Meeting Report

Expert Consultation on Optimization of Health Research Ethics Governance Systems in the Western Pacific Region

Manila, Philippines
10–12 October 2012

World Health Organization
Western Pacific Region

WORLD HEALTH ORGANIZATION

REGIONAL OFFICE FOR THE WESTERN PACIFIC

REPORT

EXPERT CONSULTATION ON OPTIMIZATION OF HEALTH RESEARCH ETHICS GOVERNANCE SYSTEMS IN THE WESTERN PACIFIC REGION

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NOTE

The views expressed in this report are those of the participants of the Expert Consultation on Optimization of Health Research Ethics Governance Systems in the Western Pacific Region who attended the meeting and do not necessarily reflect the policy of the World Health Organization.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for governments of Member States in the Region and for participants in the Expert Consultation on Optimization of Health Research Ethics Governance Systems in the Western Pacific Region, which was held in Manila, Philippines from 10 to 12 October 2012.

CONTENTS

Keywords:

Research / Ethics, Research / Ethical review / Western Pacific

LIST OF ACRONYMS

ACRES	Alliance for Clinical Research Excellence and Safety
APAME	Asia Pacific Association of Medical Journal Editors
CHED	Commission of Higher Education
CIOMS	Council of International Organizations of Medical Sciences
DCC	Director of Combating Communicable Diseases
DHS	Division of Health Sector Development
DOH	Department of Health
DOST	Department of Science and Technology
FDA	Food and Drugs Administration
FERCAP	Forum for Ethics Review Committee for Asia Pacific
FNRERC	Fiji National Research Ethics Review Committee
FNU	Fiji National University
GCP	Guidelines and Good Clinical Practice
GEP	Good Evaluation Practice
GLP	Good Laboratory Practice
GPP	Good Publication Practice
GRP	Good Research Practice
GTAC	Gene Technology Advisory Committee
GTP	Good Translational Practice
HDEC	Health and Disability Ethics Committee
HERDIN	Health Research Data and information Network
HRS	Health Research Systems
HRO	Health Research Officer
ICTRP	International Clinical Trial Registration Platform
IEC	Institutional Ethics Committee
IER	Health Information, Evidence and Research
IERC	Institutional Ethics Review Committee
IHSN	International Health Survey Network
IRB	Institutional Review Board
IT	Information Technology
MOH	Ministry of Health
MREC	Medical Research Ethics Committee
MMF	Mekong Malaria Forum
NECHR	National Ethics Committee for Health Research
NEGHR	National Ethical Guidelines for Health Research
NHRC	National Health Research Committee
NIOPH	National Institute of Public Health
NGO	Non-governmental organization
PAL	Pharmaceutical Affairs Law
PCHRD	Philippine Council for Health Research and Development
PHREB	Philippine Health Research Ethics Board
PHRR	Philippine Health Research Registry
PNHRS	Philippine National Health Research System
REC	Research Ethics Review Committee
SCOTT	Standing Committee on Therapeutic Trials
SOP	standard operating procedures
UPM-NIH	University of the Philippines Manila National Institute of Health
WHO	World Health Organization
WPRO	Western Pacific Regional Office

SUMMARY

An Expert Consultation on Optimization of Health Research Ethics Governance Systems in the Western Pacific was convened by WHO Regional Office for the Western Pacific in Manila, Philippines from 10 to 12 October 2012.

The objectives of the meeting were:

(1) to re-examine the current models of research ethics committees to create an efficient, transparent, and effective ethics review process;

(2) to discuss system measures to ensure ethical conduct of health research beyond prospective review; and

(3) to recommend key actions that may be undertaken by Member States and by the WHO Regional Office for the Western Pacific to move towards an optimal and integrated systems approach to research ethics and establishing standards for ethics review at national and global levels.

The Consultation deliberated on the organizational structures and management practices for research ethics committees, including the need for harmonization and standardization of their practices and procedures. Various measures such as accreditation, registration and networking of committees were discussed and reviewed. IT solutions offer substantial potential to improve accountability, efficiency, quality and transparency in research including more efficient management of ethical review process. New Zealand, Malaysia, and the WHO presented their online research management systems.

The Expert Consultation examined the current systems in place to ensure protection of rights and interests health research subjects in its entirety. In most of the developing countries, there is a disproportionate focus on the mechanism of research ethics committees and prospective review of individual research proposals, which is often not anchored in an overall policy or legal framework. The other system measures that will promote ethical conduct of research by improving overall transparency and accountability in health research are often neglected. More importantly, improving the supply of competent researchers to match the increase in research investments and measures to build capacity of researchers are not receiving equal focus especially in developing countries. Availability of well-trained researchers is a prerequisite for ethical conduct of research. Measures and regulations to ensure researchers' accountability and capacity to conduct ethical research beyond the ethics review process were discussed.

Overall recommendations included:

(1) *Linking ethics systems with overall governance system*: The research ethics system is only one of the components of overall health research governance and should be strongly rooted and contextualized in the overall framework of research governance.

(2) *Research ethics systems and research ethics review committees*: Research ethics systems should be characterized as multidimensional systems. The different components of research ethics systems should include a system for training researchers, a system to promote overall accountability in health research, and a specific oversight system such as REC. The research

ethics “review” process and REC is only “one” of the subcomponents, though an important part, of the “research ethics system”.

(3) *Streamlining and optimization of “ethical review” systems:* A clear harmonized national policy and standards framework, informed as much as possible by international guidelines and standards (e.g. WHO standards), should underpin the ethics “review” systems.

(4) *Shared goals and shared responsibilities*: Measures should be taken to shift the perception of ethics review committees from regulatory/enforcement bodies to mentoring/guiding bodies by involving the researcher in the review process without compromising the safety of human research subjects/participants.

(5) Countries should develop systems, guidelines, checks/balances, and programmes to reinforce and strengthen researchers' accountability and capacity to conduct ethical research.

(6) *Investing in other measures to facilitate ethical conduct of research*: Countries should invest in developing other systems/measures that promote overall accountability and transparency in health research. These measures, while improving efficiency, quality and impact of research, would also create a conducive environment for ethical research. Some specific measures may be *establishing* prospective research registration in publicly accessible registries, setting up systems to ensure appropriate reporting of all research results, and improving access to and sharing of research data.

1. INTRODUCTION

The Expert Consultation on Optimization of Health Research Ethics Governance Systems in the Western Pacific was held at the World Health Organization (WHO) Regional Office for the Western Pacific in Manila, Philippines from 10 to 12 October 2012.

1.1 Objectives

(1) To review and share the current status of research ethics governance systems and rules and regulations in the Region.

(2) To review and share comparative evidence on the effectiveness of research ethics governance systems in the Region.

(3) To recommend strategic directions for reform of health research ethics governance systems for the guidance of both Member States and WHO.

1.2 Organization

The consultation was convened by the Health Information, Evidence and Research unit of the Division of Health Sector Development, WHO Regional Office for the Western Pacific. Financial support was provided by the Japan Voluntary Contribution Fund from the Government of Japan and Australian Agency for International Development. Dr Manju Rani, Senior Technical Officer, Health Research Policy, served as the responsible officer from the WHO Secretariat. Chairpersons and rapporteurs were selected from among the participants for the different sessions. Annex 1 provides the meeting agenda and detailed programme.

1.3 Participants and resource persons

Excluding the WHO Secretariat, there were 23 participants, including 16 temporary advisers from 11 Member States (Cambodia, China, Fiji, Japan, the Lao People's Democratic Republic, Malaysia, Mongolia, New Zealand, the Philippines, the United States of America and Viet Nam) and 7 observers (Asia Pacific Association of Medical Journal Editors [APAME], Forum for Ethical Review Committees in the Asian & Western Pacific Region [FERCAP], International Organization for Migration, Philippine Health Research Ethics Board [PHREB] and the University of the Philippines). A list of temporary advisers, observers and representatives, and Secretariat members is attached as Annex 2.

1.4 Opening remarks

Dr Han Tieru, Director for Programme Management, WHO Regional Office for the Western Pacific, welcomed the meeting participants on behalf of WHO Regional Director for the Western Pacific.

He stressed the importance of improving the efficiency and benefits of research while minimizing the risks for research participants. He noted that in the Western Pacific Region, the volume of research is increasing much faster than the supply of responsible researchers and the capacity for training researchers.

He emphasized that research must respect the rights of human subjects and must benefit communities, and noted that developing countries do not yet have the research management and

governance systems that exist in developed countries. Practical solutions must be tailored to different country contexts to improve health research outcomes.

He applauded the outcomes of the first expert consultation in August 2011 and its contribution to increasing awareness of research governance and management in the Region. He expressed hope that the group would build upon the results of the first expert consultation to help countries develop their research systems to improve the health of all.

1.5 Opening remarks

Dr Eva Christophel, Acting Director for Combating Communicable Diseases, welcomed the group on behalf of the division's director.

She commented that despite economic growth, Asia Pacific continues to face the challenge of persistent communicable diseases, such as HIV, vaccine-preventable diseases and emerging diseases. Research is the weapon to combat these diseases. She highlighted communicable disease research activities in the Region, including malaria research in Cambodia, which is exploring better diagnostic tools.

Dr Christophel stressed that scientific interests cannot be held above the rights of human subjects. Public trust must be maintained and human subjects must be protected at all stages of research. Therefore, adequate research governance systems must be put in place to protect the interests of human subjects. She noted that the expert consultation would provide an opportunity to discuss ways to strengthen support for research ethics systems to make them more integrated, streamlined and effective.

2. PROCEEDINGS

2.1 Setting the scene: A system approach to health research ethics governance

Moderator: Dr Maimunah Hamid, Rapporteur: Dr Vicente Belizario, Jr

2.1.1 The Expert Consultation: objectives and overarching issues for consideration

Presenter: Dr Manju Rani

Dr Rani presented the three key objectives of the Expert Consultation (outlined in section 1.1). She stressed that the meeting would focus primarily on how to simplify, optimize and integrate research ethics systems. Expected outcomes include practical, actionable, evidence-informed recommendations suitable for WHO and countries at different stages of development.

Progress since 2011 Expert Consultation: The 2011 Expert Consultation on Improving Health Research Governance, Management and Data Sharing in the Western Pacific defined national research governance and management functions and highlighted the lack of organizational responsibility and resources for these essential functions. The key recommendations included: (1) establish national health research registries as tools for monitoring and tracking research portfolios and increasing accountability and transparency in health research; (2) establish policies and systems for systematic data archiving and sharing; and (3) review and streamline research ethics systems.

Following the 2011 expert consultation, increased awareness, advocacy and dialogue have been observed in Cambodia, Fiji, the Lao People's Democratic Republic, the Philippines and Vanuatu. The Philippines introduced mandatory registration of clinical trials and launched the Philippine Health Research Registry (http://registry.healthresearch.ph/) in August 2012. Singapore launched a national clinical trial registry in September 2012. Many countries drafted their first policy on guidelines for responsible conduct of research, and some countries realized that they already had guidelines that were never implemented. The WHO Regional Office for the Western Pacific supported the development of data-sharing policies and information technology (IT) solutions for archiving and access to public health micro data in conjunction with the International Household Survey Network (IHSN) project of the World Bank and Organisation for Economic Co-operation and Development (OECD). For research ethics, Fiji and the Lao People's Democratic Republic held initial consultations for the purpose of reforming and restructuring their research ethics review Committees (RECs) and revising standard operating procedures (SOPs). Finally, an online regional resource library (http://www.wpro.who.int/health_research/ethics/en/) was created to provide access to policies and procedures adopted by Member States in the Western Pacific Region.

Diversity of the Western Pacific Region and its relevance for the consultation: The Western Pacific Region contains some of the world's most populous, most developed and largest countries and also some of the least populous, poorest and smallest countries. Some Member States have world-class health sciences universities and laboratories, while others have very limited training capacity in health research. Some have substantial domestic funding for health research, while others predominantly rely on externally-funded research. Some engage in substantially complex research such as clinical trials and genetics research, while others conduct primarily epidemiological public health research. Therefore, the health research governance and management systems developed in a country should be suitable for the particular research context and needs of that country.

Key challenges: First, the volume of research is increasing in the Region, and in some countries, is increasing much faster than the supply of trained researchers. Hence, many developing countries face shortages of domestic researchers to conduct research and to staff ethics review committees. Second, organizational responsibility for setting policy directions and making policy decisions for overall research governance, oversight and regulation is undefined in many countries. Finally, many countries require standardization and harmonization of guidelines, policies and procedures across multiple bodies, e.g. the food and drug administrations or their equivalents, ministries of health, and ministries of science and technology with overlapping mandates, redundancies and lack of streamlining. Researchers are getting lost in the bureaucracy of multiple, sometimes redundant approval requirements, and may choose the least troublesome path to obtain ethics approval.

Definition of research ethics: A broader definition of research ethics was proposed to cover more than "protecting research subjects from direct risks and harms." This broader definition should include: relevance of proposed research to health needs; the scientific soundness of the research; the dissemination and use of results, and the ethical issues of publication bias. This is especially important in the context of externally-funded research, particularly for private-industry-funded clinical trials, which are being promoted on economic grounds in many countries.

Ethical research should also respect the altruistic and voluntary motivations of research participants to contribute to public health. In this context, truthful reporting of research results should also become a component of a definition of research ethics. Questions were raised on the differences between harm to human research "subjects" and harm to human research "users", and between ethical conduct of research and research misconduct.

Components of research ethics systems: Three interconnected components of health research ethics systems were proposed, namely: (1) systems that build the capacity of researchers to enable them to undertake scientifically- and ethically-sound research; (2) system measures that improve overall "accountability" and transparency in health research and deter unethical conduct; and (3) special oversight mechanisms in the form of prospective and independent review of research proposed (ethics 'review' systems).

2.1.2 Towards a systems approach to research ethics: establishing standards for ethics review at national and global levels

Presenter: Dr Abha Saxena

Health research systems: Health research systems (HRS) encompass parts of the health system, the education system, and the science and technology system. WHO developed a framework for health research systems, defined key functions, and proposed strategies and processes to strengthen these systems. One of the key functions of health research systems is the stewardship function, which includes creating and sustaining resources, producing and using research, and financing.

Research ethics review systems: The ethics review systems proposed by WHO as part of HRS and the overall research ethics system also emphasize a systems approach. There is no definition of research ethics systems, but a working definition could be "the people, institutions and activities whose primary purpose is to *ensure the ethical conduct of research* to generate high-quality knowledge that can be used to promote, restore and/or maintain the health status of populations".

Current status of research ethics review systems: While there are several international documents such as the Declaration of Helsinki and CIOMS guidelines which outline ethical principles that should be followed in conducting ethical research, few international guidelines exist for ethics review systems. This issue has not been discussed in a consistent and systematic way. While an independent third-party review by RECs has been recommended to ensure that the proposed research is consistent with principles and actions outlined in international guidelines and national laws and regulations, there is no comprehensive set of standards to define the functions of RECs. Gaps exist at national and regional levels in the conduct of quality reviews and harmonization of procedures and processes within a given country.

An expert consultation in 2009 proposed that WHO should develop a set of global standards against which RECs could measure their own performance. Standards are benchmarks that must be met and are generally developed from a consensus of experts in relevant fields. As RECs do not function in a vacuum, standards were also proposed for organizations that constitute and host RECs as well as for researchers.

