appropriate aspects.

GUIDELINES ON AUTHORSHIP AND PUBLICATION

The publication of research results gives rise to ethical problems and controversies when there are ambiguities regarding credit for authorship and uncertainty on the responsibility for various aspects of the research and the subsequent publication. These ambiguities and uncertainties have made it imperative for the Philippine Health Research Ethics Board to provide guidelines to clarify when researchers may be recognized as authors, and to elucidate the scope of their accountability.

Authorship

1. All qualified authors must be given due recognition by being included in the list of authors.

2. Scientists may be listed as authors of a scientific paper only if they have made substantive intellectual contributions to the pertinent research. Each listed author must have participated sufficiently in the research to be publicly responsible for specific parts of the publication.

3. To be recognized as an author, a contributor must have provided substantial input to one of the following:

   a. Conception and design
   b. Acquisition of data
   c. Analysis and interpretation of data

4. The following shall not be regarded solely as grounds for recognizing research contributors as authors:

   a. Acquisition of funding
   b. Collection of data
   c. General supervision

5. The list of authors shall include a guarantor who

Publication

6. Every listed author must share part of the responsibility for -

   a. Drafting the article or revising it for intellectual content, and
   b. The final approval of the version to be published.

7. In submitting articles for publication, the authors must provide the following to the editor:

   a. Contribution of each author to the paper;
   b. Acknowledgment of contributors other than the authors; and
   c. Statement that the authors observed ethics review committee requirements, the National Ethical Guidelines for Health Research, and pertinent guidelines on the care and use of animals.

8. The authors shall obtain the informed consent of subjects as a condition for the publication of photographs or identifiable information.

9. Sponsors or other interested parties may not impose impediments to the publication of research outcomes.

GLOSSARY

active principle (in medicinal preparations) – the substance in a medicinal preparation that is bringing about the clinical effects expected or observed

adverse events – any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment.

serious adverse event – the adverse event is serious and should be reported when the outcome is death, life-threatening, hospitalization, disability, congenital anomaly and requires intervention to prevent permanent impairment or damage

serious and unexpected adverse event – the unexpected adverse drug reaction is an adverse reaction, the nature or severity of which is not consistent with the informed consent / information sheets or applicable product information (e.g investigator's brochure for the unapproved investigational product or package insert/ summary of product characteristic for an approved product

AIDS (acquired immune deficiency syndrome) – the clinical manifestations in the advanced stages of HIV infection characterized by the breakdown of the immune system

alternative medicine – a health treatment modality which is non-allopathic, occasionally non-indigenous or imported healing method, though not necessarily practiced for centuries nor handed down from one generation to another

anonymized sample or data – biological sample or data that cannot be linked to an identifiable person through destruction of that link to any identifying information about the person who provided the sample or data

approval – favorable decision of the Ethics Committee following a review of the application

archival work – research involving the examination of records or documents

assent – authorization for one's own participation in research given by a minor or another subject who lacks the capability to give informed consent. The assent is a requirement for research in addition to consent given by a parent or legal guardian

assisted reproductive technology – all treatment or procedures that include the in-vitro handling of human oocytes and human sperm or embryos for the purpose of establishing a pregnancy (e.g., in vitro fertilization and transcervical embryo transfer, gamete intrafallopian transfer, zygote intrafallopian transfer, tubal embryo transfer, gamete and embryo cryopreservation, oocyte and embryo donation, gestational surrogacy)

behavioral research – studies regarding the actions or reactions of persons in response to external or internal stimuli

behavioral genetics – The study of genes that determine behavioral traits and phenotypes

benefits – any direct or indirect good effect of the research study to the participants

– something that promotes or enhances well-being; an advantage

direct benefits – derived by a research subject if it arises from the use of an experimental substance or device

indirect benefits – is derived when it comes about as an unintended or unlikely consequence of research participation

bias – the systematic tendency of any factors associated with the design, conduct, analysis and evaluation of the results of a clinical trial to make the estimate of a treatment effect deviate from its true value (ICH Harmonized Tripartite Guideline, General Considerations for Clinical Trial (E8)

blinding/masking – a procedure in which one or more parties of the trial are kept unaware of the treatment assignment/s. Single blinding usually refers to the subject/s being unaware, and double-blinding usually refers to the subject/s, investigator/s, monitor, and, in some cases, data analyst/s being unaware of the treatment assignment/s (ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice (E6,R1)

carrier testing – testing to identify individuals who carry recessive genes; testing designed for healthy people who have no symptoms of disease, but who are known to be at high risk because of family history

case-control study – type of investigation that attempts to look backward in time to identify characteristics that may have contributed to disease development by comparing responses of cases (those affected with the disease) and controls (the unaffected persons)

cellular metabolites – the molecular substrates and products of various cellular processes

chief/principal investigator – the person primarily responsible for the implementation of a research project

clinical equipoise – "The ethics of medical practice grants no ethical or normative meaning to a treatment preference, however powerful, that is, based on a hunch or anything less than evidence publicly presented and convincing to the clinical community. Persons are licensed as physicians after they demonstrate the acquisition of this professionally validated knowledge, not after they reveal a superior capacity for guessing." (Freedman, 1987)

– a state of clinical equipoise means that on the basis of available data, a condition of genuine uncertainty on the part of the clinical investigator/s and/or a community of medical experts exists regarding the comparative therapeutic merits of each arm in a trial. Thus they would be content to have their patients/clients pursue any of the treatment strategies being tested since none of them has been clearly established as preferable.

