

出國報告（出國類別：開會）

參加第 24 屆亞洲及西太平洋分會
亞太倫理審查論壇年會
24th International Forum for
Ethical Review Committees in the
Asia and Western Pacific Region
(FERCAP) Conference

服務機關：國立臺灣大學醫學院附設醫院

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派赴國家：尼泊爾（加德滿都）

出國期間：113 年 11 月 25 日至 113 年 11 月 27 日

報告日期：114 年 02 月 03 日

摘要

第 24 屆亞洲及西太平洋分會亞太倫理審查論壇年會 (24th International Forum for Ethical Review Committees in the Asia and Western Pacific Region (FERCAP) Conference) 於 2024 年 11 月 25 日至 27 日在尼泊爾的首都加德滿都舉行，由尼泊爾健康研究委員會 (Nepal Health Research Council, NHRC) 主辦，主題為「透過負責任地進行研究實現最大化的效益」(Maximizing Benefits through Responsible Conduct of Research)。本次會議來自 20 個國家，至少 502 位參與者 (包含實體與線上參與)，為一場聚集全世界對於研究倫理實踐與挑戰有興趣的學者與實務工作者之國際性學術年會。

此國際性學術年會，會議內容豐富，包含：專題演講 (plenary sessions) 和主題式專題平行場次演講 (parallel sessions)。第一日主題式專題有一項為「使用資訊科技於倫理審查和臨床研究 (Use of Technology in Ethics Review and Clinical Research)」，內容主要是各機構使用資訊科技應用於研究倫理審查或執行臨床研究等方式，因此，本團隊至該年會口頭報告臺大醫院開發研究倫理審查系統之經驗分享及成果研究。本次參與年會，除發表本院之成果，亦於該年會收穫許多不同的觀點與深度交流。

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壹、參與目的

一、SIDCER-FERCAP 介紹

世界衛生組織 (World Health Organization, WHO) 為解決全球健康研究所遇到基本倫理的差距與挑戰，於西元 2001 年由 WHO 的熱帶病研究與訓練特殊計畫下 (Special Programme for Research and Training in Tropical Diseases, WHO-TDR) 成立「倫理審查能力發展策略型導向計畫 (Strategic Initiative for Developing Capacity in Ethical Review, SIDCER)」。

SIDCER 設立五個地區性論壇，由倫理審查委員會、衛生研究人員和受邀的合作組織組成，五個地區性論壇分別為亞洲和西太平洋地區 (FERCAP)、前俄羅斯國家 (FECCIS)、拉丁美洲 (Latin America)、非洲 (PABIN)、北美 (FOCUS)，以上組織有一個共同目標：透過發展當地的倫理審查能力和提升對健康研究倫理的理解，進而保護受試者。每年 FERCAP 皆會舉辦年會論壇，讓參與者了解近期研究倫理之進展，並讓亞洲和西太平洋地區各國口頭或海報發表與倫理相關成果，今年可發表的主題如下：負責任地進行研究之政策、法規、指引及實踐、發展倫理指引、以社區為基礎研究之利益最大化、使用資訊科技運用於倫理、促進生物醫學和行為科學研究執行符合倫理、促進負責任的研究行為 (Responsible Conduct of Research, RCR) 教育計畫、優良的研究倫理委員會管理。

西元 2002 年臺灣正式成為 FERCAP 會員國家之一，亦成功爭取於西元 2018 年舉辦 FERCAP 國際年會。臺大醫院曾於西元 2006 年、2009 年通過 FERCAP 評鑑認證。

二、2024 年 FERCAP 年會議程

CONFERENCE AGENDA		
DAY 1 – NOVEMBER 25, 2024		
9:00 – 10:00 Nepal Time	Opening Ceremony	
	Session Chair	Kenji Hirayama
	Introduction of Country Delegates	Kenji Hirayama FERCAP Chair
	Welcome Remarks	Nepal Health Research Council Dr. Pramod
	KEYNOTE Address	
	Promoting Responsible Conduct of Scientific Research	Sharad Raj Onta
	Promoting Responsible Conduct of Research through Global Networks	Mihai Mihut WHO-TDR, Geneva, Switzerland
10:00-10:15	Session Break	
	Plenary Session	