In 2011, WHO published *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*. The publication proposed 10 standards classified under five topics for the ethics review of health-related research:

(1) Standards for the research ethics review system (standard 1)

Responsibility for establishing the research ethics review system: legal framework; network of RECs; system for monitoring the quality of review; system for training at all levels; procedures for communication, networking and cooperation among RECs; coordination of ethics review with regulations, registries and other national bodies; registration of ethics committees.

(2) Standards and guidance for entities that establish RECs (standards 2–6)

Composition of REC: REC resources; independence of RECs; training of RECs; transparency, accountability and quality of RECs.

(3) Standards and guidance for members of RECs (standards 7 and 8)

Ethical basis for decision-making in RECs: decisions about research must be based on ethical principles articulated in national and international laws, guidance documents, and human rights instruments.

Decision-making procedures for RECs: decisions on research protocols must be based on a process of committee deliberations that are inclusive and where biases and conflicts of interest are managed.

(4) Standards and guidance for the secretariat, staff and administration of RECs (standard 9)

Written policies and procedures: written SOPs and maintenance of files and records in ways that are retrievable, accountable and confidential.

(5) Standards and guidance for researchers (standard 10)

Researchers' responsibilities: appropriate qualifications, awareness of research ethics, compliance with requirements.

The standards emphasize the need to move away from research ethics review to "research ethics review systems". Some gaps and challenges were highlighted, including the variable degree of development of overall research ethics systems at the regional and country levels and poor recognition of importance of issues involved. There is inadequate governance and resources for health research and many countries do not have functioning RECs.

Dr Saxena concluded by outlining the next steps for WHO: (1) to develop a toolkit and indicators to support Member States in the implementation and measurement of the standards; and (2) to monitor and evaluate progress.

2.2 Vertical ethical review versus streamlining ethical review with other reviews: feasibility, pros and cons

2.2.1 A redesign of the system for ethical review of health research in New Zealand

Presenter: Dr Robin Olds

Dr Olds presented recent changes in the research ethics review system in New Zealand, triggered by the 2011 Health Committee inquiry into improving New Zealand's environment to support innovation through clinical trials. This inquiry set new targets for timeliness of ethical review, with expedited reviews completed in 15 days and full reviews done in 35 days. It also aimed to set standards for ethical review across different Committees.

Organizational set-up of ethics review system: There are two types of ethics review committees in New Zealand: (1) national Health and Disability Ethics Committees (HDECs), which are ministerial committees under section 11 of the New Zealand Public Health and Disability Act (2000); and (2) institutional ethics committees, which are established by

organizations such as universities. A ministerial National Ethics Advisory Committee is responsible for developing overarching "standards", and the Health Research Council Ethics Committee is responsible for approving and accrediting both types of Committees.

Certain types of research must be reviewed by HDECs, irrespective of where the research is carried out (e.g. university, hospital, community) or where the investigator is based. HDECs must review all research that proposes: (1) to involve consumers of health and disability services, relatives or caregivers, or clinical trial volunteers; (2) to use, collect or store human tissue, unless participants remain anonymous and give consent for future unspecified use of research; (3) to use health information; or (4) to establish and maintain a tissue bank.

HDECs do not review studies involving low-risk (class I) medical devices, minimal-risk observational studies and audits, and seldom reviews student-led research. HDECs review PhD-level research only when it meets the aforementioned eligibility requirements. While HDECs *check* that proposed research meets established ethical standards, researchers are responsible for *ensuring* their research meets these standards. HDECs do not provide legal advice, do not address locality-specific governance issues, do not assess scientific validity and do not substitute for a consultation with Māori or other population groups.

Recent changes in the ethics review system: Recommendations of the 2011 inquiry applied only to HDECs, not institutional ethics committees, and led to the implementation of changes for HDECs in July 2012. These changes included revised SOPs for HDECs, a new system of electronic submission of applications, and a shift from regional committees to a Central Clearing House for applications.

The revised SOPs separated scientific from ethical review and excluded scientific review from the mandate of HDECs. With this change, the number of HDECs was reduced from seven to four, and the total membership of each committee was reduced from 12 to eight, with the requirement that at least three members of the committee are lay people. Finally, registration of clinical trials in a publicly-accessible registry was made mandatory.

Currently, less than half of all proposals go through a full HDEC review, while the majority undergo an expedited review by the chair and at least one non-lay member. A full review is required for research that involves new medicine; a new indication or mode of administration of approved medicine; a high-risk medical device; a new surgical intervention; and/or one or more participants who have not been given informed consent, who are vulnerable, who have had standard treatment withheld or who have had human tissue stored or used without consent.

Financing of the review system: No fee is charged for the review of any research proposal including pharmaceutical company-sponsored clinical trials. Funding for the ethics review system is the Government's responsibility.

Specialist research review committees: The inquiry did not support creation of new specialist review committees for specific types of research (e.g. a specialist committee for clinical trials) but supported retention of existing specialist review committees of the Health Research Council such as the Gene Technology Advisory Committee (GTAC) and Standing Committee on Therapeutic Trials (SCOTT). The inquiry also did not support a pre-review of applications to HDECs, GTAC and SCOTT.

Discussion point: Notwithstanding the exclusion of scientific review from the mandate of HDECs, proposals are still required to undergo an informal review of scientific quality before being submitted to HDEC. Brief guidelines on peer review of scientific quality have been

appended to the guidelines on intervention and observational studies published by the National Ethics Advisory Committee.

2.2.2 Streamlining Ethics Review in the Philippines

Presenter: Dr Jaime Montoya

The *National Ethical Guidelines for Health Research 2011* specify the research review procedures in the Philippines. These guidelines specify that "…the reviewers should assess the protocol based on the criteria set by the REC to include: a review of technical issues (including relevant policy issues and study tools … and the technical review made by technical reviewers); [and] review of ethical issues (vulnerability of research participants, confidentiality, conflict of interest, qualification of proponent, use of placebo if relevant, etc.)."

The *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, published by the Council for International Organizations of Medical Sciences (CIOMS) in 2002, specifies that the "…scientific review and ethical review cannot be separated: scientifically unsound research involving humans as subjects is *ipso facto* unethical in that it may expose them to risk or inconvenience for purpose; even if there is no risk of injury. Normally, therefore, an ethical review committee considers both the scientific and the ethical aspects of proposed research. It must either carry out or arrange for a proper scientific review or verify that a competent expert body has determined that the research is scientifically sound."

Assessment of ethical issues as part of technical or regulatory review: Dr Montoya argued that making 'assessment of ethical aspects' an integral component of other reviews could compromise its independence and integrity, especially if the objectives of ethical assessment were subsumed under technical or regulatory review, or if the objectives of the different reviews conflicted with one another. Hence, separate processes may be necessary. .

However, concurrent technical and ethical reviews by different committees may lead to a great deal of inconvenience if either of the reviews results in modifications to the protocol. Hence, sequential rather than concurrent technical and ethical reviews may be more efficient.

An integrated scientific and ethical review by the same committee with more appropriate membership structure would make the process more efficient. The interrelatedness of the ethical and technical issues could be addressed. This may reduce meeting and wait times, and may improve synchronization of comments and recommendations from the technical and ethical perspectives.

However, the reviewers with expertise in technical review may not necessarily have the expertise for ethics review. While it may be required of an ethics committee certain degree of independence from the institutions hosting them, it may not be so for a technical review committee. Finally, separate committees would allow focus on important points and issues, ensuring thoroughness and comprehensiveness of review in all aspects from different perspectives.

Two levels of reviewing authorities in the Philippines: The FDA conducts "regulatory review" of proposed research involving new drugs or devices, which requires assessment of prior clinical trial phase data as well as ethical and technical review. In addition, such proposals are required to undergo "institutional review" (both technical and ethical) by committees affiliated with the institutions (e.g. hospitals, health facilities, etc.) where the study will be conducted. The two reviews may be serial or parallel. These reviews are related, but their emphases are different.

Serial review ensures a logical flow. Regulatory review facilitates institutional review and saves on fees if the protocol does not pass regulatory review. It also avoids conflict between the regulatory and institutional review and contributes to better coordination and working relationships between FDA and research institutions. However, these multiple reviews may take substantial time and may delay enrolment of subjects.

Discussion points:

(1) Is independent technical review considered as important as ethical review irrespective of who conducts the review? It was unanimously agreed that technical review is as important as ethical review.

(2) Technical expertise versus ethical expertise: It was argued that if the same researchers were expected to understand both technical and ethical issues while conducting the research, then each member of RECs –technical and non-technical –should have an understanding of ethical issues. Ethical review should not be the domain of so called "ethicists" or "ethical specialists". Promoting vertical ethical specialists in research may send a mixed message to researchers.

A concern was raised, however, that if science is the driving concern for researchers, then science might trump ethics. If researchers choose to ignore possible harm to subjects, then independent non-technical reviewers might be needed to represent the interest of research subjects. Hence, the integration of technical and ethics reviews is feasible with these necessary checks and balances.

(3) Status in other countries: It was raised that the ethical review guidelines in most countries including Australia, Japan and the Republic of Korea call for a combined review. In Viet Nam's Ministry of Health, technical and ethical reviews are combined, as there are not enough experts for separate committees. Technical experts anonymously review proposals and then make recommendations to the REC but have no voting power. However, it was clarified that in some institutions, such as Hanoi School of Public Health, there are separate committees that conduct sequential technical and ethical reviews.

In Mongolia, joint technical and ethical reviews are conducted. In China, while the national research institutes have separate committees for technical and ethical reviews and different standards for each, the two types of reviews are combined at the local level. Developing integrated review standards which encompass technical standards and ethical standards can be difficult, but they may be considered together at the time of review.

In Malaysia, the Ethics Committees of the Ministry of Health assess both technical and ethical aspects. In Fiji, joint technical and ethical reviews are done at the departmental level at research institutes. In addition, all the research proposals need to be reviewed at the national level. There are two Committees at the national level. This sometimes leads to two or even three reviews of a proposal with the same individuals sitting on more than one committee, resulting in inefficient use of resources and time.

(4) Can developing countries practically achieve functional technical and ethical committees? It was pointed out that countries with limited human resources, such as the Lao People's Democratic Republic, may not be able to afford two Committees. The review procedures can be streamlined with sufficient safeguards to achieve the objectives of both ethical and technical review.

(5) Format of technical and ethical review: Dr Torres argued that while technical review may not require a formal "committee", ethical review needs to follow international guidelines. Dr

Saxena, on the other hand, emphasized that an independent technical review is equally important, and may be carried out by a committee or a panel of experts.

(6) Different procedures for high- and low-risk research: Dr Olds commented that technical review depends on assessment of the level of risk. High-risk research may warrant an independent review, and the skill set required may be quite different from that required for review of low-risk research. In New Zealand, all research pertaining to new medicines and genetic testing needs to be reviewed by both the Standing Committee on Therapeutic Trials and the Gene Technology Advisory Committee, before being submitted for ethical review by the national HDEC. However, technical and ethical reviews are often combined for low-risk research.

(7) Combining ethical and technical reviews: Dr Montoya concluded that regardless of who does the technical review, integration with ethical review and efficiency of the entire process is necessary. Whether there are separate bodies or people for the two reviews, there should be a single approval for the proposal.

Another participant emphasized the need for integrated systems, as there are parallel review processes for externally-funded research by a Committee affiliated with the sponsor organization and by an institution in the country where the research will be done.

(8) Other players: Dr Lapena from the Asia Pacific Association of Medical Journal Editors said that RECs are just one safeguard on a continuum of checks and balances from the conceptualization of research to final publication. Journal editors and peer reviewers along with journal accreditation bodies and indexing bodies, act as gatekeepers and have different perspectives from their parts of the process.

2.3 Need for and role of specialist committees for specific types of research (clinical trials, genetic research, etc.): models, organizational aspects

2.3.1 Regulations for ethics in health research in China

Presenter: Dr Wang Jinqian

National open-door policy and economic reform led to an influx of foreign investments in the 1980s resulting in an increase in international cooperation projects in science and technology and health research, most of which required in-country ethics review for biomedical study. Thus the early stage institutional ethical review boards were established in hospitals, academic institutes, medical colleges etc. in China.

Scientific research in China: Between 2001 and 2011, 160 400 papers on medical science and technology were published, representing an average annual growth rate of 20.4% in the last 5 years, faster than the world average growth rate during the same period. . In terms of volume, China is one of the top 10 producers of papers in biology, biochemistry, microbiology, molecular biology and genetics, immunology, and is ranked third in the world for pharmacology and toxicology. Similarly, patent applications in China grew nearly threefold between 2001 and 2009. A total of 2567 clinical trial projects were approved between 2000 and 2010, increasing from 14 in 2000 to 473 in 2010.

Research ethics governance in China: The role of ethics governance is to protect the research participants. This involves formulating ethics principles that comply with national statutes and with international ethical principles; setting up a feasible mechanism for ethical supervision based on a management framework; and strengthening research ethics education.

Regulations in China: The Ministry of Science and Technology, The Ministry of Health and State Food and Drug Administration [SFDA] have established several regulations in China based on specific types of research. The regulations include: Interim Measures for the Administrations of Human Genetic Resources, 1998; Good Clinical Practice, 1999; Code of Practices and Ethical Principles for Human Assisted Reproductive Technologies, 2001; Ethical Guiding Principles for Human Embryonic Stem Cell Research, 2003; and Regulation on Human Organ Transplantation, 2007.

In addition to the regulations for specific types of health research, there are overarching guidelines for research ethics. These include the Interim Rules for Ethical Review of Biomedical Research Involving Human Subjects (tentative version), 2007, and the Regulation on Clinical Application of Medical Technology, 2009. The former includes sections on ethics committees, review procedures, oversight and governance.

Both the specific regulations and the overarching guidelines outline the fundamental ethical principles including the need for informed consent. All research involving human subjects are required to comply with the Declaration of Helsinki.

Ethics committees in China: There are three levels of ethics committees: institutional, provincial and national. The Medical Ethics Experts Committee at the national level in the Ministry of Health advises the provincial-level ethics advisory committees which are housed under the provincial health departments. They in turn advise and train the institutional ethics committees.

The regulation on clinical application of medical technology classifies research into three categories. The Ministry of Health directly regulates the third category – research involving high risks, grave ethical issues or unproven medical technology.

Several challenges were highlighted. These included internal issues such as formulating harmonized standards for the institutional ethical review boards, the provincial-level ethics committees and the national medical ethics expert committee, as well as external issues, such as dealing with the public, the media and nongovernmental organizations (NGOs) and responding to emerging issues such as genetically-modified foods.

Potential strategies may include improving the review and supervision system, formulating relevant regulations, executing the rules effectively, and ensuring transparency with the public and media.

2.3.2 Ethical regulations for health research in Japan

Presenter: Dr Yasuyuki Sahara

Dr Sahara provided an overview of Japanese regulations for health research. Clinical trials can be either investigator-initiated or company-initiated. Both types, if conducted for the purpose of applying for marketing approval of drugs and medical devices are governed by the Pharmaceutical Affairs Law (PAL). Investigator-initiated health research that is conducted for academic purposes is outside the purview of PAL and can include interventional studies, observational studies and human genome analysis studies.

For research outside the PAL purview, there are different guidelines depending on the type of research. There are guidelines for epidemiological studies, human genome/gene analysis; clinical studies; clinical trials using human stem cells; and gene therapy clinical trials. All research studies have to undergo review by an institutional review board/ethics review committee

(IRB/REC). Guidelines stipulate combined ethical and scientific review. Studies involving stem cells, gene therapy and clinical trials undergo an additional rigorous scientific review by the Ministry of Health.

