

13th FERCAP International Conference
Addressing Ethical Issues
Through Quality Multidisciplinary Health Research

VENUE

Sanur Beach Hotel
Bali, Indonesia
17- 20 November 2013



**Forum for Ethical Review Committees in Asia
& the Western Pacific**



Strategic Initiative for Developing Capacity in Ethical Review

hosted and co-organized by the



**Ministry of Health, Republic of Indonesia
National Health Research Ethics Committee**

with contribution from



**13th FERCAP International Conference on
Addressing Ethical Issues Through Quality Multidisciplinary Health Research
Bali, Indonesia, November 17-20, 2013**

Conference Registration:

Ongoing registration:

E-mail: atoynavarro@yahoo.com

On site:

November 17, 2013 13:00-17:00

November 18, 2013 08:00-12:00

POSTER Presentation: November 18-20, 2013

2013 Newly Recognized/Renewed Recognition/Interested Recognized ECs/IRBs

November 17, 2013

- Summit on Achieving a Harmonized Approach to the Ethical Review of Quality Multidisciplinary Studies: 08:30-17:30
- Pre-Conference Training: 13:00-17:00
Improving the Quality of Informed Consent
- FERCAP Steering Committee Meeting: 18:00-21:00

November 18, 2013

- Welcome Cocktails: 18:00-20:00

November 18-19, 2013

- Conference Proper: 08:30-17:00

November 20, 2013

- FERCAP and NAREC General Assembly: 08:30-13:00

Introduction

International and national regulations and guidelines have been formulated to ensure quality and credible data in research that should be conducted with the highest standards of human participant protection. To achieve this goal, research stakeholders need to conduct quality research, at the same time that they commit to uphold the principles and values of ethical health research for the common good. In an era of globalization, developing partnerships and alliance building among research stakeholders has become a key strategy in developing good practices and models of ethical and quality health research.

This 13th Annual FERCAP Conference will provide a forum for various stakeholders to discuss leading concepts, initiatives, and models in the conduct of ethical and quality multidisciplinary health research. The concept of good health is holistic in nature and health research requires multidisciplinary/interdisciplinary approaches to achieve relevant and useful results. The conference focus is good science and ethics in basic and applied research with valid and reliable results that are evidence based. The conference goal is to create an international network of national ethical research systems, consisting of ethically motivated, adequately informed and scientifically competent stakeholders who communicate and interact with one another to assure the public that the protection of the rights and safety of human participants are being safeguarded in the conduct of high quality research.

FERCAP by itself is a living model of partnership and alliance building in the region. The various conference speakers will highlight their thoughts and experiences in cooperative initiatives among individuals, institutions and organizations towards an integrated health research system based on common ethical values.

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Through plenary sessions, panel presentations, group discussions and reports, the best practices and initiatives in science and ethics involving various disciplines will be explored, presented and discussed to provide mutual learning among the conference participants.

Objectives

- To describe concepts, best practices and initiatives in science and ethics in health research
- To identify and describe quality structures, processes and outcomes in science and ethics in the conduct of multidisciplinary research
- To highlight ethical models and benchmarks as shown by the performance of various stakeholders (research ethics committee members, institutions, investigators, sponsors, patients and regulatory authorities) in health research.
- To identify gaps, facilitators and barriers to good science and ethics
- To suggest options and future directions of national ethical research systems to maintain the highest ethical and scientific standards in health research
- To develop relevant models of partnerships and alliance building in ethical research that promotes empowerment of stakeholders within the context of diverse Asian cultures and pluralistic socio-economic-political systems.

Conference Participants

The conference participants will come from the various sectors and disciplines involved in health research, mainly from Asia and the Western Pacific region. International representatives from national health authorities, ethics committees, researchers, research participants, academic institutions and the pharmaceutical industry will share their ideas and actual experiences to elucidate the conference theme.

Conference Outcome

The conference will contribute to better awareness, knowledge and practice about leading concepts and practices in developing models of ethical and quality multidisciplinary research.