10:15-12:30 Session 1	Addressing Ethical Challenges in Health Research and Innovation	
	Session Chairs:	Juntra Laothavorn SIDCER-FERCAP
	Ethical Challenges and Opportunities of Decentralized Clinical Trials	Jeremy Sugarman Johns Hopkins Berman Institute of Bioethics, USA
	Ethical Considerations in Climate Change and Neglected Tropical Disease Research	Vicente Belizario & Christian Cacatian University of the Philippines Manila
	Developing a Framework to Prioritize Rare Inherited Disease in LMICs	Teguh Haryo Sasongko, IMU University, Malaysia & Joseph Millum University of St. Andrews, UK
	Advancing Clinical Trials in Nepal: Overcoming Challenges and Implementing Solutions	Januka Khatri <i>et al.</i> Oxford University Clinical Research Unit, Nepal
	Leadership of the Nepal Health Research Council in Health Ethics Governance	Gehanath Baral, Kathmandu University
	Establishing Regional Collaborative Partnerships among Academic Research Organizations	Kouji Wada & Kenji Hirayama. Japan Agency for Medical Research and Development

12:30- 13:30	Lunchbreak		
13:30-15:00 Session 2	Parallel Sessions		
	Ethics Review of Social Science Research	Educating Research Stakeholders	Use of Technology in Ethics Review and Clinical Research
	Breakout Rm. 1	Breakout Rm. 2	Breakout Rm. 3
	Parallel Session 2A	Parallel Session 2B	Parallel Session 2C
	Panel Discussion: FERCAP Guidelines on the Ethics Review of Social Science Research Cristina E. Torres FERCAP Coordinator <ul style="list-style-type: none"> Use of a Standard Ethics Assessment Form B-Jay Mosquera Department of Health Philippines 	<ul style="list-style-type: none"> A Context Specific Casebook for Southeast Asian Bioethics Education Nishakanthi Gopalan & Joseph Ali, Universiti Malaya & Johns Hopkins University Conducting Educational Activities among 	Panel Discussion: Comparing Electronic IRB Experiences <ul style="list-style-type: none"> NTUH e-REC System Yi Yu Chen <i>et al</i> National Taiwan University Hospital, Taiwan Development of an Online Submission System

	Case Studies <ul style="list-style-type: none"> • Business Ethics Siti Hazlina, USM Malaysia 	Research Stakeholders Peeraya Chaowalitwong <i>et al</i> Siriraj Hospital Thailand	Vinita Agrawal Sanjay Gandhi Post Graduate Institute India
	<ul style="list-style-type: none"> • Evaluation of Calcium and Vitamin D among Premenopausal vs. Menopausal Women Arun Dhungana <i>et al</i> Kathmandu Medical College, Nepal 	<ul style="list-style-type: none"> • Using Team Based Learning in Clinical Research Education Hui Chen Lee, Cathay General Hospital, Taiwan 	<ul style="list-style-type: none"> • Effectiveness of Electronic Submission System Patompong Khaw-on Chiangmai University Thailand
	<ul style="list-style-type: none"> • Historical Research Rhodalyn Wani-Obias University of the Philippines, Diliman 	<ul style="list-style-type: none"> ○ Conducting Public Health Ethics Training among Local Policy Makers Myra Cagdag, Department of Health, Philippines 	<ul style="list-style-type: none"> ○ Satisfaction with Electronic Submission Waraya Krisnoi Chulalongkorn University, Thailand
	<ul style="list-style-type: none"> • Autism Study Machhindra Lamichhane, Tribhuvan University Nepal 	<ul style="list-style-type: none"> • Clinical Trial Training for the Research Teams Tsui Wen Hsu <i>et al</i> Cathay General Hospital, Taiwan 	<ul style="list-style-type: none"> • Using AI for Rapid Classification • Use of a Comprehensive Cloud Based Drug Tracking System Chien Liang Ho National Cheng Kung University, Taiwan
15:00- 15:15	Session Break		
15:15-17:00	Parallel Sessions		
Session 3	Strengthening Ethical and Frameworks Breakout Rm. 1	Ethical Recruitment of Research Volunteers Breakout Rm. 2	Ethical Issues in Public Health Research Breakout Rm. 3
	Parallel Session 3A	Parallel Session 3B	Parallel Session 3C
	<ul style="list-style-type: none"> • Capacity Building in Clinical Trial Frameworks in Asia and Africa Rosemarie Bernabe 	<ul style="list-style-type: none"> • Recruitment Strategies in Prison Research Mohd Jamil Universiti Malaya 	<ul style="list-style-type: none"> • Community Engagement in Promoting Rational Antimicrobial Use