Institutions are, in principle, required to pass through an IRB/REC if they plan to do health research. The number of IRBs/RECs in each institution depends on the variety and volume of research conducted in the institution. One notable feature of the Japanese Ethical Guidelines for Clinical Studies is the requirement for people/institutions establishing IRB/RECs to report annually on their membership, SOPs and meeting minutes to the Ministry of Health. This information is accessible to the public on the Ministry's website (http://rinri.mhlw.go.jp/).

Several challenges were highlighted. One challenge at the institutional level is strengthening the capacity of IRB/REC secretariats and members. Challenges at the national level include ensuring regular updates of the various guidelines, harmonization across guidelines, and strong government support for institutions such as subsidies to strengthen secretariat capacity and training courses through e-learning. Training support staff (e.g. nurses, pharmacists) for research studies is considered especially important, and there has been a steady increase in participants on the training for clinical research coordinators.

2.4 Standards and organizational innovations in management of prospective review and research ethics committees

Moderator: Dr Maimunah Hamid, Rapporteur: Dr Vicente Belizario, Jr

2.4.1 Institutional committees: issue of independence, linkages with regional and national committees

The concept of institutional ethics review committees, i.e. decentralized ethics review committees in research institutions was conceived in the United States of America roughly 40–50 years ago. However, the institution responsible for such a review — funding institution, primary sponsor institution, secondary sponsor institution or implementing institution (e.g. hospitals) — has never been explicitly identified. This uncertainty often leads to multiple reviews of the same research proposal, even in the case of single-site research.

The adoption of institutional RECs varies across Member States, as influenced by their history and motivating factors to establish review systems in these countries. For example, Cambodia has only a national REC at the level of Ministry of Health. Many countries such as New Zealand, Malaysia, the Philippines and Viet Nam have institutional RECs and one or more national RECs (e.g. four national HDECs in New Zealand), which are not associated with a particular research institution but are mandated by the Ministry of Health or national bodies.

Defining the jurisdiction of national and institutional committees: In some countries such as Japan, the Philippines and Viet Nam, certain research requires review by both an institutional committee and a national committee, though the definition of roles and responsibilities of each are not always clear. In other countries such as Fiji and Mongolia, all research must be reviewed by both an intuitional committee and a national REC, though the national REC does not always require prior institutional committee review. The definition of jurisdiction on the basis of "low" and "high" risk may be challenging, as it may be difficult to classify research *a priori* or develop clear criteria. Not all student-led research is low-risk.

Harmonizing review standards across multiple institutional committees was cited as a challenge by many. Many countries including China do not have national ethical review standards for RECs to follow. New Zealand addresses this issue by having a small number of

national committees governed by overarching guidelines to deal with high-risk studies, others suggested that registration and accreditation of institutional RECs might solve the problem. The feasibility of one national committee performing high-quality reviews with increasing volumes of research was also raised. Countries with one national committee, such as Cambodia, may consider New Zealand's model of multiple national or regional and subregional committees to prevent overload.

National committees: review bodies or policy-setting bodies?: In many developing countries, the organizational responsibility for setting research governance policies including research ethics, is not clear. In countries such as Cambodia, Fiji and the Lao People's Democratic Republic, the ethics governance structures started with the establishment of a national ethics review committee to meet the external research sponsors' requirements. In these countries, a clear distinction should be made between the national "reviewing" committees and the national "policy-setting" bodies. In Australia, New Zealand and the Philippines, the national research ethics review boards are actually policy-setting boards which do not review research proposals. The Philippines started with a national ethics committee in 1984 with both policy-making and review functions; however, the two functions were later separated, with the creation of multiple review committees at institutional, regional and national levels.

Issue of independence of institutional REC: In developing countries, most research is externally-funded, and many institutions have to compete for funding. The concept of institutional ethics committees, which originated in the developed countries, was adopted by developing countries without the guidelines and organizational safeguards. It was raised that while institutional ethics committees do well to improve awareness about research and the ethics culture of the organization, ensuring independence of the committees in this environment may be more difficult. Ensuring independence at an institutional level is also an issue in developed countries. For example, New Zealand established national committees to manage potential conflict in case of ethical oversight by individual research institutions.

Need for a binding policy or legal framework: There is an urgent need for a national policy framework and legislation that mandates ethical conduct of research and provides sanctions in case of violations. In the case of Japan, having a law for certain types of research (e.g. research for new drugs) ensures better compliance with the review procedures and other requirements than having only guidelines (e.g. requirement for each research institute to have a REC for stem cell research). However, enacting such laws in developing countries may take a long time and may be difficult to enforce. Hence administrated guidelines mandated by the ministry of health or an interministerial body may be an acceptable method.

2.4.2 Accreditation, registration and networking: objectives, options, feasibility and costs: experience in the Philippines

Presenter: Dr Cecilia Tomas

In 2006, the Department of Science and Technology (DOST) created the Philippine Health Research Ethics Board (PHREB) as the national policy-making body on health research ethics. The secretariat of PHREB is located in the Philippine Council for Health Research and Development (PCHRD) in DOST. The PHREB is supported by regional health research ethics boards that oversee ethics review committees. The ethics review committees in the Philippines are national, regional, cluster and institutional in scope.

As set out in a framework, the protection of human research participants is a priority and a shared responsibility of FDA, REC, PHREB, sponsors, researchers and research institutions.

Several national policies and regulations for health research have been developed by the Department of Health and DOST. Some of the most notable achievements include the development of research policies and guidelines in the Department of Health (1982); creation of a National Ethics Committee for direct research proposal review (1984); development of rules and regulations for licensing of local manufacturers of vaccines and biologic products, and for registration, approval and conduct of clinical trials; establishment of a functional institutional ethics review system for research in the Department of Health (2002); and implementation of guidelines for establishment of research review system in the Department of Health (2003). The most recent administrative order of DOST in 2008 mandated the registration and accreditation of all ethics review committees.

Ensuring ethical research in the Philippines: recent initiatives

Establishing a responsible and accountable health research system and empowering human participants in health research are key challenges that must be addressed to ensure the quality of ethical review in the Philippines. A recent initiative to improve the situation was the creation of a national database of RECs. As of October 2012, 109 RECs across the country were registered.

The National Ethical Guidelines for Health Research, first published in 2006, in 2011 specified guidelines for different types of health research, ethics review committees, the review process, and authorship and publication. The guidelines complement the policies and standards for registration/accreditation of RECs.

A research ethics training programme was developed for researchers, REC members and other stakeholders. Different national and international organizations including PHREB, University of the Philippines, National Institute of Health and FERCAP are involved in ethical review capacity-building at the national, regional and local levels. The number of PHREB-facilitated trainings has increased dramatically from two in 2011 to 12 in 2012.

RECs and PHREB are encouraged to collaborate with national regulatory authorities (e.g. FDA) and regional research ethics organizations to streamline the process of technical and ethical review.

Registration/accreditation policies, standards and procedures

An effective human research protection system must have appropriate oversight mechanisms for RECs. Registration helps to monitor the performance of RECs and to identify those in need of assistance. Accreditation helps to improve substantive as well as procedural aspects of scientific and ethical review and ensures that RECs are effective, efficient and independent in the performance of their duties. PHREB has been assigned as the accrediting body in Philippines.

As of 2012, registration is mandatory but accreditation is still voluntary. The current criteria for accreditation include: functionality of the structure and membership of the REC; adequacy of the SOPs and consistency in their implementation; adherence to international, national and institutional guidelines and policies; completeness of the review process; adequacy of the post-review procedures; adequacy of administrative support for REC activities; and efficient and systematic recording and archiving.

The PHREB accreditation flowchart describes the detailed procedures, from the first REC office visit and review of different documents, to the submission of the final report and issuance of certification. There are three levels of accreditation. Level 1 qualifies a REC to review research involving human participants except clinical trials. Level 2 qualifies a REC to review

clinical trials not intended for registration of new drugs. Level 3 qualifies a REC to review investigational new drugs or device protocols. RECs are assigned an accreditation level based on fulfilment of different criteria.

PHREB is responsible for the accreditation process but is supported by FERCAP, and joint PHREB-FERCAP visits occur in some cases. The cost of accreditation includes honorariums and travel, lodging, meal and other incidental expenses of the accreditation team and training faculty.

Key points:

(1) Ensuring the quality of ethics review s a vital component of a quality management system in clinical research.

(2) The regulation framework of a human protection system in research must include all relevant stakeholders such as FDA, PHREB, RECs, researchers, sponsors and research institutions.

(3) Outcome measures should be developed to assess the performance of the current system.

(4) PHREB, government regulatory agencies and other stakeholders should work in close coordination with each other.

2.4.3 Strengthening RECs in Asia and the Pacific through the FERCAP recognition programme

Presenter: Dr Cristina Torres, FERCAP

Standards 1 and 6 of the WHO Standards and Operational Guidelines for Ethics Review of Health-Related Research with Human Participants (also presented in 2.1.2) emphasize that governments have primary responsibility for ensuring adequate oversight for RECs, harmonization of standards, networking and cooperation including establishing procedures for the coordinated review of multisite research, and compliance with other quality standards.

Referring to the GCP framework and human subject protection regulations observed by both the United States of America and the European Medicines Agency, which often sponsor research, Dr Torres emphasized that developing countries need to comply with GCP in addition to the ethical standards and national regulations of the sponsor country.

Among the FERCAP strategies are to develop the ethical research infrastructure in Asia Pacific and to set a global ethical model through annual conferences, training and networking. FERCAP has already organized training in several countries in the Asia Pacific region. In addition, FERCAP surveyed about 131 RECs in 2012. The FERCAP survey for accreditation involves a review of the REC self-assessment form, a review of various documents (SOPs, meeting minutes, membership and staff files, etc.), direct observation of REC meetings, interviews and office visits. Dr Torres further recommends standardization of ethics committees training curriculum towards certification, developing quality assurance systems in national accreditation systems, conducting research on IRB procedures in Asia Pacific, and setting up partnerships with relevant organizations.

Discussion points:

(1) The costs involved with accreditation, membership and training, and how RECs can comply with the regulations of external funders.

(2) External requirements from sponsors have led to establishment of stand-alone ethics committees sometimes in the absence of adequate guidelines and policy framework, leading to a mismatch in expectations and capacity/resources of the committees.

(3) RECs responding to a country's particular needs versus complying with sponsor country regulations.

2.5 Dealing with language barriers in a globalizing research environment: implications for researchers, reviewers and committees

In a globalizing research environment, it is essential that researchers understand the context of research guidelines and regulations of the country where research will be conducted . In many countries, however, if research guidelines and regulations are even available, they may only be available in the local language. A similar challenge for RECs is when proposals are written in a language that the REC members cannot understand. As such, members of the REC may not be able to review the proposal accurately. In Malaysia, researchers are requested to submit the proposal's information sheet and consent form in all the three official languages. Malaysia requires an official translator to translate the forms using the reverse translation method.

Hence, language issues may involve additional costs which should be considered at the time of proposal development by researchers and the sponsors.

To pre-empt any violation of local research regulations, a best practice may be to provide national research guidelines including ethical guidelines in multiple languages for external researchers.

2.6 Relationship between RECs and researchers: hierarchical/impersonal to mentoring/supportive relationship

Presenter: Dr Nguyen Thanh Huong

RECs in Viet Nam review research proposals from both ethical and scientific perspectives. They also monitor, supervise and inspect ongoing studies to ensure compliance with GCP and ethical requirements; evaluate final reports and outcomes; and participate in continuing education and training activities in biomedical ethics, research and GCP.

The relationship between RECs and the principal investigator is rather strained. The principal investigator may view the initial REC review as a hindrance on the road to progress, while RECs believe that the process improves the protection of research participants and the research itself. The principal investigator may see the progress report as another opportunity for RECs to obstruct the research, while RECs believe that reviewing every protocol is important in protecting human subjects. The principal investigator may not see the value of reporting adverse events even though RECs believe that being aware of such events allows them to continually assess the risks and potential benefits of the study.

To improve the relationship, RECs should aim to be facilitative and educational instead of adversarial and burdensome. REC administrators should be service-oriented, facilitate timely, thorough and complete reviews, communicate effectively with researchers, and provide a variety of training opportunities for REC members and research teams. On the other hand, researchers should regard research as a privilege, know the rules, appreciate the benefits of the REC review process, plan ahead and join the process.

User-friendly websites with research tools such as decision trees, FAQs, tutorials and manuals for researchers may be helpful. Research institutes should commit sufficient space, staffing and resources for RECs and provide quality education and training on different aspects of research.

2.7 REC operations and standard operating procedures: need for flexibility and researcher-centric approach

Presenter: Ms Sharon Biribo

Overview of research in Fiji: Research in Fiji is conducted by Ministry of Health personnel, undergraduate and postgraduate students in training institutes, external researchers, development partners and NGOs. Observational studies and programmatic public health research including audits, health surveys, and clinical research, make up most of the research. Other types of basic laboratory-based research and clinical trials are very rare. External researchers require research permits as well as various approvals from the Ministry of Education and Ministry of Indigenous Affairs. The Government issued an HIV research decree to prevent excessive research of people living with HIV/AIDS and to reduce the stigmatization risk in the communities.

Overview of the research committees in Fiji: Formal ethics committees were only established sometime between 1998 and 2002. The primary goal of ethics committees is to protect human research participants, and the secondary goal is to support research by individuals and institutions. Risk management and governance of research are low priorities.

Approval from the National Health Research Committee is required if researchers want to access Ministry of Health facilities, patients, patient records and patient samples. The College Health Research Ethics Committee reviews staff and student projects and provides institutional approval. However, all proposals, even if approved by the College Ethics Committee, need to be approved by the Fiji National Health Research Ethics Review Committee.

Key highlights:

(1) Research ethics committees should aim to be flexible and not too procedure-oriented. Procedures should be adapted according to the research landscape and needs of the researchers and institutions, without compromising the quality of research and the safety of the participants.

(2) Efforts are needed to change the perception of RECs as bureaucratic to a guiding/mentoring resource for researchers.

(3) Coordination is needed between different institutions and approval bodies, for example, between the College of Medicine and the Ministry of Health, to minize the need for approvals from different committees for the same proposal.

(4) If RECs do not have adequate resources, time or capacity to support the researcher, alternative mechanisms should be available.

(5) Recommendations for improving health research in Fiji include setting a national health research agenda, and allocating government resources to support research governance as a whole.

Possible solutions from the perspective of a developing country include: establishing a system that supports national health research needs with appropriate procedures and policies; preparing clear definitions of terms such as research, low-risk, high-risk, vulnerable populations

and classification of data; increasing training at all levels of the research continuum to emphasize that technical and ethical integrity is the responsibility of all; and establishing clear guidelines for researchers and clear terms of reference and SOPs for committees.

Discussion points:

(1) Transparency and accountability in the system are paramount to. The roles and responsibilities of researchers, funders, participants and research committees should be clarified. Processes and guidelines, including information on the turnaround time for proposals, should be easily accessible. People will want to be part of the process if they know what is involved.

(2) Ethics committees should have a mentoring function to guide researchers through the review process. Active communication with researchers will improve the performance and efficiency of ethics review committees. Decisions should be conveyed immediately to researchers so they understand the reasons for approval or disapproval.

2.8 Use of innovative IT solutions in management of RECs: issues and solutions

Chairperson: Dr Shivnay Naidu, Rapporteur: Dr Nobuyuki Nishikiori

IT solutions may be used to set up integrated research management and governance systems to link the ethics review systems, prospective research registries, data repositories, and final research reports and publications. There is substantial potential to improve accountability, efficiency, quality and transparency in research, outcomes, and its applications.