clinical research – is a study done with human volunteers to answer specific health questions. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people and ways to improve health. Interventional trials determine whether experimental treatments or new ways of using known therapies are safe and safe and effective under controlled environments. Observational trials address health issues in large groups of people or population in natural settings. The different types of clinical researches are: Treatment trials test experimental treatments, new combination of drugs, or new approaches to surgery or radiation therapy; prevention trials look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals or lifestyle changes. Diagnostic trials are conducted to find a better test or procedures for diagnosing a particular disease or conditions. Screening trials test the best way to detect certain diseases or health conditions. Quality of life trials or supportive care trials explore ways to improve comfort and the quality of life for individuals with a chronic illness. (http://www.Clinicaltrials.gov/ct/info/whatis. Retrieved May 17, 2006)

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– a systematic study on pharmaceutical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reactions to investigational products, and/or to study the absorption, distribution, metabolism, and excretion of the products with the object of ascertaining their efficacy and safety (WHO Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products)

– Investigative work to evaluate new drugs, medical devices, biologics, or other interventions to patients in strictly scientifically controlled settings. Clinical trials may be designed to assess the safety and efficacy of an experimental therapy, to assess whether the new intervention is better than standard therapy, or to compare the efficacy of two standard or marketed interventions

cloning human genes – transfer of human DNA sequences of interest into nonhuman cells with the purpose of expression, genetic manipulation, and amplification

cohort study – type of investigation in which exposure is assessed among unaffected persons and subjects are then observed for subsequent development of the disease

comparator (product) – an investigational or marketed product (i.e., active control), or placebo, used as reference in a clinical trial (ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice (E6,R1)

– a pharmaceutical or other product (which may be a placebo) used as a reference in a clinical trials (WHO Guidelines for Good Clinical Practice

compensation – payments received by the research participants as reimbursement for lost earnings, travel costs and other expenses incurred as a study participant, as reparation for inconvenience and time spent

complementary and alternative medicine research – study done in human volunteers to determine the effects of and/or identify any adverse reactions to maneuvers word in complementary and alternative medicine

– study undertaken on a systematic and rigorous basis to generate new knowledge regarding diverse medical and health care systems, practices and products that are not presently considered to be part of conventional medicine

complementary medicine – a health treatment modality that is used together in a conventional or mainstream medicine

conception – pregnancy beginning from the process of fertilization to form a zygote or its implantation

conditional approval – approval of the protocol by the Ethics Committee to proceed after certain conditions or modifications set by the EC are met

confidentiality – a duty of health care providers and health researchers toward patients and research participants to protect privacy and to refrain from unauthorized disclosure of information pertaining to them

– prevention of disclosure of the IEC/IRB information, deliberations and documents to other than authorized individuals

conflict of interest – a conflict of interest arises when a member (or members) of the Ethics Committee holds interests with respect to specific applications for review that may jeopardize his/her ability to provide a free and independent evaluation of the research focused on the protection of the research participants. Conflict of interests may arise when an EC member has financial, material, institutional or social ties to the research.

control – the standard by which experimental observation are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is either given a standard treatment for the illness or a placebo (http://www.Clinicaltrials.gov/ct/info/whatis. Retrieved May 17, 2006)

controlled trials – a trial in which one group of participants is given an experimental drug, while another group (the control group) is given either a standard

conventional medicine – (see *Western medicine*) that discipline of medical care advocating therapy with remedies that produce effects differing from those of the disease treated

counseling – non-coercive interaction between a health professional and a patient/client and/or family that is meant to clarify personal values and priorities, health care options, expectations, risks, benefits, and resources in order to help in decision-making. It needs to be offered prior to sensitive testing (pre-test counseling) and/or after testing (post-test counseling) for comprehensive care

criminal violence – behaviors by individuals that intentionally threaten, attempt, or inflict physical harm on others (National Research Council's Panel on the Understanding and Control of Violent Behavior, citing Reiss and Roth, 1993, p. 2, emphasis in original)

cultural bias – prejudice based on community values and traditions

culture – the way of life of groups of people that is defined by mores, shared values, traditions and sociopolitical structures and institutions

debriefing – the process of obtaining information about an experience from an individual who has participated in, or observed particular events

deception – an act characterized by dishonesty, fraud, trickery or sham for the purpose of manipulating another person into making a decision that he or she would not have made otherwise

deoxyribonucleic acid (DNA) – an antiparallel double helix of nucleotides (having deoxyribose as their sugars) linked by phosphodiester (sugar-phosphate) bonds to adjacent nucleotides in the same chain and by hydrogen bonds to complementary nucleotides in the opposite chain. The fundamental substance of which genes are composed.