	University of Oslo, Norway	Malaysia	Nisha Jha <i>et al.</i> Laliput District, Nepal
	<ul style="list-style-type: none"> • Updates on Pandemic Post-trial Access Responses Pandemic Ethics Partners from Asia and Africa 	<ul style="list-style-type: none"> • What Motivates Volunteering in Interventional Trials KV Ganpathy <i>et al</i> Tata Memorial Hospital Mumbai, India 	<ul style="list-style-type: none"> • Identifying Hotspots in Visceral Leishmaniasis Endemic Areas Anand Ballabh Joshi Public Health and Infectious Disease Research Center, Kathmandu, Nepal
	<ul style="list-style-type: none"> • Updates on Ethics Capacity-Building in Uganda and Ethiopia AccessAfrica2 Partners 	<ul style="list-style-type: none"> • Role of Community Recruiters in Vaccine Clinical Trials Ralph Elvi Villalobos, Philippine General Hospital 	<ul style="list-style-type: none"> • A Thematic Analysis of TB-DOTS Healthcare Delivery Alexandra Bayola <i>et al</i> University of Sto. Tomas, Philippines
		<ul style="list-style-type: none"> • Feasibility of QuinteT Recruitment Intervention to Optimize Informed Consent Nithya Gogtay <i>et al</i> Seth GS Medical College 	<ul style="list-style-type: none"> • Prevalence of Vitamin B12 on Diabetic Patients on Metformin Shashi Sharma Rijal <i>et al</i>, Purbanchal University, Nepal
		<ul style="list-style-type: none"> • Recruitment in Community Intervention Studies Patricia M. Khu <i>et al</i> Cardinal Santos Medical Center Philippines 	<ul style="list-style-type: none"> • Community Engagement in Maternal and Infant Microbiome Study Arya Gautam, Sabitri Sciences, Nepal
		<ul style="list-style-type: none"> • Ethical Review Points in Clinical Trial Recruitment Xiao Shuping <i>et al</i> 	<ul style="list-style-type: none"> • Use of Discrete Choice Experiment in Pneumococcal Vaccine

		Beijing Tiantan Hospital, China	Jeffrey Pradeep Raj <i>et al</i> , Kasturba Medical College, India
17:30- 19:30	Cultural Presentation and Cocktails		

Day 2: November 26, 2024			
08:30-10:30 Session 4	Parallel Sessions		
	Promoting Trust in Science	Vulnerability, Informed Consent and Assent Issues	Ethical Issues in Biomedical Research
	Breakout Rm. 1	Breakout Rm. 2	Breakout Rm. 3
	Parallel Session 4A	Parallel Session 4B	Parallel Session 4C
	<ul style="list-style-type: none"> • Open Science as a Vehicle for Benefit sharing A European Union Funded Project 	<ul style="list-style-type: none"> • Reviewing Research Involving Vulnerable Participants Krishna Suvarnabhumi, Prince of Songkla University, Thailand 	<ul style="list-style-type: none"> • A Retrospective Study of the Profile of Leprosy Patients Suveksha Shaurya Shah, Lalgadh Leprosy Hospital, Nepal
	<ul style="list-style-type: none"> • Research Integrity to Promote Trust in Science Rosemarie Bernabe <i>et al</i>, University of Oslo Norway 	<ul style="list-style-type: none"> • Conducting Clinical Trials in Children Ram Hari Chapagain <i>et al</i>, Kanthi Children's Hospital, Nepal 	<ul style="list-style-type: none"> • Investigation of Infectious Vaginitis and UTI Yamini Chhetri Tribhuvan University Nepal
	<ul style="list-style-type: none"> • Promoting Trust between Science Actors and Society Panagiotis Kavouras, Greece 	<ul style="list-style-type: none"> • Evaluation of Assent Forms for Children and Minors Charlotte Jane Joseph Ministry of Health, Malaysia 	<ul style="list-style-type: none"> • Off Label Medicine Use in India Likhith Prasanna <i>et al</i> Kasturba Medical College, India
	<ul style="list-style-type: none"> • Stewards of Trust as Key Players in the Research Ecosystem Lisa Haberlein EUREC, Germany 	<ul style="list-style-type: none"> • Optimizing Informed Consent in Clinical Trials Nithya J Gogtay <i>et al</i> Seth GS Medical Center, India 	<ul style="list-style-type: none"> • Prescribing Patterns and Adherence in Glaucoma Medication Avil Gautam <i>et al</i> Eye Care Foundation Nepal
	<ul style="list-style-type: none"> • Perspectives from the European Networks of RECs 	<ul style="list-style-type: none"> • Safeguarding Vulnerability during 	<ul style="list-style-type: none"> • Fasting vs. Carbohydrate Loading to Prepare