Three systems in use in Malaysia, New Zealand and the WHO Regional Office for the Western Pacific were demonstrated.

2.8.1 Use of IT solutions in REC process management in New Zealand

Presenter: Dr Robin Olds

Since New Zealand launched its online system in July 2012, about 150 research applications have been submitted with very few issues. An outsourced private company (InfoNetica) developed the system. An annual license fee covers helpdesk support and maintenance.

Scope: The online submission and review system serves the national-level Health and Disability Ethics Committees (HDEC) and the Standing Committee on Therapeutic Trials (SCOTT). The system does not extend to the institutional ethics committees which primarily review the low-risk proposals.

The system has three key components: (a) an online application and submission portal for researchers, (b) a database for management purposes, and (c) a committee member portal for proposal review.

Choosing the committee for review: Researchers can choose among the four HDECs to review their proposal. They have the option of submitting their proposal to the next available meeting of any of the HDECs or to the next meeting of a particular HDEC in their vicinity. If the physical location of the ethics review meeting is inconvenient for the researchers, they can participate in the meeting by teleconference.

*Automated decisions about expedited and full revie*w: Based on answers given to screening questions at the time of submission, the proposal is automatically assigned to "expedited" or "full" review. The researchers are asked to specify benefits and risks associated with the proposed research and the management of risks, if any; conflicts of interests; equity of research; and impact on health inequalities. Researchers get an automatically generated acknowledgement receipt upon successful submission.

Processing of submitted proposals: Upon submission, the system notifies administrators of the protocols due for review in the next meeting. Every committee member has access to the application and receives alerts about the meetings. The system logs and tracks all the protocol-associated communications between different stakeholders such as researchers, administrator and committee members.

Organizational changes with switching to online system: With the adoption of an online submission system, the reduction of HDEC review scope only to ethics issues, and establishment of a central clearing house, staffing has been reduced slightly from 8.7 Full Time Equivalent (FTE to 6.3 FTE, and the number of regional HDECs has decreased from seven to four.

Challenges: Switching to an online system brought about several challenges, including additional training required for committee members, internet connectivity for members representing community in the committee, and interim period during which both paper-based and electronic systems had to be maintained.

2.8.2 National Medical Research Register (NMRR) in Malaysia (http://nmrr.gov.my)

Presenter: Dr Maimunah Hamid

Malaysia launched NMRR, an integrated online research management system, in 2007. NMRR was developed by an outsourced private company at a cost of about US$ 250 000.

An integrated system: Malaysia's system, which is much broader in scope than New Zealand's, integrates several different processes. NMRR has a publicly-accessible prospective research registry and a proposal-submission portal that allows researchers to submit their protocol not only for ethics review (Medical Research Ethics Committee [MREC] but also for other approval processes (financial, regulatory, institutional approval, etc.). Researchers can select committees or other regulatory bodies to which to submit the protocol.

In other countries (e.g. Australia, China, Republic of Korea, Japan), the research registries are standalone, requiring researchers to register their research separately. Submitting a proposal for ethical review is a completely separate process.

The NMRR also serves as portal to access different guidelines on conducting research in Ministry of Health facilities and includes an "Investigator Directory" that allows researchers to find other investigators working in the same technical field.

The system can be accessed by a researcher, reviewer, MREC member, manager or secretariat member using an account identification number.

Scope of research submitted and reviewed under NMRR: Currently, NMRR allows registration, submission and review of both interventional (clinical trials) and observational research conducted in Ministry of Health facilities or by Ministry of Health researchers. Universities and their institutional ethics review committees are not linked to this database. However, they are encouraged to register their research in the system.

Public access: A public user can access a minimal data set containing 20 data fields (as recommended by the WHO International Clinical Trials Registration Platform) for all the studies in the Directory of Medical Research. In addition, a public user can access the Investigator Directory.

Processing of proposals: The NMRR secretariat checks the submission and forwards the proposal for review and approval to MREC and other NIH institutions. The MREC secretariat decides whether a proposal will undergo an expedited or full review — both of which are managed by the system. For full review, the reviewers' comments are consolidated and given to the investigators through the system.

Staffing: The NMRR system is managed by a secretariat consisting of six professional NIH staff and 15 support staff. For IT, there are two people who respond to inquiries and ensure submissions are complete.

2.8.3 WHO Regional Office for the Western Pacific

Presenter: Dr Manju Rani

Development of the system: The WHO Regional Office for the Western Pacific launched the online research management system in March 2012 and uploaded the data retroactively from January 2011 onwards. The development of the system stemmed from the need to better monitor and track research portfolios, investments and outcomes in a transparent manner and to improve accountability.

The system was developed through in-house customization of open-source software (OJS). The customization process cost between US$ 4000 and US$ 5000. It provides an integrated solution with multiple functions: online proposal submission; efficient management of the REC review process; monitoring of health research investments and outcome of approved research studies; publishing research outputs; and information exchange, networking and coordination among different stakeholders. Similar to Malaysia's system it includes a prospective, publicly-accessible research registry which provides basic information on all the approved research projects.

Working of system: Access to the system is tailored to each type of user (e.g. administrator, researchers, REC secretary and members, reviewers). The system generates automated e-mails and reminders, e.g. for submission of final reports six to 12 months after the specified end-date of the research. The REC secretary and researchers can send e-mails through the system, and all communications are logged. An automatic notification is sent to all the relevant people if any change is made to a research proposal. Researchers submit their progress reports and final reports through the system.

Customization of the system for use in other countries: The system in its current form may be suitable for use in countries which have limited human and financial resources and only one or two RECs, such as Cambodia, Fiji and the Lao People's Democratic Republic,. The WHO Regional Office for the Western Pacific is working with some of these countries to customize the system to suit their needs.

Customization of the WHO Regional Office for the Western Pacific system for the Lao People's Democratic Republic: The system was customized to provide a single submission platform for the two RECs in the Lao People's Democratic Republic. Based on the jurisdiction of the two committees, researchers can select the committee for their proposal review upon proposal submission (somewhat similar to New Zealand's system). The submission process also guides

researchers through the process of submitting papers to international journals, as the processes are somewhat similar. The national research coordinator/administrator can track all the proposals submitted to both committees, though they are not able to take any action (approval, etc.). This can only be done by the appropriate REC secretary.

Benefits for researchers: The portal serves as a one-stop shop for information, reduces paperwork, allows convenient online proposal submission, helps researchers track the status of their proposal, archives their proposal for future use, and avoids loss of submission information. The public registry function allows researchers to check if there are any ongoing studies submitted by other researchers in the same technical area. It also serves as a capacity-building tool as the submission process forces researchers to think through the technical and issues involved in their proposal.

Benefits for sponsors and funding organizations: The funders and sponsors can track proposals through the publicly-accessible database of approved research. The system also allows them to network with other sponsors who fund research in similar technical fields.

Benefits for REC Secretariat: The system allows the REC secretariat to manage and track the submissions over time; use built-in e-mail templates to communicate with researchers, REC members, internal and external reviewers; and create a panel of external experts/reviewers. Hence, it enables an efficient and transparent review process and helps track performance (time taken in review, proportion of proposal undergoing different types of review, etc.).

Research coordination and management capabilities: As a research coordination and management tool, the system can help track the overall research portfolio, total investments, and priority setting. It can also facilitate linking the final research report with other research studies and manage the other research output such as research data which may be of wider and long-term value.

Challenges: System operationalization requires an appropriately staffed and trained secretariat. Some countries with limited resources may face challenges in maintaining infrastructure (e.g. server failure or electricity shortage), ensuring compliance by internal and external stakeholders, acquiring human resources and funds to manage the system, and utilizing the information provided. For the system to be successful, researchers must supply the correct information and follow the steps to submit their proposals. Though setting up the system will require some initial investments in infrastructure and training, these investments will be a fraction of total research investments.

Research for Health and Innovation Organiser (RHInnO): A health research management system developed by the Council on Health Research for Development (COHRED) was briefly introduced.

Discussion points on use of IT-based research management solutions:

(1) It is important to regularly obtain system users' feedback in order to ensure continuous improvement of the system.

(2) *Implementation in Member States*: Dr Greg Koski expressed that every country should be able to implement an IT-based system immediately if there is commitment from. However, it will take time to increase awareness, train staff and customize the system to the local requirements.

(3) A national system with a national body to oversee all IRBs is feasible, and could promote standardization and efficiency.

(4) Standardization of the review process: While standardization within a country is definitely achievable, standardization across countries faces challenges due to differences in infrastructure, research capacity and human resources. Changes in organizational set-up in a particular country have so far proven difficult.

(5) Use of readily-available systems versus development of new systems: It may be desirable to use readily-available systems that offer tried and tested functionalities at a lower cost and can be upgraded regularly. While many countries choose that option, substantial customization is still required to meet local organization and process needs.

2.9 Re-examining the structure and roles of RECs

Chairperson: Dr Robin Olds, Rapporteur: Dr Nobuyuki Nishikiori

2.9.1 Revisiting the assumption and membership of RECs with regard to community and special representation (e.g. lawyers): impact on review and practical feasibility: Mongolia

Presenter: Dr Burmaajav Badrakh

The role of the layperson: The primary role of RECs is to reflect the values of local communities and national culture and to ensure representation of the interests of women and vulnerable populations. Hence, REC membership should include laypersons to provide a perspective, unaffected by professional interest, exposure and prejudice. Laypersons sit on bioethics committees such as the National Bioethics Committees of UNESCO, and other committees in Belgium, Norway, South Africa, Spain, and the United Kingdom of Great Britain and Northern Ireland.

RECs in Mongolia: The Minister of Health issued the national Ethical Guidelines for Biomedical Research Involving Human Subjects in 2007. The national guidelines require representatives of layperson and lawyer on all RECs. Like other REC members, these representatives receive training in research ethics.

Selecting lawyer and layperson representatives has proved to be challenging despite awareness-raising and publication of several guidelines. There are nine RECs in the Ministry of Health and in various research institutions. Out of these, two RECs could not find a lawyer representative and three RECs could not find a layperson representative. It may be beneficial to conduct a study on the selection and role of lawyers and laypersons in RECs, develop detailed guidelines for inclusion of lawyers and laypersons in RECs, developing a training module and other training materials, and improve public awareness of the roles of the layperson and lawyer in RECs.

Discussion points:

(1) Definition of layperson: The definition of layperson is not uniformly understood. In New Zealand, where RECs are required to have at least three laypersons as members. layperson is defined as an individual who is not a health practitioner or a health researcher, and whose nature of employment is not in conflict with the research. A layperson should also have some training in ethics and morality.

Others argued that laypersons and lawyers do not have the qualifications to serve on RECs. For example, if a lawyer knows little about ethics, the process often becomes a regulatory review rather than an ethical review.

(2) Challenges*:* In the Philippines, where at least one layperson is required to be present at REC meetings, identifying someone able to contribute from the point of view of the community and review consent forms and information sheets has proven to be a challenge. Hence, training will be required. RECs need to foster a collaborative environment where laypersons without a health background can freely contribute to discussions.

(3) Procedure for selecting the layperson: In the Philippines, laypersons are selected based on referrals. They are invited to attend trainings and are placed on probation while their membership is reviewed. They should be independent and not tied to any institution. Church pastors and community representatives often sit on RECs.

(4) Ethicists as REC members: Having an ethicist on the committee may cause members to rely on advice, instead of being properly trained in ethics. It is important for researchers to understand ethics and apply it in the field.

(5) Feasibility of community representation*:* In the rapidly changing research landscape actual research sites may be far removed from review sites. For example, a WHO regional office REC may be reviewing proposals for research to be conducted in multiples countries, or a national REC may be reviewing proposal for research in multiple provinces. It is not clear how community or layperson representation can be practically achieved in these situations.

2.10 Review committees in countries with few trained researchers and predominance of external funding

2.10.1 Cambodia

Presenter: Dr Chhea Chhorvann

Cambodia currently has only one REC, the National Ethics Committee for Health Research (NECHR) and no institutional REC. NECHR is responsible for reviewing all the research projects in Cambodia. It was established by the Ministry of Health in May 2002 and recognized by the Prime Minister in November 2004. The SOPs of NECHR were developed in 2002, revised in 2006, and revised again in 2008, but are poorly accessible and disseminated to researchers.

NECHR membership is appointed by the Government and includes an epidemiologist, a sociologist, a lawyer, a statistician, clinicians, a microbiologist and pharmacists. Including laypersons on the committee still needs to be discussed. Currently, there are 18 members and, a quorum requirement of 50% plus one for the full review board. NECHR currently does not have a biostatistician or epidemiologist, and most members have little research experience or knowledge about research methods.

NECHR membership has not changed since the initial appointments in 2002. The SOPs of NECHR do not specify fixed durations for the appointments, making membership, open-ended. Most NECHR members are high-ranking officials with little time and expertise to review protocols. English is the predominate language of proposals, which makes it difficult for some members.

Number of research protocols reviewed: In 2012, NECHR reviewed at least 112 protocols, but it is not known how many underwent expedited versus full reviews. Government institutions submitted 46% of the proposals in 2012. Though most of the principal investigators are Cambodian, most of the proposed research is externally-funded.

Challenges: Since most of the research is externally-driven, and there is no national health research agenda, NECHR cannot determine the relevance and/or necessity of research proposals. Furthermore, NECHR does not have the capacity to assess the qualification of researchers and the appropriateness of the research methods. Finally, there is lack of documents on research ethics or responsible conduct of research in the Cambodian language, making it even more difficult for NECHR to learn from the experiences of research review processes in other countries.

Strategies implemented to overcome challenges: NECHR encourages relevant institutions/ministries to develop research agendas (ex. HIV/AIDS research agenda). NECHR also encourages more joint research projects between local and international investigators by requesting support from the local agencies before any protocols can be approved. Still, weak research capacity in the country may prevent local researchers from fully benefitting from such collaboration.

Review of proposals by NECHR: A secretariat team of epidemiologists and experts (called secretaries) has been assigned by the NECHR chair to facilitate the administrative work and also to provide technical support to NECHR members. Secretaries receive applications, screen them for completeness, and send protocols to all NECHR members two weeks before the meeting. They also prepare technical summaries including methodologies for the proposals assigned to them and present them during the full board review. However, secretaries are not asked to vote. A review fee of US$ 400 is charged for protocols, except for those submitted by students, to cover the operating cost of NECHR and its secretariat office.

Discussion point: concerns about membership*:* Open-ended appointments by the Prime Minister is a key concern. The current membership, structure consisting of high-ranking policy-makers is more suitable for a policy-making committee than a review committee. The organizational responsibility for policy-making for overall research governance, including research ethics is not clear. It was suggested that members are appointed for a fixed-term and more committees are set up at the institutional level, possibly at the University of Health Sciences, as one committee may not be able to review all proposals while maintaining quality.

2.10.2 Lao People's Democratic Republic

Presenter: Dr Kongsap Akkhavong

History of research ethics: Before 2000, the topic of ethical considerations in health research was neither known nor discussed in the Lao People's Democratic Republic. In 2000, the Mekong Malaria Forum, established with support from the European Commission, sponsored the first training of Lao participants at a seminar on ethics for health research in Bangkok. Two workshops on research ethics were held in 2000 and 2001 with support from WHO and the European Union.