deoxyribonucleic acid sequencing – method of analyzing the base sequence composition and order of a DNA sample using chemical tagging and physical measurements

devices – a piece of equipment designed to served a clinical purpose

diagnostics – procedure or technique used in the identification of a disease or determination of the health status of an individual

disapproval – a negative action of the Ethics Committee on the protocol. The study

disclosure of data – the giving of information in connection with proposed research undertaking or the sharing of the results of the study especially as they pertain to the individual's of the family's health situation

disease allele – one of the variant forms of a disease gene at a particular locus, or location, on a chromosome. Different alleles produce variation in inherited characteristics such as hair color or blood type. In an individual, one form of the allele (the dominant one) may be expressed more than another form (the recessive one)

disease susceptibility/predisposition – the pathophysiological conditions and genetic inclination that favor the development of a disease condition

domestic violence – violence committed by one family or household member against another (Merriam-Webster's Dictionary of Law (c) 1996)

double blinding – is one in which neither the subject nor any of the investigator or sponsor staff who are involved in the treatment or clinical evaluation of the subjects are aware of the treatment received (ICH Harmonized Tripartite Guideline, Statistical Principles for Clinical Trials (E9) p8)

drugs – a substance used as medication or used in the diagnosis, cure, mitigation, treatment or prevention of disease

duress – wrongful and usually unlawful compulsion (as threats of physical violence) that induces a person to act against his or her will: 'coercion" (Merriam-Webster's Dictionary of Law (c) 1996)

efficacy – is the ability of a treatment modality to produce an effect to alleviate a disease

embryo – the stage of human development following implantation (starting 10-14 days), when the primitive streak begins to form up to fetal stage

epidemiologic research – investigative studies intended to establish "the distribution and determinants of disease frequency in human populations"

– study undertaken on a systematic and rigorous basis to generate new knowledge regarding the determinants of the incidence of diseases as well as their related risk factors, etiology and causation

epidemiology – the basic medical science that focuses on the distribution and

ethical clearance – a certification that a research proposal has complied with ethical requirements

– action of an ethics review committee on a research protocol that signifies approval and permission to proceed with the research.

ethical principles – rules or codes conforming to accepted professional standards of conduct (Merriam-Webster's Dictionary of Law (c) 1996)

– usually refer to the ex prima facie universal principles of respect for persons, beneficence, non-maleficence and justice

respect for persons – involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy (Institutional Review Board Guidebook, US Department of Health and Human Services http://kartero.pchrd.dost.gov.ph/horde/utilgo.php?url=http%3A%2F%2Fwww.hhs.gov%2Fohrp%2Firb%2Firb_introduction.htm_&Horde=85a91621422a63bcc765ef05290c2baf)

beneficence – the quality or state of doing or producing good especially performing acts of kindness and charity (Merriam-Webster's Dictionary of Law (c) 1996)

– the requirement to serve the interests and well being of others, including respect for their rights. It is the principle of doing good in the widest sense (http://kartero.pchrd.dost.gov.ph/horde/util/go.php?url=http%3A%2F%2Fwww.arts.ac.2FCode_of_Practice_on_Research_Ethics.pdf&Horde=85a91621422a63bcc765ef05290c2baf)

– is the professional duty to do or produce good. By "good" is meant the performance of acts of kindness and charity (http://kartero.pchrd.dost.gov.ph/horde/util/go.php?url=http%3A%2F%2Fhealth.enotes.com%2Fpublic_health_encyclopedia&Horde=85a91621422a63bcc765 ef05290c2baf)

– entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing anticipated benefits and minimizing possible risks of harm. (Institutional Review Board Guidebook, US Department of Health and Human Services http://kartero.pchrd.dost.gov.ph/horde/util/go.php?url=_http%3A%2F%2Fwww.hhs.gov%2Fohrp%2Firb%2Firb_introduction.htm&Horde=85a91621422a63bcc765ef05290c2baf)

the principles of doing, or permitting, no foreeable harm including infringement of rights as a consequence of the research. It is the principle of doing no harm in the widest sense (http://kartero.pchrd.dost.gov.ph/horde/util/go.php?url=http%3A%2F%2Fwww.arts.ac.uk%2Fdocs%2FCode_of_Practice_on_Research_Ethics.pdf&Horde=85a91621422a63bcc765ef05290c2baf)

justice – the quality of being just, impartial, or fair; the administration of law; the establishment or determination of rights according to law or equity (Merriam-Webster's Dictionary of Law (c)1996); requires that the benefits and burdens of research be distributed fairly (Institutional Review Board Guidebook, US Department of Health and Human Services http://kartero.pchrd.dost.gov.ph/horde/util/go.php?url=http%3A%2F%2Fwww.hhs.gov%2Fohrp%2Firb%2Firb_introduction.htm&Horde=85a91621422a63bcc765ef05290c2baf)

ethics review – the evaluation of a research protocol by an ethics review committee that promotes the safety and protection of the dignity of human participants

– a systematic process by which an independent committee evaluates a study protocol to determine if it follows ethical and scientific standards for carrying out biomedical research on human participants. Compliance with these guidelines helps ensure that the dignity, rights, safety and well-being of research participants are promoted.

ethics review committee – a Committee constituted to review the ethical aspects of a research proposal and its possible implementation

Ethics Committee (IEC/IRB) – Independent Ethics Committee / Institutional Review Board is an independent body (either a review board or committee) whose responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in a trial and to provide public assurance of that protection.