	Dirk Lanzerath EUREC, Germany	Digital Transformation Florabelle Taguiling University of the Philippines Diliman	for Femur Fracture Surgery Narendra Kumar Chaudary <i>et al</i> Nepal Orthopaedic Hospital
	•	•	• Pain Management of Cancer Patients Mijala Bajracharya Manmohan Memorial Institute of Health Sciences, Nepal
10:30-10:45	Session Break		
10:45-12:30	Parallel Sessions		
Session 5	Navigating the Complexities of Implementation Research in Nepal Breakout Rm. 1	Evolution of Bioethics and Its Application to Human Research Breakout Rm. 2	Ethical Issues in Special Topics in Health Research Breakout Rm. 3
	Parallel Session 5A	Parallel Session 5B	Parallel Session 5C
	Panel Discussion: Ethical Complexities in Implementation Research in LMICs	• Evolving Landscape of Research Ethics Gretchen Geneblaza Velarde <i>et al</i> University of the Philippines Diliman	• A Systematic Literature Review of Pro-Environmental Behavior Richan Shresta <i>et al</i> Kathmandu University Nepal
	Panelists • Archana Shrestha, Kathmandu University School of Medical Sciences	• Meta-ethical Perspectives in Health Research Sachin Ghimere Tribhuvan University Nepal	• Ethical Issues in Forensic Genetic Testing Ma. Corazon de Ungria University of the Philippines Diliman
	• Megha Raj Banjara, Central Department of Microbiology, Tribhuvan University	• Ethical Oversight of Various Disciplines Ma. Frances Mallari University of the Philippines Diliman	• Genotype Characterization in Hepatitis C Virus in Patients

			Hari Prasad Kattel Tribhuvan University Nepal
	<ul style="list-style-type: none"> Sabitri Sapkota, Executive Director 	<ul style="list-style-type: none"> Digitization of Data as a Path to Responsible Conduct of Research Jyoti U. Devkota Kathmandu University Nepal 	<ul style="list-style-type: none"> Ethics Review of Bioequivalence Studies Rita S. Sitorus Universitas Indonesia
	<ul style="list-style-type: none"> Diptesh Aryal Nepal Intensive Care Research Foundation 	<ul style="list-style-type: none"> Artificial Intelligence Chatbots in Indian Health Care System Akshay Balakrishna <i>et al</i>, Kasturba Medical College, India 	<ul style="list-style-type: none"> Neonatal Sepsis and Development Outcomes Swechhya Vaidya Paropkar Maternity and Women’s Hospital Nepal
	<p>Session Outcome: Actionable strategies for managing ethical issues in IR in LMICs.</p>	<ul style="list-style-type: none"> Decoding Ethics of Authorship. Salik Ansan <i>et al</i>. Bhopal Hub, India 	<ul style="list-style-type: none"> Ethical Management in Off Label Drug Use Bai Caizhen <i>et al</i>, Beijing Tiantan Hospital, China
12:30-13:30	Lunch Break and Poster Viewing		
13:30-15:00 Session 6	Monitoring Protocol Implementation Breakout Rm. 1	Perspectives of Ethics in the Health Sector Breakout Rm. 2	Improving REC Performance Breakout Rm. 3
	Parallel Session 6A	Parallel Session 6B	Parallel Session 6C
	<ul style="list-style-type: none"> Possible Under-reporting of Protocol Deviations and Violation Nurain Mohd Noor <i>et al</i>, Ministry of Health Malaysia 	<ul style="list-style-type: none"> Ethical Leadership in Public Health Carl Abelardo T. Antonio, University of the Philippines Manila 	<ul style="list-style-type: none"> The Need for Bioethics Training for Community Volunteers and Researchers Ashok Kumar Mandal <i>et al</i>, Universiti Malaya, Malaysia