Current situation: There are two RECs in the Lao People's Democratic Republic. The first REC was established at the University of Health Sciences in 2001 to review the research sponsored or conducted by the university. The second REC—National Ethics Committee for Health Research (NECHR)—was established in July 2002 with its secretariat at the National Institute of Public Health (NIOPH). Sixteen members were appointed from NIOPH, Ministry of Health, Ministry of Education, Ministry of Justice, Lao Women's Union, etc., with no specified duration of appointment. In the beginning, NECHR functioned relatively well because ethics was a new topic, and members participated in ethics training workshops abroad and interacted with committee members from neighbouring countries. However, over time, members lost interest in reviewing the proposals.

Membership issues: Similar to Cambodia, most NECHR members are senior officials with little understanding or experience in health research. Many of the members who were appointed in 2002 have retired (though continue to be members on paper) or have lost interest. There are no incentives (financial or otherwise) for NECHR members or the secretariat. With little refresher training for NECHR members and no sharing of experiences among ethics committees, the NECHR has become practically defunct. Lack of any evaluation or assessment of the REC and its review process has further undermined its functionality.

The Lao People's Democratic Republic is considering restoring NECHR with active members. New SOPs for proposal submission and review are being developed. However, it may be difficult to motivate members in the absence of any incentives. A proposal review fee may help support operating expenses and provide incentive to NECHR members.

Next steps: Improved transparency and accountability in health research will enhance ethical conduct of research. With assistance from the WHO Regional Office for the Western Pacific, the country launched a national health research portal to provide basic information on all the approved research proposals. In addition, Guidelines for the Responsible Conduct of Health Research in the Lao People's Democratic Republic have been drafted to define the roles and responsibilities of health researchers and investigators. Future improvements to research governance and efficiency include revamping and reforming the research ethics committee at NIOPH and developing systems and policies for health research data sharing.

2.10.3 Fiji

Presenter: Mr Shivnay Naidu

RECs in Fiji have been functioning satisfactorily with clear guidelines, support from the ministry, and collaboration with academic institutions, particularly the Fiji National University (FNU). Challenges include securing commitment and time from REC members, dealing with pressure from managing expectations of external organizations, and aligning research studies with national health priorities.

Strengths of RECs: The RECs are well-placed in Fiji to carry out research proposal reviews its functions. They receive support from senior management, FNU and development partners, and have dedicated and motivated staff. A dedicated health research officer serves as the secretary of national REC (Fiji National Research Ethics Review Committee).

As of September 2012, a total of 60 proposals were submitted for review, with 47 approved by the National Health Research Committee (NHRC) and four approved by the Fiji National Research Ethics Review Committee (FNRERC). While the REC review process works fairly well in Fiji, improvement to meet the changing needs of researchers and the changing scope and types of research will be beneficial..

Tools and resources: The tools and resources required by the RECs include: policies, guidelines and SOPs on proposal review and approval; terms of reference for the committee; and codes of conduct for researchers and the committee. The RECs also need staff and funds to facilitate administrative functions, policy development, SOPs, guideline development and review. While Fiji, currently, has no national standards, it has guidelines that set the platforms (codes of conducts, terms of reference), processes and procedures for the conducting of health research in the country. Examples of tools include National Health Research (1999), A Health Research Guide for Fiji (2007), and Health Information Policy (2011).

Future directions: Guidelines under development in Fiji include: Guidelines for the Responsible Conduct of Health Research in Fiji: Roles and Responsibilities of Health Researchers and Investigators; SOPs for Fiji National Research Ethics Review Committee; and Policy on Public Health Research Data Management and Sharing. These guidelines are being developed with assistance from the WHO Regional Office for the Western Pacific. Fiji is also reviewing the online health research management system developed by the WHO Regional Office (Fiji Health Research Portal), to replace the current manual submission.

Challenges: Currently, there needs to be training and capacity-building of REC members on ethical review, SOP and policy development, good research practices. If the online system is introduced, additional training would be required for REC members and researchers.

Other challenges include attending REC review meetings as a priority for members, encouraging development partners/donors to do research aligned with Fiji's health needs, and managing other research areas such as research on medical devices (e.g. hyperbaric chambers), traditional medicine and lifestyle/behavioural changes. Another challenge is ensuring submission of final reports to REC and establishing necessary monitoring mechanism in place. Recently, the Ministry of Health's Research Office developed a monitoring mechanisms using Microsoft Excel to record start and end dates, and to monitor the submission of progress reports and final reports.

Discussion point: Outsourcing research proposal reviews by smaller countries, such as some of the Pacific Island countries. Some small community hospitals establish under-resourced ethics committees for multi-centre trials, which do not serve much purpose. Outsourced reviews might be a solution for very small island states that do not have sufficient in-country human resources.

2.11 Group Work 1: Re-examining the current models and system of RECs: issues and solutions

Chairpersons: Dr Vicente Belizario, Dr Nguyen Thanh Huong
Rapporteur: Dr Jaime Montoya

Participants were divided into two groups to discuss and develop concrete recommendations to simplify, optimize and improve effectiveness of research ethics systems.

The first group focused on small countries: Cambodia, Fiji, the Lao People's Democratic Republic, Mongolia and New Zealand. The group was moderated by Dr Chhea Chhorvann and Dr Sharon Biribo. The second group focused on mid-size and large countries: China, Japan, Malaysia, the Philippines, the United States of America and Viet Nam. The group was moderated by Dr Vicente Belizario and Dr Nguyen Thanh Huong.

A semi-structured guide was used to conduct the group discussions. Outcomes of the group discussions are summarized below:

2.11.1 Policy and standard-setting

(1) There is an urgent need for overarching national policies/laws/guidelines which will be binding for all departments and stakeholders and will deal with all the issues related to research not only research ethics or review. These national policies/guidelines/laws should provide the policy or legal mandate to RECs to perform their current functions. If the RECs are governed by national policies/laws/guidelines, it may be easier to secure necessary budget and support from public authorities.

(2) There is a lack of clear organizational responsibility for policy-setting in research ethics in many developing countries. There also has been insufficient allocation of human and financial resources for research governance including research ethics.

In some countries (e.g. Cambodia, Fiji, Lao People's Democratic Republic), the starting point of the research ethics system had been the establishment of committees, instead of a national policy or legal framework. In many instances, establishing the first committee did not involve dialogue among national stakeholders, and were driven by external procedural requirements for review of externally-funded research.

Furthermore, in some countries where a single national ethics review committee was set up by an administrative order of the ministry of health, there is confusion on whether the same committee is responsible for policy-setting as well.

The policy-setting function should not be done by the research review committee. Governments should specify organizational responsibilities and mechanisms for developing national policies and guidelines on health research, which may involve dialogue among different stakeholder ministries or governments. China recommended developing holistic frameworks for health research including etchis considerations,as part of the overall health system,. The organizational responsibility for overall research coordination may be specified by the Government for both health research and overall research.

(3) *Organizational responsibility and conflict of interest:* In addition to the situation in Cambodia and the Lao People's Democratic Republic, a conflict of interest was pointed out in New Zealand, where the Health Research Council is responsible for allocating resources to different health research projects as well as for overseeing research ethics. In the United States of America, since combining those two functions is considered a conflict of interest, a separate and independent office was established to oversee human research participants.

The key policy-making body for research ethics in the Philippines, PHREB, is not tied to any particular government agency or department and is able to avoid conflict of interest as it serves in an advisory capacity to all four agencies that are part of the Philippine National Health Research System.

(4) Multiple authorities setting guidelines without coordination sometimes leads to conflicting policies*:* In Japan, many ministries (e.g. Ministry of Health, Ministry of Finance, and Ministry of Education) are responsible for health research policy setting, but there is no coordinating mechanism. Over time, the ministries have developed guidelines for research implementation and ethics but without much dialogue and harmonization in the process. In the absence of a general policy on research, specific guidelines developed for genetics, gene therapy (2003–2004) and clinical trials may not be fully in sync with key overarching issues. Similarly, in Viet Nam, pharmaceutical law (drug law) and clinical law, both of which have implications for research ethics, are developed and issued independently by different departments. In China, five different departments have issued more than 20 regulations related to ethics. These regulations relate to GCP, state food and drug administration, traditional medicine administration, organ transplantation organization, stem cell research, etc. China is making efforts to compile all rules and regulations including those for hospital-based IRB, in a single book.

(5) Format of national policies on health research and ethics: Whether a parliamentary policy, or a government order from a Prime Minister's office, which transcends individual ministries, a chosen option will depend on a country's particular socio-political situation and research landscape. One size may not fit all. In addition, ethical thinking is not the same as legal thinking.

The United States of America's ethical review system, for example, has disintegrated into a system of regulatory review that focuses on compliance to regulatory/procedural requirements.

2.11.2 Simplification and efficiency

The group discussed various options for simplifying the research ethics review system. It first considered the types and number of reviews a single research proposal undergoes on average and the resources spent on reviewing the proposal by different committees and authorities at different levels. It deliberated on innovative processes (or restructuring of systems) that may improve the system by reducing the time, human and financial resources required for the review process, without jeopardizing the protection of human subjects.

It discussed more efficient and feasible options to organize the review process in the context of multisite, multi-country, multiple-institution collaboration. The group also examined the cost and feasibility of using IT solutions to facilitate these goals.

It was agreed that simplification and improved efficiency should not come at the expense of compromising the human subjects. With this overall goal in mind, several themes for simplification and efficiency were discussed:

(1) Integrated technical and ethical review with appropriate safeguards and composition of REC.

Smaller countries, despite their very limited human resources, have adopted similar REC review mechanisms. There is need to customize the systems according to the capacity and resources of a particular country. In developing countries, where substantial research is externally-funded or commissioned, another challenge is to assess the relevance of proposed research to the country health context and its appropriateness to the cultural context.

(2) *Harmonization of review guidelines, process, standards and SOPs across the committees in country*

As a first step, comprehensive national guidelines that spell out relevant review standards and procedures and that are binding across all the institutions and committees should be developed.

An effective programme of accreditation of RECs, including accreditation authority, criteria and processes, may further facilitate harmonization. Accreditation may also build confidence among the research community that processes are consistent with international standards. While ccreditation has been adopted by many countries, including the Philippines and the United States of America, itse impact on the efficiency, effectiveness or quality of review is yet to be seen. However, considering substantial variation in the volume and complexity of health research across countries, there may not be a “one-size-fits-all” solution and each country has to apply what is suited to its environment and needs.

(3) Minimizing repetitive and redundant multiple reviews: Repetitive and redundant reviews are consequences of either multi-agency (funder, sponsor, research institute) reviews of single-site research or multisite reviews of a multisite research.

Coordinating procedures and standards, accreditation and a *trust-based system* among committees will facilitate this objective. Policy directives and guidance for the RECs to ensure compliance with single or reciprocal review, as well as networking among RECs will also be beneficial to the process.

In Malaysia, even if the research is conducted in multiple facilities of the Ministry of Health, a single review is done by the Ministry's REC. An initiative on "cluster REC" has been undertaken in the Philippines to deal with the issue of multi-site research projects.

Some of the regional forums such as FERCAP and international bodies such as WHO can facilitate networking among RECs across the countries. Even for multi-country studies, the idea of setting up a regional committee through WHO or FERCAP was put forward.

(4) Accreditation of research sites*:* In addition to accreditation of RECs, Dr Koski proposed accreditation of research sites – ACRES project which involves both industry and academics in Washington, DC, the United States of America.

2.11.3 Transparency and accountability

Measures to increase transparency and accountability in the REC review system would lead to improved effectiveness. It was agreed that transparency and accountability should be promoted while maintaining the privacy and confidentiality of research subjects. Some of the potential measures suggested during the group work included:

(1) *Accreditation and certification of REC*: This will ensure ongoing external and internal input into RECs' operation. RECs should also be encouraged to conduct regular self-assessment using standard assessment forms.

(2) Improved communication and exchange of information (formal or informal) between different stakeholders including researchers, civil society and the general public: The sharing of information and experiences can be between RECs in a country or among countries. Public disclosure of information about RECs, membership meetings and meeting minutes through a website is recommended. The Philippines provides the information on registered RECs in the country through the website of the Philippines Ethics Review Board. In Japan, there are ethical guidelines for Clinical Studies, which requires an institution to report information about their RECs annually via a web-based system.

(3) REC meetings to the broader community: Instead of conducting the ethics review behind closed doors it may be beneficial to invite a limited number of observers, either experts or members of the community to REC meetings.

(4) Use of transparent IT system automated processes: This will facilitate classification of research proposals into different risk categories and hence different review procedures. IT solutions can also facilitate integration of review process, so that a single submission goes to all the necessary review groups. Finally, IT solutions can allow better information sharing and more transparency in the review process.

(5) Publically-accessible prospective research registries: These will also increase the transparency in the research reviewed and approved by the RECs. These registries should be mandated by a policy-making or governing body. Experience across countries has shown that it can be difficult to monitor research implementation. RECs normally do not follow up on the final research reports.

2.11.4 Organization of RECs

The group discussed key shifts to change the way the current ethical review systems are organized membership, involvement of researchers, interactions with researchers, etc). These

reforms will help change the role and perception of RECs from policing bodies to mentoring and guiding bodies.

(1) Ethics review systems (RECs) as part of the overarching research ethics system, which is further rooted in an overall research governance system:

(a) The ethical code of conduct should be part of the overall code of conduct for researchers: This overall code of conduct for researchers should emphasize scientific responsibility, compliance with other regulations, and responsibility to provide access to and disseminate research results. All these issues have important implications for ethical conduct of research.

(b) RECs should be responsible for mentoring researchers and educating the public. The system should empower all research participants. RECs should also have a quality improvement arm, an education arm, and a compliance arm. The ethics committee is just a small component of the ethics review system.

(2) Policing to mentoring and guiding

The role of RECs to standardize policies, review standards and procedures, and ensure compliance and changes in the paradigm may contradict with the mentoring and guiding functions of the RECs. This need not be the case as the coordinated review standards and procedures should allow sufficient flexibility for RECs to take into account specific contextual issues.

(3) Responsibilities of REC: RECs are just one piece of the puzzle to ensure the ethical conduct of research. Other components of the system are equally important and should similarly be improved.

2.12 Measures and regulations to ensure researchers' accountability and capacity to conduct ethical research

Chairperson: Dr Kongsap Akkhavong, Rapporteur: Dr Jaime Montoya

2.12.1 Models and measures to increase researchers' accountability and responsibility beyond REC review

Presenter: Dr Greg Koski

The missing link to an effective health research ethics system is ensuring a responsible investigator. Henry Beecher pointed out the importance of focusing on investigators and emphasizing their accountability to ensure a stronger research ethics system.

It is important to consider the broader environment or system of which RECs are a part. In a system, all parts have to work together to achieve. Therefore, there is a need to look beyond the REC.

Similar to an airline security system, which is expected to protect airline passengers from potential harm but has no evidence of its impact on passenger safety, there is little evidence that an ethics review system is effective in protecting human subjects.

The current ethical review process tends to be too focused on procedural compliance, and is too often disproportionate to the actual risks involved. Quoting Carol Levine, who described

the system as born in scandal and reared in protectionism, Dr Koski believed that the system is actually getting in the way of doing meaningful research. Researchers, the public and patient advocates are calling to reform of a system that is perceived as expensive, burdensome and time-consuming.

Though there is a value in having independent review and oversight, an assumption behind the REC-centric system —that scientists want to hurt people—needs to be changed, as researchers will not do well by hurting people.