experimental design – the structure of research, identifying the various elements of a research project and how they relate to one another

family studies – mapping of disease genes through the establishment of genetic linkage within a family

feasibility – capability to be accomplished or implemented

fetus – stage of human development when the first neural cells start differentiating

gender – socially defined feminine or masculine roles, attitudes, and values

gender bias – partiality, unfairness, prejudice manifested towards an individual or group of individuals based on sex and sexual orientation

gender-sensitive counseling – counseling that includes awareness of existing gender differences, issues and inequality in its framework for interaction with the patient/client

gender sensitivity – the ability to perceive existing gender differences, issues, and inequality and to incorporate these into strategies and actions

genes – the functional and physical unit of heredity passed from parent to offspring. Genes are pieces of DNA, and most genes contain the information for making a specific protein

gene activity – refers to the degree of expression of a particular gene or levels of transcription

genetic association studies – describes a situation in which a particular allele is found either significantly more or less frequently in a group of affected individuals than would be expected from the frequency of the allele in the general population from which the affected individuals were drawn

genetic counseling – the provision of information and assistance to affected individuals or family members at risk of a disorder that may be genetic, concerning the consequences of the disorder, the probability or developing or transmitting it, and the ways in which it may be prevented or ameliorated

genetic research – the study of the structure and functions of individual genes, genetic variation in human populations, and the applications of genetics in diagnosis and patient care

genetic screening – a population-based method for identifying a subset of individuals at risk of developing or of transmitting a specific genetic disease or disorder

gene testing – analysis done on affected persons or carriers within family already identified because of a history of high risk for having or transmitting a specific genetic disorder

Good Clinical Practice Guidelines (GCP) – an international

standard provides public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the International Declaration of Helsinki, and that the clinical trial data are credible (CPMP/ICH/135/95)

- standards and procedures for clinical trials that encompass the design, protocol approval, monitoring, termination, audit, analyses, reporting, and documentation of human studies. It defines the responsibilities and activities of the sponsor, principal investigators and monitor involved in the clinical trials. The code GCP ensures that the studies are scientifically and ethically sound, and all the clinical properties of the product under investigation are properly documented. For compete information, reference is made to the published WHO and International Conference on Harmonization Code of Good Clinical Practice (Department of Health Administrative Order No. 47-A series of 2001 [August 30, 2001])

- a standard for clinical studies which encompasses the design, conduct, monitoring, termination, audit, analyses, reporting and documentation of the studies and which ensures that the studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical products (diagnostic, therapeutic or prophylactic) under investigation are properly documented (World Health Organization, Guidelines for Good Clinical Practice (GCP) for trials of-pharmaceutical products)

- set of principles and rules that define the responsibilities of the sponsor, the researcher and participants in a clinical drug trial that ensures ethical conduct of research and integrity of research data

good laboratory practices – are standards and procedures whereby a laboratory achieves a defined, consistent, and reliable standard in performing laboratory tests and activities (Department of Health Administrative Order No. 47-A series of 2001 [August 30, 2001])

Good Manufacturing Practice Guidelines – national standards and regulations for licensing of laboratories engaged in the manufacture and production of drugs, vaccines and other pharmaceuticals intended for human administration or consumption

- that part of quality assurance which ensures that products, including vaccines and biologics are consistently produced and controlled to quality standards appropriate for their intended use, including all phases of vaccine clinical trials, and as required by registration and marketing

WHO/Pharm/94.571 (Department of Health Administrative Order No. 47-A series of 2001 [August 30, 2001])

- the part of pharmaceutical quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by marketing authorization (World Health Organization, Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products. WHO Technical Report Series, No. 850, 1995, Annex 3)

government-sponsored health research – health research that is undertaken using government funds or resources

guardian – one who has or is entitled or legally appointed to the care and management of the person or property of another (Merriam-Webster's Dictionary of Law (c)1996)

– one who is legally responsible for the care and management of the person or property of an incompetent or a minor

guidelines – a set of rules or recommendations intended to effect a course of action

health equity – is the absence of systematic disparities in health (or in major social determinants of health) between groups with different levels of underlying advantage/disadvantages e.g. wealth, power, prestige

health research – generation of new knowledge (biomedical, clinical, social) to identify and deal with health problems, health systems and policies as well as those that impact on health such as socioeconomic, environment, energy and agricultural policies (PNHRS TWG Chairs, Feb 2004)

– investigational activities that aim to generate data that shall contribute to improvement in the diagnosis, prevention and management of diseases, and in the delivery of care and for the enhancement of the quality of life of individuals and health conditions in communities

herbal medicine research – study undertaken to generate new knowledge regarding the use of herbs and plants to prevent and treat diseases and ailments or to promote health and healing

Herbal medicines – finished, labeled medicinal products that contain as active ingredient/s serial or underground part/s of plant or other materials or

(TAMA of 1997). Plant materials include juices, gums, fatty oils, essential oils, and other substances of this nature. Herbal medicines, however, may contain excipients in addition to the active ingredient/s. Medicines containing plant material/s combined with chemically defined active substances, including chemically defined isolated constituents of plants, are not considered herbal medicines

high-risk group – social group known to have a high prevalence of a health problem because of shared environmental, occupational, nutritional or genetic factors including practices that contribute to ill-health

HIV (human immunodeficiency virus – type 1) – viral infectious agent that causes destruction of cellular immunity in individuals acquired through tissue fluid transmission from infected persons

HIV/AIDS research – study undertaken on a systematic and rigorous basis to generate new knowledge regarding the prevention or treatment of HIV/AIDS