FERCAP 2013 Conference Agenda

Day 1: November 18, 2013

08:30-09:00 Opening Ceremony

Session Chairs: Kenji Hirayama, FERCAP Chair

Magdarina Agtini, FERCAP Steering Committee (Indonesia)

Report of the Committee.....NHREC/FERCAP SC Member

Welcome Speech.....Made Mangku Pastika, Governor
of Bali Province

Introduction of Guests/Delegation.....Kenji Hirayama, FERCAP Chair

Keynote Address and Opening Remarks....Nafsiah Mboi, Minister of
Health, Indonesia

**09:00-10:00 Session 1: International Alliance Building for Ethical Health
Research**

Session Chairs: Vichai Chokevivat, SIDCER Chair

Kenji Hirayama, FERCAP Chair

WHO Support for Good Science and Ethics

Khanchit Limpakarnjanarat, World Health Organization (WHO)
Representative in Indonesia

**WHO/TDR and SIDCER/FERCAP: Continuing Engagement for
Ethical Health Research**

Fabio Zicker, World Health Organization Special Programme for Research
and Training in Tropical Diseases (WHO-TDR)

**Human Subject Protection in Biomedical Research: Can We Do
Better?**

Junjira Laothavorn, Kesara Na-Bangchang, SIDCER-FERCAP (Thailand)

10:00-10:30 Tea/Coffee Break

**10:30-12:00 Session 2: Improving the National Regulatory Environment to
Promote Ethical Research**

Session Chairs: Young Mo Koo, Asan Medical Center, Korea, FERCAP Vice-Chair

Magdarina Agtini, National Commission on Ethics of Health Research
(Indonesia)

**National Health Research Systems and Regulations for Ethical
Research in Indonesia**

Suriadi Gunawan, National Commission on Ethics of Health Research
(Indonesia)

Update on the Indian Regulatory Environment: The Ranjit Roychoudhury Committee Report on Clinical Trial Approvals
Vasantha Muthuswamy, Forum for Ethical Review Committees in India (India)

Regulatory and Ethical Requirements for Herbal Medicine
Hary Wahyu T., National Agency of Drug and Food Control (Indonesia)

Regulations in Mental Health Research in China
Yifeng Shen, Shanghai Mental Health Center (China)

12:00-13:30 **Lunch Break and Poster Viewing**

13:30-15:00 **Session 3**

<p>Parallel Session 3A Session Chairs: Sopit Thamaree, National Research Council of Thailand</p> <p>Suryani As'ad, Ethics Committee of Faculty of Medicine, University Hasanuddin (Indonesia)</p>	<p>Addressing Ethical Issues in Research with Vulnerable Populations</p> <p>Implementing Reproductive Health Research Guidelines in Ethics Review Mohammad Hakimi, Department of Obstetrics and Gynecology, Universitas Gadjah Mada Faculty of Medicine (Indonesia)</p> <p>Ethical Challenges in HIV Research in Thailand Krittaecho Siripassorn, Bamrasnaradura Infectious Diseases Institute (Thailand)</p> <p>Assessing the Cultural Competence of Nurses Conducting the Informed Consent Process among Patients with HIV-AIDS Salud Zladiwar and Johann Bolinao, The Medical City and Research Institute for Tropical Medicine (Philippines)</p> <p>The Role of the Lay Person in Ethics Review Sudha Ramalingam, Ramalingam Sankaran, Vasantha Muthuswamy, PSG Institute of Medical Sciences and Research (India)</p>
<p>Parallel Session 3B Session Chairs: Istiadjid Eddy Santoso, National Commission on Health Research Ethics (Indonesia)</p> <p>Nafrialdi, National Commission on</p>	<p>Addressing Ethical Issues in Clinical Trials</p> <p>Ethical Issues in Research with Healthy Volunteers Rianto Setiabudy, School of Medicine, University of Indonesia</p> <p>Addressing Ethical Issues in Infectious and Communicable Disease Research Dewi Murniati, Fatmawati, Maya Morinda M, Prof. Dr. Sulianti Saroso Hospital, Jakarta (Indonesia)</p>