Compliance with regulations is not what protects human subjects. How the research is actually done is more important. The twin pillars of ethical research are "independent ethical review" and "informed consent", but it is impossible to have informed consent in the absence of well-trained, responsible and knowledgeable investigators. An essential third essential pillar of ethical research, therefore, is "responsible investigator".

I*mportance of researchers' training*: Investigators are in the best position to protect the well-being of participants, but they are also in the best position to do harm, sometimes due to lack of training than intentional harm. About 80% of investigators who conduct clinical trials are simply not trained to do research, while other investigators are engaged in too many clinical trials at the same time to do them responsibly. FDA audits consistently reveal deficiencies in research conduct, even at the most fundamental level, for which the researcher is mostly responsible. Hence, the importance of training researchers to design both ethically and scientifically sound research cannot be overemphasized.

Emphasizing researchers' responsibility: Ethical responsibility should be placed not only on RECs, but also on researchers and sponsors. The research ethics system needs to undergo a paradigm shift from "protectionism" to "performance". In a performance-focused paradigm, research protocols would be both ethically- and scientifically-sound when they arrive at RECs. RECs should have the power to conduct reviews at any time, and the investigators should be held accountable. There should be incentives for researchers who do excellent work, and the privilege to do research should be taken away from those who do not. Rather than spending too much time on reviewing protocols, 90% of which may not need any review, resources may be better used for monitoring.

Standardization: An ethics system must be an international endeavour to increase efficiency and standardization. As the standardization of air travel policies by the International Transportation Association has led to a safe and efficient global transportation network, an international standardization of research ethics leading to a network of accredited research sites may substantially improve research quality. An international endeavour, Accreditation of Research Sites (ACRES), is an alliance of like-minded organizations that hopes to improve the way clinical research is done through better education, training and site monitoring. While a global endeavour, ACRES will be implemented at the national and regional level.

Discussion points:

(1) ACRES*:* It was clarified that ACRES is not an accrediting body, and that several national and global accrediting bodies already exist. ACRES aims to develop standards based on agreed upon approaches by different stakeholders. These standards can then be used by independent third parties around the world. The countries or research sites that become part of the global network will then use the same accreditation standards. This is somewhat similar to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) process.

(2) Accreditation in the United States: The International Organization for Standardization (ISO) is one of the administrative agencies responsible for accreditations to ensure rules are applied consistently.

(3) Training researchers: It is the responsibility of institutions, not of RECs, to train researchers. In the Philippines, training on research ethics and methodology are integrated into residency programmes, undergraduate medical programmes, and high school curriculums. It is important that researchers understand research ethics early on and are certified before they can conduct research.

(4) Researcher responsibility versus oversight system: There is a need for an overall code of conduct in health research. Investigators are not bound by the Hippocratic Oath, like physicians. Researchers may prioritize generating knowledge over ethics; hence, researchers' accountability may not be sufficient to prevent ethical violations. In addition, the primary focus of the pharmaceutical industry may be generating profits instead of benefitting humankind. Researcher responsibility does not mean that continued oversight and review are not needed. Establishing a code of conduct for research, which Mr Beecher advocated, could address those concerns.

(5) Ethical review versus ethical conduct of research: Ethical review of research does not guarantee ethical conduct. Many REC-approved researches have been subject to plagiarism, data manipulation, animal subject issues, and conflict of interest with human subjects. Editors, reviewers and publishers are also gatekeepers for ethical conduct of research and research accountability.

2.13 Current guidelines, regulations and capacity-building measures in Member States

2.13.1 Malaysia

Presenter: Dr Maimunah Hamid

Institutes of research: The six institutes of research in Malaysia focus on biomedical research, epidemiological research and behavioural research. All six institutes are supported by a secretariat.

Creating a research culture: Undergraduate education in Malaysia emphasizes research training to build a research culture. Undergraduates are exposed to research conduct through courses on methodology, analysis, dissemination, translation and research ethics. Special initiatives include courses on good research practice (GRP), good clinical practice (GCP) and good laboratory practice (GLP). An emphasis is also placed on research translation into action beyond publication.

Investment in training and capacity-building: There is continual training for researchers via institutional workshops where researchers who are currently doing research come together to talk about data collection, management, data analysis, etc. Interested individuals (mostly practising clinicians) are tapped as core trainers to carry out local and state-level training. Additionally, every five years, Malaysia defines the health research priority areas. Clinicians who plan to be involved in clinical research must undergo GCP training as per the *Malaysian Guideline for Good Clinical Practice*.

Research handbooks: *The Medical Research Handbook: Planning a Research Project* (Amar-Singh HSS, et al, 2008, 2011) is used extensively by researchers and for training workshops. The book is available online at http://www.crc.gov.my/documents/researchHandBook.pdf It discusses and gives examples on

how to translate research into practice, analyse data, write a report, publish and disseminate findings. The book includes a section on ethical issues in research, which covers researchers' responsibility, tips on projects that require ethical approval, and steps for submitting research proposals to the National Medical Research Register (NMRR).

Courses: Several courses are available to researchers, including certification courses on GRP, GCP and GLP, which can be conducted by any health facility. The training certificate has to be uploaded to NMRR . GRP focuses on establishing and promoting a code of good practice in all aspects of research, whether the research is funded, non-funded, team-led, project-based or individually-led. GCP focuses on the protection of the rights, safety and well being of study subjects, and assures the integrity of scientific testing and study conduct. GLP ensures studies are systematically planned, performed, monitored, recorded, reported and archived. The course contents have to be approved by the National Committee for Health Research. A refresher course may be required for those who took course more than five years prior.

Policy-maker involvement: At least one policy-maker is identified for each research study to ensure that issues have been identified and studied, to ensure that updates are passed on to policy-makers, to facilitate the progression of the project, to promote ownership and mutual responsibility, and to increase the policy-maker's understanding of the research process and its limitations.

Platforms for translating research into evidence: There are both formal and informal platforms. Informal platforms include closed-door presentations to facilitate "buy-in" of higher-level policy-makers and to improve chances of translating evidence as well as meetings and functions to discuss research needs.

Formal platforms are those that involve the Ministry of Health. At the local level, research may be presented to state health directors. At the national level, the Director-General of Health may meet with all programme heads and state health directors. Other formal platforms depend on research area/content. For example, patient safety research is presented to the Patient Safety Council.

2.13.2 China

Presenter: Dr Jinqian Wang

Researchers should work in an environment where they will know how to move forward when an issue arises regarding ethical conduct of research.

There are three components to setting up this environment. First, a researcher's goal should be aligned with the needs of the nation and its people. Second, the researcher should understand that the safety of the human subject should always come first. Third, an innovative research environment should be guided by regulations and processes.

The main tasks in the current research ethics system are to promote "institutional" ethical guidelines or handbook for researchers in addition to the national and provincial-level guidelines, to strengthen ethical training on both ethic committee members and researchers, to continuously build up and get application of regulations for ethical supervision and governance. The disincentives and penalties for those who violate institutional, provincial and national guidelines are also necessary.

2.13.3 Philippines

Presenter: Dr Vicente Belizario

Research governance structure: One of the best practices in the Philippines is a comprehensive national governance framework with clear institutional networks and linkages, public-private partnerships, and research community support.

The core agencies in the Philippine National Health Research System (PNHRS) are the Department of Health, Department of Science and Technology (DOST), Commission of Higher Education (CHED), and University of the Philippines Manila–National Institutes of Health (UPM-NIH). The governing council of PNHRS oversees research management, ethics, research utilization, resource generation/mobilization, and capacity-building. The regulatory bodies include Food and Drug Administration, which reviews and approves clinical research involving pharmaceuticals for marketing authorization, and oversight of sponsors of such researchers. Another regulatory body is Philippine Health Research Ethics Board, which is responsible for the National Ethical Guidelines for Health Research, and which oversees RECs including a national registry and accredits RECs.

National Ethical Guidelines for Health Research (NEGHR, 2011): The NEGHR is a national statement which incorporates international guidelines and local regulations. It has an interdepartmental scope of authority beyond the Ministry of Health through the Administrative Orders of DOST (AO 001s2007) and CHED (MO34s2007). This is the primary guidance document for sponsors, investigators and RECs.

An ethical review of research also assesses the quality of research, which includes assessments of the research protocol's compliance with national guidelines and institutional requirements, the scientific qualifications of investigators to address the demands of the research, and the scientific merit and ethical acceptability of research. The sponsor is responsible for ensuring the conduct of research in accordance with national guidelines, and the institution is responsible for ensuring an ethical environment with policies in place for monitoring.

Early challenges in capacity strengthening in research ethics: These included advocating for a regular training programme particularly since 2005, obtaining institutional support as many administrators did not see the importance of research ethics, cooperation of investigators since they viewed research ethics as an obstacle, a general lack of awareness, and the need to train personnel.

Capacity strengthening in research ethics: The Philippines has many training providers, but UPM has the capacity to hold regular trainings. UPM-NIH Training Center for Health Research Ethics & GCP has been offering short courses since 2005. The course offerings include: (1) Good Clinical Practice and Research Ethics for Investigators and REC Members; (2) Standard Operating Procedures for RECs; and (3) Continuing Ethics Education: Health Research Methodologies and Research Ethics for all Stakeholders. Class size ranges from 20 to 80 participants per course. The objectives and content of the courses were developed in collaboration with Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)-FERCAP, but the courses are conducted by a pool of experts in the Philippines both on-site and off-site. Participants include a wide range of research stakeholders (investigators, REC members and policy-makers). Course fees are supported by institutional training funds from government and private entities, as well as personal funds from participants. The majority of funds, however, come from private institutions.

Total number of trainees to date is 2231. 317 participants were trained in 2012 as of October. Of the participants, 34.8% are investigators, 24% are REC members, 11.3% are research staff, 4.5% are policy-makers, and 2.3% are sponsors. Sponsors and contract research

organizations (CROs) often sit in the trainings as researchers. Special training for sponsors and CROs are currently not available. Institutional representation is as follows: 21.9% from government hospitals; 29.4% from nongovernment research institutions; 12.2% from government research institutions; and 39% from nongovernment hospitals. Currently, most participants come from the National Capital Region (NCR) because of the concentration of research institutions and RECs in the metropolitan area.

Challenges: The current challenges include the need to expand the core of training personnel to include those from outside NCR, to provide a post-training forum for sharing successes/challenges and discussing/solving problems, and to develop assessment tools for outcome mapping (e.g. changes in practice or behaviour). Training institutions must work hard with stakeholders other than Institutional Review Boards, such as sponsors, FDA, investigators, institutions and participants, who are at the centre of research. The importance of networking and sharing experiences was emphasized.

2.13.4 Viet Nam

Presenter: Dr Nguyen Ngo Quang

Viet Nam has a hierarchical health system with four levels: national, provincial, district and commune. The national level comprises national, general and special hospitals, research institutes, medical schools, and the health service provision sector. The provincial level consists of provincial hospitals, medical schools, health service provision units, and preventive health facilities. The district level has district hospitals, district committees, preventive health facilities, training classes, and pharmacies. The commune level includes commune health centres, commune-level committees, and village health workers.

Background: The priority for research in Viet Nam is to ensure the safety and efficacy of new products, but not necessarily increasing the number of clinical trials. Ensuring safety and efficacy of new products require combined responsibility and "knowledge" of the principal investigator, health authority, REC and sponsors in developing protocols and conducting research.

Rationale for establishing and standardizing the clinical trial network: Viet Nam is in the process of establishing a clinical trial network. The rationale for such a network are to meet the increasing demands and needs for drugs and medical equipment (domestic and internationally as well as to provide the population with access to new medical products that meet safety and efficacy requirements. The clinical trial system will provide the legal corridor for this access. Hence, there is an urgent need to establish and standardize the clinical research system in compliance with WHO ethics guidelines, the GCP- ICH, local laws and regulations.

Clinical trial system in Viet Nam: The clinical trial system is overseen by the Ministry of Health and the Independent Ethics Committee. The management agency for the clinical trial system is the Science-Technology and Training Administration (STTA) of the Ministry of Health, with the Independent Ethics Committee housed under the Ministry of Health. There are also clinical research units (CRUs) in 12 hospitals and research institutions, and institutional review boards (IRBs) at medical universities, hospitals and research institutions. These bodies follow regulations and GCP guidelines in overseeing the clinical trial site, principle investigator, sponsor and contract research organization. The fundamental elements of clinical trials include protecting human subjects, ensuring the quality of the study, and ensuring the accuracy and integrity of the data.

Clinical trial research capacity in Viet Nam: Legal documents relating to clinical trials and research ethics include the Drug Law (2006), Science and Technology Law (2008), Clinical Trial Regulations For Medical Equipment (2006) and drugs (2008; updated 2011), Good Clinical Practice Guidelines (2008), operational regulation of RECs (2002, 2008. 2012), requirement for technical training for REC members, and GCP training of principal investigators and other researchers.

The Independent Ethics Committee was established in compliance with the WHO ethics guideline and GCP-ICH guidelines, and has been registered with United States National Institutes of Health since 2008. SOPs were subsequently established and regular meetings (one or two per month) were held to review clinical trial protocols.

The evaluation and approval procedure for a clinical trial starts with the protocol approval by the local IRB, followed by submission to and approval by the Independent Ethics Committee, and ends with approval by the Minister of Health.

Progress and achievements: These include guidelines for IRBs and Clinical Research Units at hospitals and research institutions, training for researchers and IRB members on research ethics, and offering GCP classroom and online training. Another achievement has been the establishment and operation of the Independent Ethics Committee and its website (http://iecmoh.vn.) Guidelines for biomedical research based on the WHO guideline and those for contract research organization and sponsor management organization operations in Viet Nam were also issued. The latter guidelines defined their legal responsibility, professional requirements, operating modes, their role in serious adverse event reports, and their responsibility toward the sponsor and management agency during the clinical trial. There has also been international collaboration in establishing the clinical trial center in Viet Nam, which will have ethics review responsibilities much like the clinical trial unit in hospitals.

Discussion point: While this presentation focused exclusively on clinical trial research in Viet Nam, a substantial amount of non-clinical trial research is also ongoing. A national health research system assessment was undertaken in 2006 with mapping of universities, research institutes and externally funded research.

2.14 System measures to ensure ethical conduct of research beyond prospective review systems

Chairperson: Dr Greg Koski, Rapporteur: Dr Jaime Montoya

2.14.1 Facilitating more transparency in health research: prospective registration

Presenter: Dr Li Youping

Two major initiatives in China to improve transparency in research were presented. The first initiative, the Chinese Cochrane Centre as part of The Cochrane Collaboration, focuses on systematic review, while the second initiative, the Chinese Clinical Trial Register (ChiCTR) as part of WHO International Clinical Trial Registration Platform (ICTRP), focuses on prospective registration of intervention research in publicly accessible registries.

The Cochrane Collaboration: This non-profit NGO has 15 Cochrane Centres across the world. The organization supports its centres with methodology support, unified standards, global promotion and quality control, and continuous improvement systems. The steering group of the Cochrane group consists of five types of representatives from the consumer network, experts from various fields, and Cochrane Centres. Each Cochrane Review Group focuses on only one

type of disease. A systematic review is produced for professional readers such as physicians. There are other review groups that rewrite the abstracts based on public demand.

To improve transparency and quality control and reduce duplication, a prospective registry of systematic reviews was established. Titles of research are registered in the Cochrane Library, followed by publication of the protocol after three months. The full text is published after a year and a half. Through the Cochrane Library' search portal, one can access information at different stages of systematic review. The library also keeps track of unpublished protocols, even if the data and research are not deemed as useful.