HIV test – immunology-based laboratory test that establishes the presence of HIV infection in an individual

human subjects – see *research participants*

hypothesis – a tentative explanation for an observation, phenomenon, or scientific problem that can be tested by further investigation

independent consultant – An expert who gives advice comments and suggestions upon review of the study protocols with no affiliation to the institute or investigators proposing the research proposals

information in the public domain – data or information available and open to public observation like the list of names in the telephone directory, or events in streets and public transportation

informed consent (verbal, video, written) – the process of obtaining approval to participate in an investigative study or permission to a medical intervention. Consent must be freely given in verbal, video or written form. An important part of the process is the adequacy, appropriateness, and timeliness of the information for decision-making

intellectual property rights – the legal basis by which indigenous communities exercise their rights to have access to, protection, and control over their cultural knowledge and products, including but not limited to traditional

intellectual property sharing – to participate in, use, enjoy, or experience jointly or in turns the property that derives from the work of the mind or intellect or an idea, invention, trade secret, process, program, data, formula, patent, copyright, or trademark or application, right, or registration relating thereto (Merriam-Webster's Dictionary of Law (c) 1996)

interaction – the chemical or biological reactivity of the active principle or herbal preparation with other administered substances

international collaborative research – joint or shared conduct of research by at least two countries or governments (e.g. Philippines and one other foreign government/country)

– investigative work conducted at an international level, with involvement by investigators coming from different countries

interventional study – research that includes measures or technology that may affect the course of an illness

invasive procedure – biological sampling using a method involving intrusion into the human body, such as obtaining a blood sample by using a needle and syringe (UNESCO International Declaration on Human Genetic Data)

investigator – a person responsible for the conduct of the critical trial at a trial site. If trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and be called the principal investigator (ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice (E6, R1)

– a person responsible for the trial and for the rights, health and welfare of the subjects in the trial. The investigator should have qualifications and competence in accordance with local laws and regulations as evidenced by an up-to-date curriculum vitae and other credentials. Decisions relating to, and to provisions of, medical or dental care must always be the responsibility of a clinically competent person legally allowed to practice medicine or dentistry (WHO Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products)

– a qualified scientist who undertakes scientific and ethical responsibility, either on his/her behalf or on behalf of an organization, for the ethical and scientific integrity of a research project at a specific site or group of sites

legally authorized representative – one that represents another or others, upon their permission in accordance with law, in a special capacity (Merriam-

– A person who has authority, under the law, to stand for, or make decisions in behalf of another

legally competent person – qualified or fit to perform an act, in accordance with law, free from addiction or mental defects that renders one incapable of taking care or oneself or one's property (Merriam-Webster's Dictionary of Law (c)1996)

linkage analysis – gene hunting technique that traces patterns of disease in high risk families for the purpose of locating a disease-causing gene by identifying genetic markers of known chromosomal location that are co-inherited with the trait of interest

material transfer agreement – an agreement between the source institution (or community) and the recipient institution (agency or community) that defines responsibilities and ownership of the material under study

minimal toxicity data – the lowest dose of the preparation that shall elicit toxicity signs and symptoms in the participants or in animals

minors – persons who have not yet reached the age of majority, 18 years old

monitor – a person appointed by and responsible to the sponsor or contract research organization for monitoring and reporting progress of the trial and for verification of data (WHO, Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products)

moral agent – a sentient individual whose acts impact on others and are affected by the act of others

multicenter trial – a clinical trial conducted according to a single protocol but at more that one site, and therefore, carried out by more than one investigator (ICH Harmonized Tripartite Guideline, General Considerations for Clinical Trial (E8)

multifactorial inheritance – heredity characterized by the involvement of several genes and environmental factors

mutagenicity – the capacity of a chemical or physical agent to cause genetic alterations

national health care delivery system – the total structures – private and publi organizations, agencies, and individuals, including policies and mechanisr – that provide health care to individuals and communities in the countr

National Unified Health Research Agenda (NUHRA) – national health research priorities identified by major stakeholders

non-disclosure of data – the withholding of or refusal to reveal information derived from research

non-invasive procedure – biological sampling using a method which does not involve intrusion into the human body (e.g., oral smears)

North-South research collaboration – in the broad sense, would refer to the relationship or interaction between the developed and developing countries or rich and poor countries

participatory research – research that involves the participation of the investigator in the activities of the research population. It could also involve involves research subjects in the definition of the research agenda, the conduct of research, monitoring and evaluation, and dissemination of results.

patent – government instrument that assigns ownership of a product or creative work that is accompanied by certain rights

pharmacodynamics – the study of what a drug does to the body

pharmacogenetics – the field of biochemical genetics concerned with drug responses due to genetically-controlled variations

pharmacokinetics – the study of what the body does to a drug

Phase I clinical trial – the first trials of a new active ingredient or new formulations in man, often carried out in healthy volunteers. Their purpose is to establish a preliminary evaluation of safety, and a first outline of the pharmacokinetic and, where possible, a phramacodynamic profile of the active ingredients in humans. (WHO, Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products)

Phase II clinical trial –trials performed in a limited number of subjects, often at a later stage of a comparative (e.g., placebo-controlled) design. Their purpose is to demonstrate therapeutic activity and assess short-term safety of the active ingredient in patients suffering from a disease or condition for which the active ingredient is intended. This phase also aims at the determination of appropriate dose ranges or regimens and (if possible) clarification of dose-response relationships in order to provide an optimal background for the design of extensive therapeutic trials (WHO Guidelines for Good Clinical Practice (GCP) for trials of

Phase III clinical trial – trials in larger (and possibly varied) patient groups with the purpose of determining the short- and long-term safety/efficacy balance of formulation/s of the active ingredient, and of assessing its overall and relative therapeutic value. The pattern and profile of any frequent adverse reactions must be investigated and special features of the product must be explored (e.g., clinically relevant drug interactions, factors leading to differences in effect such as age). These trials should preferably be of a randomized double-blind design, but other designs may be acceptable (e.g., long-term safety studies). Generally, the conditions under which these trials are carried out should be as close as possible to normal conditions of use. (WHO Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products)