	<ul style="list-style-type: none"> • Development and Implementation of a Monitoring Tool Robyna Irshad Khan. Aga Khan University Pakistan 	<ul style="list-style-type: none"> • A Bibliometric Analysis of Sick Building Syndrome Upama Ghimere <i>et al</i> Southeast University Nanjing, China 	<ul style="list-style-type: none"> • Enhancing the Role of Lay Members Numtip Smerchuar Phayao University Thailand
	<ul style="list-style-type: none"> • Protocol Deviations in Regulatory Clinical Trials Chaudhari VL <i>et al.</i> Seth GS Medical College, India 	<ul style="list-style-type: none"> • Ethics Reporting in Publication Journals Jay A. Yacat <i>et al</i> University of the Philippines Diliman 	<ul style="list-style-type: none"> • Addressing Common issues of Researchers during Protocol Development Eti Nurwening Sholikhah <i>et al</i> Universitas Gadjah Mada, Indonesia
	<ul style="list-style-type: none"> • A Retrospective Review of Protocol Non-Compliance Edwin Ruamero, Jr. University of the Philippines Manila 	<ul style="list-style-type: none"> • Rethinking the Term ‘Lay Person’ Shamima Parvin Lasker <i>et al.</i> Bangladesh Bioethics Society 	<ul style="list-style-type: none"> • Improving REC Communication with Research Stakeholders Kevin Martinez Department of Health Philippines
	<ul style="list-style-type: none"> • Value of REC Audit of Ongoing Studies Ami Fazlin <i>et al</i> Ministry of Health, Malaysia 	<ul style="list-style-type: none"> • An Ethical Perspective of Research Fatigue Felishana Cherop MOI University, Kenya 	<ul style="list-style-type: none"> • Ethical Issues in Reporting Research Results. Mohan Raj Sharma. Tribhuvan University Hospital, Nepal
		<ul style="list-style-type: none"> • Perspectives in the Use of Electronic Health Information Siddhanth Rangineni <i>et al</i>, Kasturba Medical College, India 	<ul style="list-style-type: none"> • Ethics Review of Extended Open Label Trials Yumei Zhang <i>et al</i> Beijing Tiantan Hospital, China
Session 7	Plenary Session		
15:30-17:00	Ensuring Responsible Conduct of Research		
	Session Chairs:	FERCAP Steering Committee	
	Upholding Research Integrity through Responsible Conduct of Research	Asyraf Syahmi Mohd Noor, Ministry of Health, Indonesia	

	Ethical Consideration in a Community Vaccine Trial	Ashata Dahal, Oxford University Clinical Research Unit, Nepal
	Addressing Ethical Issues in Machine Learning Applications	Juntra Laothavorn FERCAP-SIDCER, Thailand
	Integrating the WHO Global Benchmarking Tool Elements with Responsible Conduct of Research	Cristina E. Torres FERCAP
	Establishment of Regional Pipelines for Medicinal Products Against Pandemics	Kenji Hirayama FERCAP Kwanchanok Yimtae Mahidol University
17:00-17:30	Closing Ceremony Invitation to the 2025 FERCAP Conference	Kenji Hirayama Faculties of Medicine, Mahidol University, Thailand

三、參與之目的

- (一) 參與研究倫理委員會倫理審查及受試者保護之相關課程。
- (二) 透過年會中各國代表經驗交流，加強研究倫理業務之推動，提升本院倫理審查水準提升、行政及相關業務。
- (三) 至國際年會口頭報告臺大醫院開發研究倫理審查系統之經驗分享及成果研究，提高國際能見度。

貳、過程

一、研究計畫

計畫名稱：使用臺大醫院倫委會申請暨審查管理系統（e-REC）進行優良研究倫理審查管理（Using NTUH e-REC systems for good research ethics review management）

中文摘要：

研究背景：本會過去曾自行開發線上申請及審查系統，但耗時太久而未能成功，西元 2011 年，國立陽明大學使用生技醫藥國家型科技計畫（NRPB）經費，從美國國家衛生研究院（NIH）引進「臨床資訊管理系統（CIMS）」，並將「臨床計畫追蹤與管理系統（PTMS）」（為 CIMS 子系統之一）介面中文化、修改審查流程以符合本國現況，本院 2012 年全面使用 PTMS 系統進行申請案件及審查。然而，全臺灣有 14 間醫院共同使用 PTMS 系統，故無法依照各院標準作業流程與表單客製化內容，以致填寫表單內容非常繁複，且本院研究案件較多，整體系統運作速度較慢，使用者建議之友善功能無法及時施行，需新增或修改功能須待每半年一次的系統會議討論，不僅無法即時改善使用者困擾，系統運作速度慢也使審查專家/委員、承辦人員延長審查時效，無法兼顧本院研究品質且有使用者滿意度低等問題。如何利用線上申請審查系統提升研究審查品質與時效係每個研究倫理委員會的重要課題。