The number of contributors has increased dramatically from 5437 researchers from 64 countries in 2000 to 27 792 researchers from 109 countries in 2010. The 10 countries with the largest number of participants in 2010 mostly developed countries, were: Australia, Brazil, Canada, China, Germany, Italy, the Netherlands, Spain, the United Kingdom of Great Britain and Northern Ireland and the United States of America.

The disadvantages are that the research data are mostly in English. Some are in Spanish, Italian and Chinese. Therefore, the depth and scale of participation among developing countries should be urgently strengthened. Ethics review is not emphasized.

WHO ICTRP: The prospective registration system comprises a search portal, central repository, 14 primary and partner registries. Through the search portal, anyone can access ongoing clinical trial information from the central repository. By country, the registered number of clinical trials are as follows: Australia (5912), China (1589), Germany (692), India (1852), the Islamic Republic of Iran (2020), Japan (7658), the Netherlands (3011), Sri Lanka (68), the United Kingdom of Great Britain and Northern Ireland (10174) and the United States of America (117 277).

WHO took the lead to help countries establish primary registries and drew up access criteria and standard registration requirements involving pre-registration, ethics review, methodology review, whole quality control and output monitoring. Bilingual registration is required in non-English speaking countries, and supervision and sharing registered information with the global and local public are encouraged. The disadvantages are that registration is not mandatory, and existing registries had not adopted a unified standard before the WHO ICTRP was established in 2007.

ChiCTR: The Chinese Clinical Trial Registry (ChiCTR) strictly follows the requirements by WHO ICTRP. ChiCTR has free and bilingual registration and registers all quality control items such as randomized methods, allocation concealment, blinding, and statistical methods. It also monitors publication of final results one year after the trial is completed.

All studies that evaluate the effects of interventions on human subjects, including drugs, non-drug treatments, procedures, instruments and devices, which are designed as randomized controlled trials, case-control studies, cohort studies, non-controlled studies or other observational studies of prevention and treatment, prognosis studies, cause studies and diagnostic tests, though not mandatory, should be registered,. Only ethics-reviewed clinical studies can be accepted for registration, so a copy of an approval letter from an ethics committee is required upon registration. An informed consent form and a protocol that meets the GCP standard also have to be uploaded when registering the trial. Currently, 2240 trials have been registered, 1524 of which are intervention trials and 716 observational studies.

ChiCTR was approved by WHO ICTRP and the Ministry of Health of China. It integrates the talents of the Cochrane Centre in China and the resources from West China Hospital, the

largest hospital in China. ChiCTR created a special module that combines trial registration and publication cooperation. So far, 98 medical journals have joined, making it possible to coordinate the development of a new strategy that includes good research practice (GRP), good publication practice (GPP), good translational practice (GTP) and good evaluation practice (GEP).

GRP involves pre-registration, which enables management and quality control through completion of the trial. GPP involves educating researchers and editors of journals about standards for writing academic articles on clinical trials. ChiCTR also provides secondary research registration. GTP involves providing decision-making consultation and developing practice guidelines. GEP involves outcome evaluation to improve the quality of the entire process. The current challenge is guaranteeing continued financial support and development of these practices.

These three models have common characteristics. They are based on significant public demands and integrated planning. They all can provide methodology support, standardization and transparency, public supervision and feedback. Continued financial and policy support from both international agencies such as WHO and national governments is required. In addition, efforts are required for timely data verification and increased utilization of the data. Ethics review and methodology supervision also need to be strengthened.

2.14.2 Prospective health research registries – to improve ethical conduct of research

Presenter: Dr Jaime Montoya

The Philippine Health Research Registry (PHRR) (http://registry.healthresearch.ph) is a publicly-accessible database of ongoing health research. It was launched in August 2012. PHRR conforms to the WHO-mandated clinical trial data field requirements and uses universal primary and secondary identification numbers.

PHRR is able to track ongoing health research, who funds what kinds of projects, compel researchers to submit final reports, help avoid duplication of research, ensure equal opportunity for participation in clinical trials, help companies recruit the most number of patients in the shortest amount of time. PHRR also encourages research collaboration, promotes transparency and accountability, and propagates the ethical research culture.

Challenges in setting up PHRR: Four challenges were faced in setting up PHRR. The first challenge was accommodating varied information needs of stakeholders. Extensive consultation with stakeholders were done before, during and after the development of the registry to agree on the data fields that would be included in the registry.

The second challenge was obtaining technical staff. PCHRD could deploy only two programmers to work on PHRR development. Development of the registry took eight months, and staff needed to work overtime during the course of development.

The third challenge was developing the registry without a template. The programmers had no guidance on how other registries had been developed. Practically from scratch, the team developed the features that would make the registry user-friendly and with enough security features that would ensure a secure uploading and maintenance of information.

The fourth challenge was ensuring compliance to register by the researchers. While FDA has made the registration of clinical trials mandatory, registration is still not mandatory for research funded by the Department of Health or the Department of Science and Technology.

Continued intensive information dissemination is needed to encourage researchers and institutions to register.

Research data sharing in Philippines: Data sharing can help maximize returns on investments in research by optimal utilization of data from different perspectives. Data sharing enables other investigators to work with data for purposes not originally intended, resulting in the identification of important correlations or associations that may serve as basis for policy or future studies. Data sharing also helps avoid repetition of studies.

Data sharing also helps to encourage young researchers to analyse data and encourage collaboration among researchers from both public and private sectors. More studies may result as an offshoot of the main study. Furthermore, data sharing promotes transparency and accountability. For publicly-funded research, the public is entitled to see the results. Data sharing ensures that investigators analyse data with scientific rigor. It also encourages the scientific community to scrutinize, analyse and use data for common good.

Institutional requirements: To implement effective data sharing, research institutions need to ensure that researchers who access important data receive adequate training and supervision on the proper use and analysis of data.

System requirements: For the data repository to be effective, there should be readily-accessible websites, an absence of bureaucratic approval processes, safeguards to protect the public from irresponsible use of data, and data formats that can be readily-used and analysed by researchers. There is also a need to ensure there is no infringement or violation of existing laws related to intellectual property or government fund use. Finally, the system should continuously evolve to meet the changing needs of the scientific community and public.

The current efforts to set up PHRR and data sharing complement the existing database for local Health Research Data and Information Network (HERDIN) (www.herdin.ph) research conducted since the 1990s}/HERDIN includes both published and unpublished literature.

Discussion points*:*

(1) Responsibility to ensure registration of research: While the principle investigator is responsible for registering the research, both funding and sponsor agencies can play an important role in ensuring registration of research.

(2) Use of standardized software: In-house support is important to ensure continuous improvement. The online integrated research management system demonstrated by the WHO Regional Office for the Western Pacific and by Malaysia combines the registry function with the REC submission and review system. The WHO Regional Office for the Western Pacific will make its software available to the smaller countries for customization.

2.15 Archiving and sharing of health research data to improve transparency and ethical conduct of research

2.15.1 Data sharing – potential, issues, and challenges: New Zealand

Presenter: Dr Robin Olds

Data sharing and open access publishing help achieve the best value from public investment (i.e. taxes) when primary research data are available for valid second users and when

publications are freely available. Greater transparency also supports research integrity. The challenges, are knowing what data are worth storing ensuring equity.

Data curating and storage involves real monetary cost. Organizations therefore need to start thinking about funding for services beyond what is normally funded to help with organizing the metadata. Another challenge is data ownership. The researcher only collects the data. In New Zealand, the data always belongs to the individual participant, who has the right during and after the research to change their minds about sharing their data. The indigenous Māori people in New Zealand have a different perspective on data sharing, that giving away data for unknown future use may be perceived as exploitation.

Another challenge is resistance, especially among public health researchers. Biomedical scientists are used to sharing their data, such as is the practice in genomic research. For public health researchers, however, their data represent intellectual capital (if not property) and are used to leverage international collaboration and funding.

For example, the researcher of an ongoing birth cohort study, where 1000 individuals were recruited and monitored throughout their lifetime, hopes to use the data as leverage to receive additional funding. Although there is an incredible richness of data in biological samples, the ability of the study to be carried on depends on the researcher's ability to actually obtain the future additional funding.

The question is then how to change the minds of researchers to consent to future unspecified use of their data when their resistance is not due to an issue of compliance but of data sharing. In New Zealand, data sharing policies are expected to materialize by next year.

Discussion point:

Data sharing has many sensitive issues that need to be addressed upfront. Dr Abha Saxena added that some lessons may be learnt from those who run biobanks. She noted that there are two levels of consent – one at the level of information collection and another at the user level. Dr Rani responded that New Zealand has an advanced public health survey data repository online and that Cambodia and the Lao People's Democratic Republic are currently trying to catch up. The surveys in these two countries are funded by external agencies and are archived by the funder and not by the country. Without access to their data, the countries cannot build their research capacity.

2.15.2 Data archiving and sharing – WHO Regional Office for the Western Pacific

Presenters: Dr Manju Rani and Mr Cedric Faure

Dr Rani and Mr Faure presented the health research data repository developed at the WHO Regional Office for the Western Pacific and its potential for replication in small- to medium-sized countries. Data archiving and sharing are major issues in research governance. Data sharing is especially important for large-scale population surveys, which have long-term public health significance. The repository is a tool to bring more efficiency and transparency.

The repository uses the metadata editor and National Data Archive (NADA) platform, which were developed through the International Health Survey Network (IHSN) project of the World Bank and Organization for Economic Cooperation and Development (OECD) (http://www.ihsn.org/home/software/ddi-metadata-editor). A brief demonstration was given on the platform and the user interface. The researchers can access questionnaires, data sets, and survey metadata. The metadata editor is used to enter all the metadata information about a survey

including the actual dataset. Through the microdata catalogue, which is the core of the application, the user can search datasets by country, topic or study description. Once the user locates the survey they want, they can access the technical information, such as questionnaires. Researchers can also compare metadata across different data sets.

Discussion points:

(1) Anticipated use of the system: In the Philippines, there are at least 20 population surveys that need to be accessible and utilized at the central level. Dr Rani noted that population survey data, rather than clinical data, has been made the starting point for the public health microdata repository for this reason. In five years, the accumulated data can be used for analysis.

(2) The platform is being tested for archiving and sharing data from research studies/surveys sponsored by WHO. Researchers will have exclusive rights to the data for two years but need to upload their data after two years. A future direction will be to ensure formats for data fields are compatible for clinical data as it might be valuable to integrate data sets from both clinical trials and population surveys. Archiving data from population surveys will be the first step.

2.16 Group Work 2: System measures to ensure ethical conduct of health research beyond prospective review

Participants were divided into two groups to discuss system measures to ensure ethical conduct of health research beyond the review of research proposals by REC.

The first group was composed of small countries: Cambodia, Fiji, the Lao People's Democratic Republic, Mongolia and New Zealand. This group was moderated by Dr Kongsap Akkhavong and Dr Shivnay Naidu. The second group was composed of middle- and large-income countries: China, Japan, Malaysia, the Philippines, the United States of America, and Viet Nam. This group was moderated by Dr Yasuyuki Sahara.

The key outcomes of the group discussion are summarized below:

(1) Scalable policy and programmatic *options for increasing the supply of trained researchers in developing countries*: Research investments in developing countries are increasing rapidly and outpace the supply of researchers who are competent in implementing technical and ethical research. This may lead to increased ethical violations due to ignorance and incompetence rather than intention.

Several issues were identified. Criteria are needed for defining a "trained" researcher or adequacy of training and who should be trained (e.g. members of a research team, data collectors, support staff). Training should include in-service training, continuous training, and informal self-training. Training in research should begin even in primary or secondary schools and continue through pre-medical and medical schools. A distinction between formal and informal training should be made. Informal on-the-job training could provide a research assistant with the skills and knowledge needed to become a principle investigator.

The duration of the training courses is not standardized. Varying durations and content may be required depending on the past experience and current competence levels of researchers. Training may take many forms and purposes including a forum for consultation or a seminar for continuing education. The importance of hands-on training was emphasized, as some people may be skilled in writing protocols but have no field experience in research implementation. In the United States of America, two years of specialized training is required to become a clinical

investigator. Some of the existing training courses developed in the United States of America or Europe may be used in universities in developing countries.

Assessing researcher's capacity to undertake the research: Before undertaking research, there should be evidence that the researcher is adequately trained. Most RECs require reviewing the curriculum vitae of the principal investigator, which may provide evidence of the competence. Ideally, researcher training should conform to national and international standards, but many countries do not have such standards, and it may be difficult to compare a three-week to a three-day training on a CV. In Malaysia, the track record of a researcher is a very important criterion. Clinical research training does not only entail clinical competence. In Europe, detailed analysis of needs and requirements from investigators and members of the research team is emphasized. Additionally, researchers should be interested and committed to the endeavour, so there should be an appropriate demand and reward system.

Responsibility for training: Governments play a central role in providing resources for research training. Research institutes and funders (both internal and external) should set aside resources for training the research teams.

To summarize, options to increase the supply of trained researchers in developing countries include ensuring research workforce development is part of research funding collaboration, matching capacity-building in externally-funded projects to conference-based training or in-country short courses as appropriate, upgrading and strengthening programmes in universities, facilitating more political commitment and intersectoral coordination, updating the research methodology curriculum, and providing short courses for in-service staff.

(2) Mechanisms and framework to reinforce researchers' and research institutions' accountability

There is undue emphasis on REC review to ensure ethical conduct of research. This may have diluted the perceived accountability of researchers and research institutions to ethically conduct research. Mechanisms or frameworks to reinforce researchers' and institutions' accountability include empowering and consolidating the existing health research governance bodies to carry out their mandate, establishing explicit guidelines, regulations and/or codes of conduct specifying roles and responsibilities of researchers and institutions as well as consequences of violating the code of conduct for researchers, and observing an overarching research policy.

Defining accountability: The group defined accountability as being able to meet the expectations of all research stakeholders including human research participants. It implies that the research proposed is relevant to country health needs (essential health research), is making best use of the limited human and financial resources, and is appropriate to its capacity and organizational context. Accountability also implies that research results are made available to the target communities who participated in the study. The study outcomes must be communicated to the policy-makers and programme managers and should be published as much as possible.

Accountability hierarchy: The researchers are accountable to their professional society and to their field, to the funding and sponsoring agencies, and most importantly to the communities and human research participants.

Enforcing accountability: Mechanisms to reinforce accountability may be at different levels e.g. university level or institutional level. Many countries have issued explicit guidelines or codes of conduct that emphasize and define the role and responsibilities of researchers and institutions. Different professional or specialty societies may also have codes of conduct and

researcher requirements that may be publicly-known. In Malaysia, professional societies might be helpful in setting up mechanisms for accountability.

Sometimes sanctions are imposed as is the case in the Philippines. Establishing a registry for researchers who are allowed to do research was suggested. If researchers are found in violation of the code of conduct, they may lose their title on the register and be prevented from conducting research. However, organizational accountability is also important, and having a researcher registry may diminish the responsibility of an organization or professional society.

Requiring researchers to obtain clearance to publish from the government may help ensure accountability as is the practice in Malaysia. However, this approach may limit the freedom in the research process. To facilitate internal accountability, it may be better if external researchers with domestic researchers to ensure that data are correctly interpreted in the appropriate social, linguistic and cultural context.