Phase IV clinical trial – studies performed after marketing of the pharmaceutical product. Trials in this phase are carried out on the basis of the product characteristics on which the marketing authorization was granted and are normally in the form of the post-marketing surveillance, or assessment of therapeutic value or treatment strategies. Although methods may differ, these studies should use the same scientific and ethical standards as applied in pre-marketing studies. After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, etc., are normality considered as trials for new pharmaceutical products. (WHO Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products)

Philippine Health Research Ethics Board – was created on March 1, 2006 through DOST Special Order No. 091 series of 2006 as a policy-making body for research ethics in the Philippines

Philippine National Health Research System – formally organized in 2004, it was conceptualized in support of a vibrant, dynamic, and responsible health research community working on a unified health research agenda with enhanced cooperation between the Department of Health, the Department of Science and Technology, and the Commission on Higher Education. The Philippine Health Research Ethics Board is one of the six groups working under its Governing Council.

placebo – a substance that is not biologically active, does not interact with other substances nor is it expected to affect the health status of an individual

an inactive pill, liquid, or powder that has no treatment value. In clinical trial, experimental treatments are often compared with placebos to assess the experimental treatment's effectiveness. In some studies,

active drug or experimental treatment (http://www.Clinicaltrials.gov/ct/info/whatis. Retrieved May 17, 2006)

placebo-controlled trials – clinical trials that assign the administration of a placebo to the control group while the test drug is given to the experimental group

population-based genetics – the study of the distribution of genes in populations and of how the frequencies of genes and genotypes are maintained or changed

pre-clinical trials – investigation of the pharmacologic properties of a drug or preparation done in animals prior to human studies. Pre-clinical studies shall include pharmacodynamics, pharmacokinetics, and toxicity studies (BFAD Guidelines for Registration of Pharmaceutical Products, 1997)

predictive testing – determination of the presence of disease-associated genes prior to the onset or manifestation of the disease

predisposition or risk testing – determination of genetic parameters in an individual associated with increased risk of disease

prenatal testing – determination of whether a fetus has (or probably has) a designated condition for which an increased risk is indicated by later maternal age, family history, or other well-defined risk factors

prior dose finding – quantity or dosage of the herbal medicine established in earlier studies or practice to be effective

privacy – a conceptual space defining the individual's boundary as a person, intrusion of which is limited human rights and by law

- the assurance of the secrecy of the identity of or information about research participants

product adulteration – presence of foreign substances or impurities in the drug preparation that results in dilution or loss of its efficacy

protein – a macromolecule composed of subunits of linear chains of amino acids attached to each other by peptide bonds

proteomic data – information from the comprehensive analysis and cataloguing of the structure and function of all the proteins present in a given cell or tissue

the background of the study, research question and objectives, the conceptual design, the methodology and data collection, and planned analysis of data.

– a study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of participants as well as answers specific research questions. The protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and length of the study. In a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and determine the safety and effectiveness of their treatment (http://www.Clinicaltrials.gov/ct/info/whatis. Retrieved May 17, 2006)

protocol amendment- a written description of a change to, or formal clarification of a protocol.

psychosocial needs – the needs of an individual pertaining to her social and psychological well being

quality of life – a state or condition in ones being wherein he/she is able to live as one normal person wants to live it

quasi-experimental design – the structure of a research project that does not make use of random assignment to groups

randomization – the process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias (ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice [E6, R1])

Regional Health Research Ethics Board – proposed policy-making body for research ethics in a particular region in the Philippines

regulatory requirements – approval of clinical trial by a regulatory agency. For example, for pharmaceutical and biologic products it means obtaining a "permit for clinical investigational use" which is a "registration document issued by the Bureau of Food and Drugs for the purpose of allowing the conduct of Phase I, Phase II, and Phase III clinical trials of investigational biologic products in the country" (Department of Health Administrative Order No. 47-A series of 2001 [August 30, 2001])

reportability (of test results) – the inclusion of an event (e.g., a diagnosis, evidence of violence against persons) in a list of items that are mandated by law to be reported to the Department of Health by designated individuals or

rescue medication – the drug or procedure used in applying conventional medicine intended to manage a disease

research – organized set of activities intended to generate data that are generalizable into new knowledge, principle or technology

– Investigative work undertaken on a systematic and rigorous basis using quantitative and qualitative methods to generate new knowledge

research ethics review committees

National Ethics Committee – organized in 1984 through a Special Order No. 84-053 issued by the Executive Director of the PCHRD to ensure that health research involving human participants is conducted in accordance to international ethical principles. The seven-member committee reviews protocols of researches to be done in sites without functioning Ethics Review Committees

Cluster Ethics Review Committee – an ethics review committee shared by (common to) several institutions where the volume of researches and resources do not make it feasible to have an ethics committee in each institution. The functions of the cluster committee and the respective institutional responsibilities shall be contained in a memorandum of agreement amongst the institutions concerned