研究目的：探討自行開發系統以提升審查時效及優良研究倫理審查管理。

研究方法：本中心進行整體使用者需求評估，依各項需求規劃細節及執行方案，且為符合國內外評鑑要求、案件時效與品質的考量，多次討論功能需求以達本中心的理想需求與系統上可開發功能之平衡，亦將過去系統全數研究案件匯入新系統。對於研究團隊，e-REC 系統建立動態式申請書、送審文件提示功能、線上簽署文件，對於委員，審查表提示功能、彙整式審查頁面，對於行政人員，提供統計報表、線上產出許可書等功能，且為利使用者使用，e-REC 系統亦介接院內其他系統與其他單位需求功能，節省申請人及相關單位之程序。為確認對於 e-REC 系統使用者滿意度與建議，本中心進行問卷設計與調查，以 Likert 四分量表計算滿意度。

研究結果：依本中心進行之使用者滿意度問卷調查，從 2022 年至今 e-REC 系統介面友善度、穩定性等高達 99%滿意比例、「新案審查服務與效率」滿意比例達 97%、「免審審查服務與效率」滿意比例達 100%、「變更案審查服務與效率」滿意比例達 95%。對於倫理中心研究倫理組整體服務滿意度亦提高，滿意比例超過 95%。過去免審審查未有電子系統，未有 e-REC 系統前免審案件平均 13 個日曆天；使用 e-REC 系統後免審案件時效平均 11 個日曆天。使用 PTMS 系統，內部研究團隊取得許可書時間平均為 3 天，外部廠商取得許可書時間平均為 5 天，使用 e-REC 系統內部研究團隊及外部廠商取得許可書時間平均為 1 天。e-REC 系統開發及上線成功，順利推動無紙化審查、使用者表單無紙化，申請表單以提示字顯示亦減少承辦人員端接聽電話的時間，提升了行政功能及效率。

二、簡報內容

**Using
NTUH e-REC system
for
Good
Research Ethics Review
Management**



National Taiwan University Hospital
Ethics Center Section Research Ethics
Yi-Yu Alice Chen

Yi-Yu Alice Chen

Current Position
National Taiwan University Hospital
Ethics Center Section Research Ethics (2023-current)
E-REC project manager

Highest Educational Attainment
National Taiwan Normal University
Department of Health Promotion and Health Education (Ms.)







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**01
Project Team**

Information Technology Office
Chia-Chang Wen
Shih-I Chang
Chao-Wei Peng
Han-Fang Cheng