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Health Research Ethics (Indonesia)	<p>Surgical Innovation and Ethical Dilemmas Mohammad Hakimi, Faculty of Medicine, Universitas Gadjah Mada (Indonesia)</p> <p>Reviewing Ethical Issues in Endocrinology Research Subhash Yadav, Sanjay Gandhi Post-Graduate Institute for Medical Sciences Institutional Review Board, Lucknow (India)</p> <p>Addressing Ethical Issues in Tuberculosis Research Paul Kumaran, National Institute for Research in Tuberculosis (India)</p>
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15:00-15:30 **Tea/Coffee Break**

15:30-17:00 **Session 4**

<p>Parallel Session 4A Session Chairs: Cristina Torres, FERCAP</p> <p>Siti Fatimah Muis, National Commission on Health Research Ethics (Indonesia)</p>	<p>Addressing Ethical Issues in Community Research</p> <p>Addressing Ethical Issues in Public Health Research Vicente Belizario Jr., National Institutes of Health, University of the Philippines Manila</p> <p>Conducting Ethical Research during Disasters Istiadjid Eddy Santoso, National Commission on Health Research Ethics (Indonesia)</p> <p>Ethical Issues in Innovative Vector Studies Tri Wibawa and Arief Budiyanto, Faculty of Medicine, Universitas Gadjah Mada (Indonesia)</p> <p>Ethical Issues on the Use of Foreign-Made Tests in Determining Personality Traits and Psychological Distress among Gifted Filipino Teenagers Andrea Martinez, College of Arts and Sciences, University of the Philippines Manila</p>
<p>Parallel Session 4B Session Chairs: Rianto Setiabudy, School of Medicine, University of Indonesia</p> <p>H. Rusdi Ismail, National Commission on Health Research Ethics (Indonesia)</p>	<p>Addressing Ethical Issues in Biomedical Research</p> <p>Ethical Issues Related to Animal Use in Biomedical Research Wienta Diarsvitri, Nusdianto Triakoso, Meinar Nur Ashrin, Ninis Trisyani, Hang Tuah University, Surabaya (Indonesia)</p> <p>Ethical Issues in Genetic Screening for Thalassemia in Indonesia Septi Dewi Rachmawati, Brawidjaya University, Malang (Indonesia)</p>

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	<p>Developing Guidelines to Address Ethical Issues in Human Genomic Research Teguh Haryo Sasongko, Universiti Sains Malaysia</p> <p>Legal vs. Ethical Issues in Informed Consent in Genetic Research Wen-Tsong Chiou, Academia Sinica (Taiwan)</p>
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Welcome Reception: 18:00-21:00

Day 2: November 19, 2013

08:30-10:00 **Session 5: Fostering Quality Improvement in Ethical Review Procedures**

Session Chairs: Aphornpirom Ketupanya, Central Research Ethics Committee
Anoja Fernando, Sri Lanka Medical Association

Developing Quality Improvement Tools for Internal Audit of Research Ethics Committees

Juntra Karbwang and Arthur Navarro, FERCAP (Thailand)

Use of “IRB Quality Metrics” for Performance Assurance of the Ethics Committee

Pornpimon Adams, Sukanya Prakobtham, Chanthima Limphattarachoen, Srisin Khusmith, Krisana Pengsaa, Jaranit Kaewkungwal, Mahidol University (Thailand)

Ethical and Quality Issues in Social and Behavioral Research

R. Sjamsuhidajat, National Commission on Health Research Ethics (Indonesia)

Improving Efficiency through Common eIRB System

Deoksoo Kim, Kangbuk Samsung Hospital, Sungkyunkwan University (Korea)

10:00-10:30 **Tea/Coffee Break**

10:30-12:00 **Session 6: Expanding Networks to Improve Quality of Ethical Research**

Session Chairs: Vicente Belizario, FERCAP Steering Committee
Im Hee Shin, Daegu Catholic University Medical Center (Korea)

Standardizing Clinical Procedures across Countries

Greg Koski, ACRES (United States of America)

Corporate Responsibility towards Quality Ethical Research

Aileen Dualan, Novartis Pharmaceutical (Singapore)

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**Institutional Initiatives for Capacity Strengthening for Health
Research Ethics in the Philippines**

Harvy Joy Liwanag, Edlyn Jimenez, Vicente Belizario, Jr., Cristina E. Torres, National Institutes of Health, University of the Philippines Manila