Institutional Ethics Review Committee – ethics review committee organized in a particular institution to ensure that health research is conducted according to international ethical principles, national and institutional guidelines

research involving traumatized populations – study undertaken on a systematic and rigorous basis to generate new knowledge regarding groups living in communities that have experienced hardships and stress due to natural calamities or human atrocities

research on assisted reproductive technology – study undertaken on a systematic and rigorous basis to generate new knowledge regarding reproduction that makes use of modern technology

research participants/subjects – an individual who participates in a biomedical research project, either as the direct recipient of an intervention (e.g. study product or invasive procedure), as a control, or through observation. The individual may be a healthy person who volunteers to participate in the research or a person with a condition unrelated to the

a patient) whose condition is relevant to the use of the study product or questions being investigated

research protocol - A document that provides the background rationale and objective(s) of a biomedical research project and describes its design, methodology and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol

respondent – one who answers or defends in various proceedings (Merriam-Webster's Dictionary of Law (c) 1996)

ribonucleic acid (RNA) - A single-stranded nucleic acid similar to DNA but having ribose sugar rather than deoxyribose sugar and uracil rather than thymine as one of the pyrimidine bases

risk – the probability of harm or discomfort to study participants

– the probability of harm or discomfort to study participants. Acceptable risk differs depending on the conditions for which the product is being tested.

minimal risk – harm or discomfort comparable to those experienced in the daily existence of people living under ordinary circumstances and development

risk factors – determinants of disease development

scientific review – also called technical review, is the evaluation of the research protocol to ascertain scientific soundness and appropriateness of the objectives and design of the proposed study and the qualifications of the researcher

selective disclosure of information – deliberate withholding of certain information from a patient or from a research participant usually justified by the principle of non-maleficence or, in the case of research, avoiding the introduction of bias on the part of the patient

single-gene diseases – a disorder that is determined by mutant alleles at a single locus

social and behavioral research – study undertaken on a systematic and rigorous basis to generate new knowledge regarding he impact of sociological, psychological, anthropological and other social factors on health and

critical perspective – this perspective is recursive and focused on bringing about change in practices. Researchers utilizing this perspective generally have an agenda for social change. Studies under this perspective begin with an important stance about social issues and is aimed at creating political debate and discussion to bring about change. It is practical and collaborative.

interpretive perspective – this perspective holds that in seeking to understand their world, people develop subjective meanings of their experiences which are varied and multiple. The researcher then looks into the complexity of views rather than reducing them to a few ideas. Open-ended questions suit this perspective. Historical and social contexts are important to consider. The assumption is that the basic generation of meaning is always social resulting from the interaction within social groups.

positivist perspective – this is sometimes referred to as the "scientific method" and is likewise called quantitative research, empirical science or postivist/postpositivist research. This reflects a deterministic philosophy which says that causes probably determine effects or outcomes. It is reductionistic because it reduces ideas into discrete sets to test in hypotheses and research questions. It utilizes careful observation and measurement of objective reality. Most of research in this perspective starts with test of a theory.

social research – social research covers a broad range of disciplines and perspectives. Sociology, anthropology, political science, economics, psychology, population studies, history, geography and linguistics are specific areas within social science which are directly concerned with health issues. Interdisciplinary social research involves two or more of these disciplines utilizing both quantitative and qualitative approaches which are consistent with either positivist interpretive or critical perspectives.

sponsor – an individual, a company, an institution or an organization which take responsibility for the initiation, management and/or financing of a clinical trial (ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice [E6, R1])

– an individual, company, institution or organization that takes responsibility for the initiation, management and /or financing of a research project

– an individual, a company, an institution or an organization that takes

trial. When an investigator initiates and takes full for a trial, the investigator then also assumes the role of the sponsor responsibility (WHO Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products)

standard of care – health care intervention or regimen that is generally accepted by health practitioners and experts as beneficial to an individual needing such care

prophylactic – professionally accepted level and type of preventive management to prevent the occurrence of a particular health condition

diagnostic – professionally accepted level and type of examination to determine a patient's health condition

therapeutic – professionally accepted level and type of treatment or assistance for a particular health condition

stem cell research – the study of the properties, development, and transformation of primordial progenitor cells prior to establishment of specialized cells

stigma – the negative regard (e.g., shame and dishonor) of the community or society to particular groups because of disability, illness, occupation, poverty, etc. as dictated by culture

study/investigational product – a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used fro an unapproved indication, or when used to gain further information about an approved use (ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice [E6,R1])

susceptibility – genetic condition leading to the development of a disease

technical review – see *scientific review*

teratogenicity – the degree or measure of the ability to cause malformations of an embryo or fetus

termination of the research – the research study may be ended before its scheduled completion when the safety or benefit of the study participants

test preparation – the formulation or preparation of the herbal remedy or product that is going to be used in the study

traditional and alternative health care – the sum total of knowledge, skills and practices on health care, other than those embodied in biomedicine, used in the prevention, diagnosis and elimination of physical and mental disorder (TAMA 1997)

Traditional and Alternative Medicine Act (TAMA) – the 1997 law creating the Philippine Institute of Traditional and Alternative Health Care (PITAHC) to accelerate the development of traditional and alternative health care in the Philippines, providing for a Traditional and Alternative Health Care Development Fund and for other purposes

traditional healer – the relatively old, highly placed respected person in the community, with a profound knowledge of traditional remedies

traditional medicine – the sum total of knowledge, skills, and practices in health care, not necessarily explicable in the context of modern, scientific, philosophical framework, but recognized by the people to help maintain and improve their health towards the wholeness of their being, the community and society, and their interrelations based on culture, history, heritage, and consciousness

traditional medicine expert – a health care provider employing traditional medicine modalities to give a cure

traumatized populations – are individuals who live in communities that have experienced extreme forms of life- threatening stress due to natural calamities or human atrocities such as armed conflict, political repression as well as criminal and domestic violence.

trial-related expenses – costs incurred in the course of litigation

- Expenses incurred by study participants related to their participation in a research study such as transportation, meals, loss of income.