Finally, publishers play an important role in enforcing accountability. Journals need to ensure that researchers have actually conducted the research in accordance with ethical principles, in addition to checking if REC approval was obtained..

(3) Current measures other than ethical review (e.g. policies, interventions) that contribute to ethical conduct of health research

Other innovative measures that promote ethical conduct include registration, post-review or evaluation through progress reports and site visits. Registration of research has been made mandatory in many countries including the Philippines, though only for clinical trials. Prospective registration in publically-accessible registries has substantial potential to improve ethical conduct of research.

Role of REC beyond proposal review and initial approval: The REC should also conduct continuous monitoring including site-visits and management of serious adverse events. RECs must obtain progress reports and may prioritize high-risk protocols for closer scrutiny. However, monitoring is the least developed ability of ethics committees, even for countries such as Malaysia, and few RECs have sufficient resources to carry out this function.

To overcome challenges in implementing these measures, country leaders/ministers need to be engaged and understand the importance of the health research governance system. There needs to also be dialogue between researchers and policy-makers. WHO may consider holding orientation training for policy-makers. The goal of research should be translational and result in knowledge transfer.

(4) Reducing research wastage and improving research efficiency: A recent *Lancet* article pointed to a high-level of research wastage due to incomplete research, flawed methodology, or lack of reporting of results.

There were questions on the status and mechanisms for sharing of final research results with potential users of research especially in the context of externally funded non-pharmaceutical research. Some best practice examples were shared.

The HERDIN database in the Philippines includes both published (full papers) and unpublished papers (abstracts). Malaysia does not have a database for grey literature; researchers funded by the Ministry of Health provide copies of their research to libraries for reference. In Viet Nam, information on studies, particularly in electronic format, is still scarce, and publication in international journals is limited. For China, data sharing through English publications is not be

fully appreciated by some target audiences, so translation may be important. Secondary data are important for analysis, especially for long-term follow-up.

Publications should not be as the sole source of dissemination because they are not the best medium for target audiences such as legislators or policy-makers. There needs to be better knowledge transfer of research outcomes towards policy development and programme implementation.

3. CONCLUSIONS

(1) Research ethics governance and optimization is part of improving research ethics systems. Research ethics review is just a subsystem of the research ethics system. RECs are just one component of overall health research system.

(2) Good science is just as important as good ethics; hence, technical review should be done with the same rigour as ethical review.

(3) Different countries and settings may adopt different procedures as per their unique context, needs, type of research conducted and the human and financial resources for research ethics systems. However, the processes and procedures should be harmonized across research ethics committees in a country under a unifying national policy framework. There is a need for a quality management system for research ethics, accreditation and recognition.

(4) To ensure ethical conduct of health research, researchers, RECs and other stakeholders need to be enabled and empowered. There is a need for more capacity-building, success and impact metrics. Strengthening links between researchers and RECs is important to foster open communication, service orientation, service provision, support and mentoring. Networking and collaboration towards strengthening the research ethics system is also of importance.

(5) IT and research ethics systems: Based on the experiences in New Zealand, Malaysia and the WHO Regional Office for the Western Pacific, IT solutions offer considerable potential to improve accountability and efficiency by improving transparency and streamlining procedures. A national system involving multiple committees offers substantial potential for harmonization and standardization. It also ensures efficient document management by archiving protocols, reports and results (data). Standardized IT solutions across countries may help to harmonize processes globally. However, substantial differences in capacity, organizational structures and human resources across countries may still require customization of the system and processes.

(6) Major issues brought forth by developing countries included: lack of organizational clarity for RECs and health research governance overall, and setting up policy to ensure the conduct of ethical research. The key challenges of the national RECs highlighted included: restructuring the REC system as a whole and addressing an overburdened national committee (Cambodia); securing commitment and time of members and building their capacity (Lao People's Democratic Republic); and aligning with the national health agenda and dealing with pressures from external donors, organizations and research institutions (Fiji).

(7) Ignorance, inadequate training and lack of capacity to conduct research in a competent manner, while unintentional, may lead to ethical violations. Hence, research training programmes in developing countries is needed to ensure ethical conduct of research.

4. RECOMMENDATIONS AND ACTION ROADMAP

(1) Linking the ethics systems with the overall governance system: Some Member States or institutions within the Member States, have set up research ethics committees even without an overall research governance framework. The research ethics system is only one of the components of overall health research governance and is ideally strongly rooted and emphasized in the overall framework of research governance.

Practical action point*:* It is recommended that Member States examine and establish an overall framework of research governance as per their local context, needs and resources.

(2) Research ethics systems and research ethics review committees: Ideally, research ethics systems are recognized as multidimensional. Recommended components of a research ethics system include systems for training, emphasis on accountability of researchers, and oversight system comprising of REC or similar bodies. The research ethics review process by a REC, while important, is only one component, of the research ethics system.

Action points: Some small Member States have set up stand-alone RECs that are responsible for both policy-making and review of the research proposal. It is recommended to separate the two functions, and develop a more holistic and comprehensive research ethics systems. Multiple options/measures aside from the ethical review process and committees, such as mentoring, empowering, training, educating different stakeholders may be considered. Dialogue between countries may help facilitate learning in this area.

(3) Streamlining and optimization of ethical review systems*:* A clear, harmonized national policy and standards framework, informed by international guidelines and standards (e.g. WHO standards), may underpin the ethics review systems.

Action points*:*

(a) In Member States where multiple agencies and institutions are responsible for setting policy and guidelines, one overall coordinating body should be designated to ensure consistency across different policies.

(b) Member may consider a system approach towards ethical review, with the development of explicit policies and guidance for researchers, research institutions and other entities regarding the constitution of ethics review committees, their mandate, role, and responsibility, resources, membership composition and tenure, procedure and elements of review.

(c) It is recommended to examine ethical review system for any redundancies and time delays. Innovative measures to promote efficiency may help improve the process. Some of these measures may include benchmarking and performance metrics and self-assessment tools (accreditation/registration of RECs).

(d) Consider cost-effective and innovative IT solutions to further improve efficiency, transparency and quality of review systems. Integrated solutions that link registration processes and publishing/archiving of results may be ideal.

(e) WHO may be helpful in mobilizing resources and developing systems that may be replicated across countries.

(4) Shared goals and responsibilities: It is recommended to shift the perception of ethics review committees from regulatory/enforcement bodies to mentoring/guiding bodies by involving the researcher in the review process (e.g. researchers present their proposal during the review process, regular/open communication and collaboration between researchers and committees. Researchers and committees must both prioritize the safety of human research subjects/participants.

Improving the transparency of committee deliberations by making meeting minutes public, where feasible, should also be considered.

(5) Limited emphasis on building capacity of researchers, reinforcing their accountability, and the limited supply of trained researchers in many developing countries are major barriers to ensure ethical conduct of research.

It is recommended that countries develop systems, guidelines, checks/balances, and programmes to address these limitations. Developing code of conduct for investigators and certifying researchers may be helpful. In addition, Member States may review and develop suitable training programmes through universities and provide incentives to improve the supply of trained researchers.

Ideally, ethical concepts of research are mainstreamed, and supplementary courses are available for researchers planning to undertake research in developing countries.

Special case studies/databases/compendiums may be developed to instruct researchers on how to reduce risk and maximize benefits for human research subjects in different research situations and circumstances. Global and regional platforms for sharing research training resources developed by different organizations and Member States may be pursued.

(6) Investing in other measures to facilitate ethical conduct of research: Countries may consider developing other systems/measures that promote overall accountability and transparency in health research. These measures, while improving efficiency, quality and impact of research, would also be conducive to ethical research. These may include:

(a) publicly-accessible research registries—these registries could be stand-alone or linked to the research ethics submission system;

(b) systems to ensure appropriate reporting of research results—ideally, the results of all approved research are available in a public domain in an accessible and understandable format;

(c) data access and sharing where appropriate and feasible; and

(d) publication ethics as consistent with research ethics.

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ANNEX 1

AGENDA AND PROGRAMME

1. Opening session

2. Session 1: Setting the scene: a system approach to health research ethics governance

3. Session 2: Standards and organizational innovations in management of prospective review and research ethics committees (RECs)

4. Session 3: Use of innovative IT solutions in management of RECs: issues and solutions

5. Session 4: Re-examining the roles of REC and their relationships

6. Session 5: Group work 1: Re-examining the current models and system of RECs: issues and solutions

7. Session 6: Recommendations on innovations in RECs with a focus on simplification and streamlining

8. Session 7: Measures and regulations to ensure researchers' accountability and capacity to conduct ethical research

9. Session 8: System measures to ensure ethical conduct of research beyond prospective review systems

10. Session 9: Group work 2: System measures to ensure ethical conduct of health research beyond prospective review

11. Session 10: Conclusion: Discussion and agreement on plan to follow up on the implementation of outcomes of consultation

12. Closing

Day 1: Wednesday, 10 October 2012

Time	Title	Presenter
8:00–8:30	Registration	
8:30–8:40	Opening remarks	Dr Han Tieru, DPM
8:40–8:45	Welcome	Dr H. Bekedam, Director, DHS
8:45–-8:55	Welcome remarks	
	A round of self-introduction by the participants	Dr E. Christophel, A/Director, DCC
Session 1: Setting the scene: A System Approach to Health research Ethics Governance	**Moderator**	Dr Maimunah Hamid
	Rapporteur	Dr Vicente Belizario
8:55–9:15	The overarching issues for consideration by the Expert Consultation (meeting objectives and expected outcomes)	Dr Manju Rani , WPRO
9.15–-9.45	WHO standards for Ethical review of health research (2012)—feasibility, appropriateness	Dr Abha Saxena, WHO, HQ
9:45– 10:15:	*Group photo and coffee break*	
10:15–10:45	Vertical 'ethical' review or streamlining/incorporating 'ethical review' with other existing review systems (technical review, or regulatory review—Pros and cons	Dr Robin Olds & Dr Jaime Montoya
10:45–11:15	General Committees and/or Specialist committees (clinical trials, stem cell, genetic research)—models, organizational aspects	Dr Jinqian Wang & Dr Yasuyuki Sahara
11:15–12:00	Review committees in countries with few trained researchers and predominance of external funding—Issues, alternatives, pros/cons DISCUSSION	Dr Kongsap Akkhavong (Lao PDR) and Dr Chhea Chhorvann (Cambodia)
12:00 –13:00	*Lunch*	
Session 2: Standards and organizational innovations in management of prospective review and research ethics committees	**Moderator**	Dr Maimunah Hamid
	Rapporteur	Dr Vicente Belizario
13:0–0-13:30	Institutional Committees—issue of independence and alternatives; Linkages with regional committees, national committees?	Dr Jinqian Wang (China)
13:30–-14:00	Dealing with language barriers in a globalizing research environment: implications for researcher, reviewers and committees [guidelines, protocols in non-native language]	Dr Cecilia Tomas (Philippines), Dr Cristina E. Torres (FERCAP)
14:00–15:00	Accreditation, Registration and networking: objectives, options, feasibility and costs, and experience in member states DISCUSSION	
15:00-15:30	*Coffee break*	
15:30–16:30	Relationship between RECs and researchers: hierarchical/impersonal to mentoring/supportive relationship	Dr Nguyen Thanh Huong (Viet Nam)
	REC operations and SOP: Need for flexibility and researcher centric approach	Ms Sharon Biribo (Fiji)
16:30–17:00	Conclusions for the day	Dr Maimunah Hamid, and WPRO (Secretariat)

18:30–20:00	*WELCOME RECEPTION hosted by the Regional Director*

Day 2: Thursday, 11 October: Issues Related to Research Ethics Committees

Session 3: Use of Innovative IT solutions in management of RECs: Issues and solutions		**Moderator:**	Dr Shivnay Naidu
		Rapporteur:	Dr Nobuyuki Nishikiori
8.30–10.30	Use of IT solutions to streamline proposal submission process, reduce paper-work, and duplicative review and submission processes [will include discussion on use of commercial IT softwares if used in any of the countries] Feasibility of a centralized IT-based review management system with a single submission portal and a network of registered committees		Dr Maimunah Hamid (Malaysia) Dr Manju Rani Dr Robin Olds (New Zealand)
10:30–11:00	*Coffee break*		
Session 4: Reexamining the roles of REC and their relationships		**Moderator :**	Dr Robin Olds
		Rapporteur:	Dr Nobuyuki Nishikiori
11.00–12.30	Revisiting the assumptions and membership of RECs—community and special representation (e.g. lawyers)— impact on review and practical feasibility Resources of the committees: voluntary membership and charging for review-pros and cons Ethics review committees: Continuing review of the research and adverse events monitoring—status (tools and resources with RECs to do so), feasibility, effectiveness, need, and alternatives. DISCUSSION		Dr Burmaajav Badrakh (Mongolia) Dr Shivnay Naidu (Fiji)
12:30–1:30	*Lunch*		
Session 5: Group Work 1: Re-examining the current models and system of RECs: Issues and solutions			
1:30–3:00	Group work on the rethinking organization, role/ functions, and resources to simplify, optimize and improve effectiveness of RECs. Developing concrete recommendations on the issue discussed on day 1 and day 2		Two groups
3:00–3:30	*Coffee break*		
Session 6: Recommendations on Innovations in RECs with focus on simplification and streamlining		**Chairperson**	**Dr Robin Olds**
		Rapporteur	Ms Sharon Biribo
3:30–4:30	Group work Presentation and finalization of recommendations		Draft recommendation statement
4:30–5:00	Conclusion for the day		

Day 3: Friday, 12 October: Focusing on researcher responsibilities

System Measures beyond RECs to improve ethical conduct of research

Session 7: Measures and regulations to ensure researchers' accountability and capacity to conduct ethical research		**Moderator:**	Dr Kongsap Akkhavong
		Rapporteur:	Dr Jaime Montoya
8:30–9:00	➢ Models and measures to increase researchers accountability and responsibility beyond REC review		Dr Greg Koski
9:00–10:00	➢ Current guidelines, regulations, capacity building measures in member states ➢ Malaysia ➢ China ➢ Philippines ➢ Vietnam		Dr Maimunah Hamid Dr Zhai Xiaomei Dr Vicente Belizario Dr Nguyun Ngo Quang
10:00–10:30	*Coffee break*		
Session 8: System measures to ensure ethical conduct of research beyond prospective review systems		**Moderator:**	Dr Greg Koski
		Rapporteur:	Dr Jaime Montoya
10:30–11:00	Bringing more transparency in health research: prospective registration		Dr Li Youping
11:00–11:30	Requirement of sharing of final research results in a useable and sharable form		Dr Manju Rani
11:30–12:00	Data sharing—potential, issues and challenges		Dr. Robin Olds, Dr. Jaime Montoya
12:00–1:00	*Lunch*		
Session 9: Group work 2: System measures to ensure ethical conduct of health research beyond prospective review		**Moderator:**	Dr Greg Koski
		Rapporteur:	Dr Jaime Montoya
1:00–2:30	Group work on system measures to ensure ethical conduct of health research beyond prospective review		*Two groups*
2:30–3:30	Group work 2 presentations		
3:30–4:00	*Coffee break*		
Session 10: Conclusion 2: Discussion and agreement on plan to follow-up on the implementation of outcomes of consultation		**Co-facilitator**	Dr Greg Koski
		Co-facilitator	Dr Jaime Montoya
4:00–5:00	Finalization of conclusions and recommendations and action roadmap *Closing*		

ANNEX 2

LIST OF TEMPORARY ADVISERS, OBSERVERS/REPRESENTATIVES, AND SECRETARIAT

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