Ethical Issues Related to Data Sharing in Research

Susan Bull, Ethox Centre, University of Oxford (United Kingdom)

12:00-13:30 **Lunch Break and Poster Viewing**

13:30-15:00 **Session 7: Improving Ethics Review of Social and Behavioral
Research**

Session Chairs: Vasantha Muthuswamy, Forum for Ethical Review Committees in India
Chih Shung Wong, Taiwan Association of Institutional Review Boards

Ethical Dilemmas in Qualitative Behavioral Research

Akiko Matsuyama, School of International Health Development, Nagasaki
University (Japan)

Addressing Ethical Issues in Research on Violence Against Children

Laurie S. Ramiro, College of Arts and Sciences, University of the
Philippines Manila

**Proposing Guidelines for Research Ethics Committees That Review
Social and Behavioral Research**

Cristina E. Torres, FERCAP Coordinator (Philippines)

Panel Discussion on Proposed Guidelines

Reactors:

Michael Tai, Academia Sinica IRB (Taiwan)

Young Min Chang, Ehwa Womans University IRB (Korea)

15:00-15:30 **Tea/Coffee Break**

15:30-17:00 **Session 8: Improving Informed Consent in Research**

Session Chairs: Marita V. T. Reyes, Philippine Health Research Ethics Board
Suriadi Gunawan, National Commission on Ethics of Health Research
(Indonesia)

**Common Informed Consent Issues Encountered during Ethics
Review**

Ramnath Misra, Sanjay Gandhi Post-Graduate Institute for Medical
Sciences Institutional Review Board, Lucknow (India)

**Consent and Assent Issues in Pediatric Research – An Ethical
Analysis**

Paik Yeong Cheah, Mahidol Oxford Research Unit (Thailand), Michael
Parker, The Ethox Centre, University of Oxford (United Kingdom)

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**Participants Understanding of Informed Consent in Clinical Trials:
A Systematic Review and Meta-analysis**

Nguyen Tien Huy, Nguyen Thanh Tam, Le Thi Bich Thoa, Kenji
Hirayama, Juntra Karbwang Laothavorn, Institute of Tropical Medicine,
Nagasaki University (Japan)

**Developing Enhanced Informed Consent for Better Comprehension
Multi-Country Group Participants, FERCAP Pre-Conference Training**

17.00-17:30 **Closing Ceremony**

Closing Remarks

Kenji Hirayama, FERCAP Chair

2014 FERCAP Conference Announcement

Philippine National Health Research System Representative

**2014 Conference Theme: Embedding Ethics Review in Health
Research Systems**

November 20, 2013

FERCAP GENERAL ASSEMBLY

Agenda

- | | | |
|-------------|---|--|
| 8:30-9:30 | Call to Order
FERCAP Treasurer's Report
FERCAP Annual Report/Directions | <i>Kenji Hirayama, FERCAP Chair</i>
<i>Kesara Na-Bangchang</i>
<i>Cristina E. Torres</i> |
| | Signing of Memoranda of Agreements for Joint FERCAP Survey/
National Accreditation
FERCAP and the Philippine Health Research Ethics Board
FERCAP and the National Research Council of Thailand | |
| 9:30-11:30 | SIDCER/FERCAP Recognition Ceremony | <i>Arthur M. Navarro (Emcee)</i> |
| 11:30-13:00 | Country/Area Meetings
Revision of FERCAP Terms of Reference
Nomination of Country/Area Representative
Strengthening the FERCAP/NAREC Networks | |

**ECs/IRBs for Recognition (Total: 49)
November 20, 2013**

BHUTAN (1)

1. Research Ethics Board of Health (REBH), Ministry of Health (MOH) - Bhutan
[Thimphu] - *Renewal*

CHINA (18)