undue influence – improper influence that deprives a person of freedom of choice or substitutes another's choice or desire for the person's own. Note: It is a doctrine of equity that a contract, deed, donation. Or testamentary disposition can be set aside if the court finds that someone has exercised undue influence over the maker at the time that the contrast, conveyance, or will was made. To establish a prima facie case it is usually necessary to show a susceptibility to undue influence (as from mental impairment), the opportunity and disposition on

would not have been made except for the undue influence. (Merriam-Webster's Dictionary of Law (c)1996)

vulnerable groups – classes of individuals who have characteristics that lessen their capacity to protect their own interests or promote their own welfare

waiver of informed consent – the act of intentionally or knowingly relinquishing or abandoning the right to consent to medical treatment by a patient or to participation in a medical experiment by a subject after achieving an understanding of what is involved and especially for the risks (Merriam-Webster's Dictionary of Law (c)1996)

– Permission given by an Ethics Review Committee for research to be conducted without the informed consent of subjects, under exceptional circumstances, such as when research has to be undertaken in an emergency situation

Western medicine – or biomedicine, allopathy, regular medicine, conventional medicine, mainstream medicine, orthodox medicine or cosmopolitan medicine, refers to medical care that advocates therapy that produces effects differing from those of the diseases treated (TAMA 1997)

zygote – the product of the biological union of the human sperm and egg (process of fertilization) until the blastocyst (32-cell) stage prior to implantation in the endometrium (0 to 4-5 days)

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SUBJECT INDEX

APPENDIX A
TEMPLATE FOR PATIENT INFORMATION AND INFORMED CONSENT FORM

Project Title: _____

Sponsor: _____

Investigator/s: _____

_____

Purpose and conduct of study:
- Why is the study being done?
- What has been done previously?
- How will the present study be conducted?
- What is the nature and extent of involvement of research participants?

Risks and inconveniences
- Will there be discomforts? Are these described clearly?
- Will there be risks? Are these explained fully?
- Are there other effects the participants need to know in order to make a decision?

Possible benefits for the participants
- What benefits can the participants expect?

Compensation
- Will there be reimbursement of travel expenses? Compensation for loss of income? Meal expenses?
- Are there other financial considerations?

Provision for injury or related illness
- Will the participant be given free treatment in case of injury or illness incurred as a result of participating in the study?

Contact person
- Who is the person knowledgeable about the research and rights of the participant? How can he/she be contacted?

Voluntariness of participation
- Is the participant free of any coercion in participating?
- Is there assurance that the participant can withdraw anytime without affecting treatment/care due him/her?

representative in case of minors, the mentally handicapped or the incapacitated?

Confidentiality

Is there a statement that describes the measures that will be taken to keep and ensure the confidentiality of the participant's records?

CONSENT FORM

I have read and understood the above information and had been given the opportunity to consider and ask questions on the information regarding the involvement in this study. I have spoken directly to my doctor who has answered to my satisfaction all my questions. I have received a copy of this Patient Information and Informed Consent Form. I voluntarily agree to participate.

Patient's Signature:

Name of Patient	Signature of Patient	Date

Witness or Legal Guardian's Signature:
(Only when patient cannot read or sign this Informed Consent)

Name of Witness/ Legal Guardian	Signature of Witness/ Legal Guardian	Date

Physician's Signature:

I, the undersigned, certify that to the best of my knowledge, the patient signing this consent form has read the above information sheet fully, that this has been carefully explained to him/her, and that he/she clearly understands the nature, risks, and benefits of his/her participation in this study.

APPENDIX B
ETHICS REVIEW COMMITTEE (ERC)
Standard Application Form
FOR ETHICAL EVALUATION OF PROPOSAL

General Instructions:

Accomplish ten copies of this application form and attach them to copies of the proposal to be submitted to the National Ethics Committee (NEC).

Note: The ERC evaluation will normally require eight weeks from receipt of the proposal from the proponent.

For further information, contact:

The NEC Secretariat
Room 306, 3rd Floor, DOST Main Bldg., Bicutan, Taguig City
Telephone No. (632) 837-7535; Telefax Nos. (632) 837-2924, 837-2942
e-mail: pchrd@ehealth.ph

1. Reference Number: _____
2. Name of Organization / Institution: _____
3. Name: _____
4. Address / Contact Nos.: _____
5. Project Coordinator or Principal Investigator:
   Name: _____
   Position: _____
   Address: _____
   Contact Nos.: (Tel / Fax / Mobile Nos. / e-mail address _____
6. Project Title: _____
7. Planned Date of Start: _____
8. Project Abstract / Ethical Concerns: (Attach summary of proposal and ethical concerns)
9. The NEC has assessed and granted ethical clearance to this proposal:

Name of NEC Chair	Signature
_____	_____

10. Date: _____

APPENDIX C
List of Documents that the Proponent/s Should Provide the Ethics Review Committee

1) Ten (10) copies of the final protocol and, if applicable, amendments

2) Ten (10) copies of informed consent (written in English and Filipino or dialect spoken and understood by research participants)

3) Ten (10) copies of Information Sheet (written in English and Filipino or dialect spoken and understood by research participants)

4) Curriculum vitae of project investigator/s

APPENDIX D
NATIONAL ETHICS COMMITTEE

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Dela Salle University Health Sciences Center

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Professor, Department of Environmental and Occupational Health
College of Public Health, UP-Manila

APPENDIX E
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