2. Peking University Third Hospital Medical Science Research Ethics Committee
[Beijing]
3. Institutional Review Board of the First Affiliated Hospital of Nanchang University
[Nanchang]
4. Institutional Review Board of The Affiliated Hospital of Liaoning University of
Traditional Chinese Medicine [Shenyang]
5. Ethics Committee of Southwest Hospital [Chongqing] - *Renewal*
6. Ethics Committee of Xiyuan Hospital of China Academy of Chinese Medical Sciences
[Beijing] - *Renewal*
7. Institutional Review Board of Beijing Tiantan Hospital Affiliated to Capital Medical
University [Beijing] - *Renewal*
8. Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine
[Guangzhou] - *Renewal*
9. Ethics Committee of Ruijin Hospital, Shanghai JiaoTong University School of
Medicine [Shanghai]
10. Ethics Committee of the First Affiliated Hospital of Guiyang College of Traditional
Chinese Medicine [Guiyang]
11. Fudan University Shanghai Cancer Center Institutional Review Board [Shanghai] -
Renewal
12. Institutional Review Board of Wuxi People's Hospital [Wuxi]
13. Independent Ethics Committee for Clinical Research of Zhongda Hospital, Affiliated
to Southeast University [Nanjing]
14. Ethics Committee of Xinhua Hospital Affiliated to Shanghai JiaoTong University
School of Medicine [Shanghai]
15. Human Subject Research Ethics Committee of the Second Affiliated Hospital, School
of Medicine, Zhejiang University [Hangzhou/Zhejiang Province]
16. Ethics Committee of Beijing Tongren Hospital, Capital Medical University [Beijing]
17. The Medical Ethical Committee of The General Hospital of Shenyang Military
Command [Shenyang]
18. Clinical Trial Ethics Committee of Qilu Hospital of Shandong University [Jinan]
19. Medical Ethics Committee of NanFang Hospital of Southern Medical University
[Guangzhou]

INDIA (3)

20. Institutional Ethics Committee, National Institute for Research in Tuberculosis
(NIRT), Indian Council of Medical Research (ICMR) [Chennai]
21. Institutional Ethics Committee, National Institute of Epidemiology (NIE), Indian
Council of Medical Research (ICMR) [Chennai]
22. Institutional Ethics Committee, Y.R. Gaitonde Centre for AIDS Research and
Education (YRG CARE) [Chennai]

INDONESIA (2)

23. Health Ethics Committee, Faculty of Medicine of Udayana University - Sanglah Hospital [Denpasar, Bali]
24. Health Research Ethics Committee, Faculty of Medicine, University of Brawijaya [Malang, East Java]

MALAYSIA (1)

25. Medical Research & Ethics Committee (MREC), Ministry of Health (MOH) - Malaysia [Kuala Lumpur]

PHILIPPINES (5)

26. University of the Philippines Manila Research Ethics Board (UPMREB) [Manila] - *Renewal*
27. Manila Doctors Hospital Institutional Review Board [Manila]
28. Makati Medical Center (MMC) Institutional Review Board [Makati, Metro Manila]
29. Department of Health (DOH) XI Cluster Ethics Review Committee (CERC) [Davao]
30. Veterans Memorial Medical Center Institutional Review Board [Quezon City, Metro Manila]

SOUTH KOREA (10)

31. Yeungnam University Medical Center Institutional Review Board [Daegu] - *Renewal*
32. Keimyung University Dongsan Hospital Institutional Review Board [Daegu] - *Renewal*
33. Kyungpook National University Hospital Institutional Review Board [Daegu] - *Renewal*
34. Busan Dong-A University Hospital Institutional Review Board [Busan] - *Renewal*
35. Anam Hospital Institutional Review Board, Korea University Medical Center [Seoul] - *Renewal*
36. Kangdong Sacred Heart Hospital Institutional Review Board [Seoul] - *Renewal*
37. National Cancer Center Institutional Review Board [Gyeonggi-do] - *Renewal*
38. CHA Bundang Medical Center Institutional Review Board, CHA University [Gyeonggi-do] - *Renewal*
39. Ewha Womans University Institutional Review Board [Seoul]
40. Chonbuk National University Hospital Institutional Review Board [Jeonju]

TAIWAN (4)

41. Far Eastern Memorial Hospital Research Ethics Review Committee [Taipei] - *Renewal*
42. Institutional Review Board of the Tri-Service General Hospital, National Defense Medical Center [Taipei] - *Renewal*
43. Changhua Christian Hospital Institutional Review Board [Changhua] - *Renewal*
44. Institutional Review Board of Taipei Veterans General Hospital [Taipei] - *Renewal*

THAILAND (5)

45. Human Ethics Committee of Thammasat University No. 1 (Faculty of Medicine) [Rangsit, Pathumthani] - *Renewal*
46. Traditional and Alternative Medicine Ethics Committee (TAMEC), Department for Development of Thai Traditional and Alternative Medicine (DTAM), Ministry of Public Health (MOPH) [Nonthaburi] - *Renewal*
47. Mahidol University Institutional Review Board [Salaya, Nakhon Pathom]
48. Research Ethics Committee, Faculty of Nursing, Chiang Mai University [Chiang Mai]
49. Naresuan University Institutional Review Board [Phitsanulok]

**FERCAP ECs/IRBs for Resurvey in 2014
(Total: 28)**

CHINA (10)

01. Shanghai Changhai Hospital Ethics Committee, Second Military Medical University (SMMU) [Shanghai | 2007, 2010]
02. Affiliated Hospital of Nanjing University of Traditional Chinese Medicine Institutional Review Board [Nanjing, Jiangsu | 2007, 2010]
03. Ethics Committee of the Second Affiliated Hospital of Tianjin University of Traditional Chinese Medicine [Tianjin | 2010]
04. Renji Hospital Ethics Committee for Clinical Trial Review [Shanghai | 2011]
05. Institutional Review Board of Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine [Shanghai | 2011]
06. Sun Yat-sen University Cancer Center Institutional Review Board [Guangzhou | 2011]
07. Institutional Review Board of Shanghai Mental Health Center [Shanghai | 2011]
08. Peking University First Hospital National Unit of Clinical Trial Ethics Committee [Beijing | 2011]
09. Institutional Review Board of The First Affiliated Hospital of Henan College of Traditional Chinese Medicine [Zhengzhou | 2011]
10. Clinical Trial Ethics Committee of Zhong Shan Hospital, Fudan University [Shanghai | 2011]

INDIA (1)

11. Institutional Ethics Committee of Sanjay Gandhi Postgraduate Institute of Medical Sciences [Lucknow | 2011]

INDONESIA (1)

12. Komisi Etik Penelitian Kesehatan Fakultas Kedokteran Universitas Hasanuddin (Faculty of Medicine, University Hasanuddin Ethics Committee) [Makassar | 2011]

PHILIPPINES (1)

13. Research Institute for Tropical Medicine (RITM) Institutional Review Board, Department of Health (DOH) - Philippines [Muntinlupa, Metro Manila | 2007, 2010]

SOUTH KOREA (5)

14. Chonnam National University Hospital Institutional Review Board [Kwangju | 2007, 2010]
15. Inje University Busan Paik Hospital (IJUBPH) Institutional Review Board [Busan | 2007, 2010]
16. Soon Chun Hyang University Bucheon Hospital Institutional Review Board [Bucheon | 2011]
17. Korea University Guro Hospital Institutional Review Board [Seoul | 2011]
18. Gachon University Gil Hospital Institutional Review Board [Incheon | 2011]

TAIWAN (10)

19. National Taiwan University Hospital Research Ethics Committee (NTUH REC) [Taipei | 2006, 2009]
20. Chang Gung Memorial Hospital (CGMH) Institutional Review Board [Taoyuan | 2006, 2009]

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21. National Cheng Kung University Hospital (NCKUH) Human Experiment and Ethics Committee [Tainan | 2007, 2010]
22. Kaohsiung Medical University, Chung-Ho Memorial Hospital Institutional Review Board [Kaohsiung | 2007, 2010]
23. Taichung Veterans General Hospital (TCVGH) Institutional Review Board [Taichung | 2007, 2010]
24. Chung Shan Medical University Hospital Institutional Review Board [Taichung | 2007, 2010]
25. Buddhist Tzu Chi General Hospital - Taipei Institutional Review Board [Taipei | 2009]
26. Taipei Medical University-Joint Institutional Review Board (TMU-JIRB) [Taipei | 2010]
27. Taipei City Hospital Institutional Review Board [Taipei | 2011]
28. Kaohsiung Kai-Suan Psychiatric Hospital Institutional Review Board [Taipei | 2011]