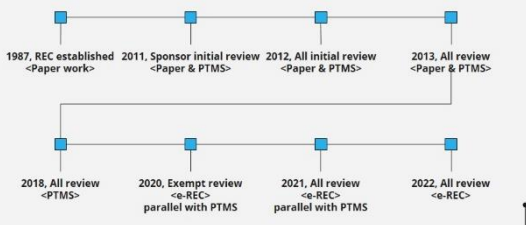
Our team
#NTUH
#E-REC

ETHICS
Ethics Center
Chun Fang Tai
Yi-Yu Chen
Ying-Chun Pan
Pei-Hsuan Tsai



**02
System's History**

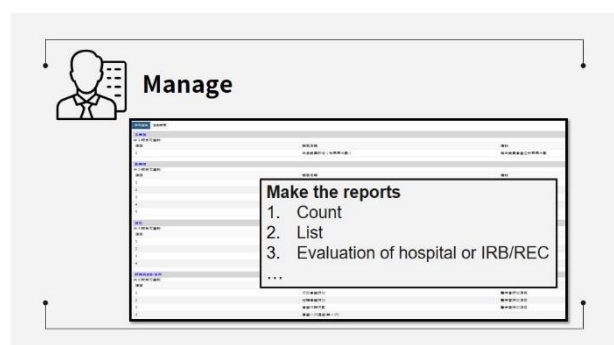
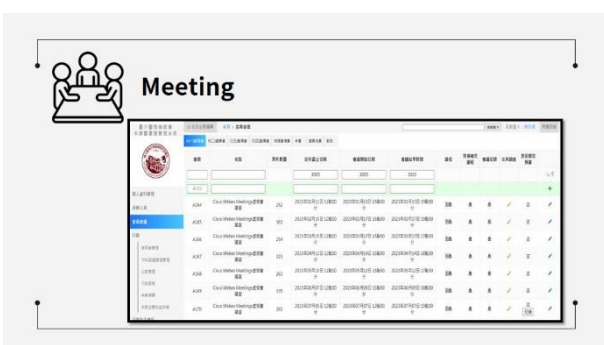
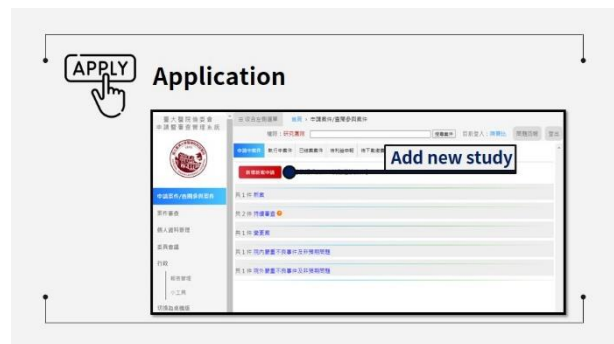
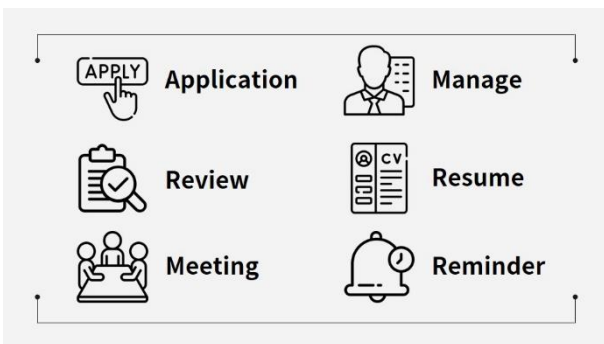
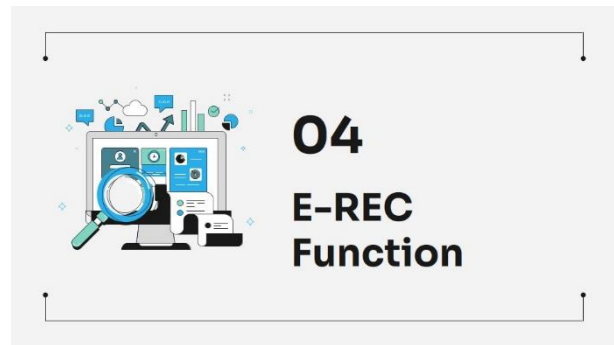
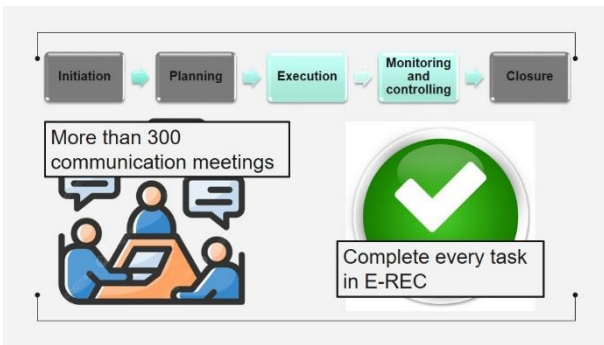
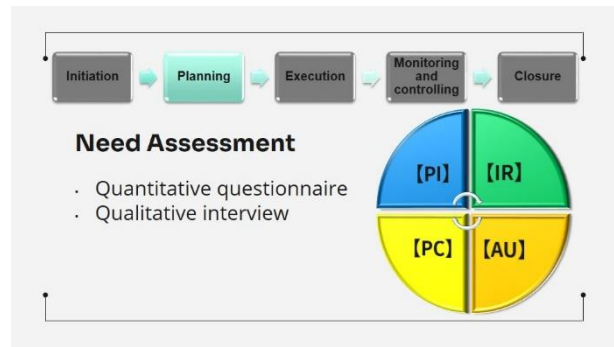
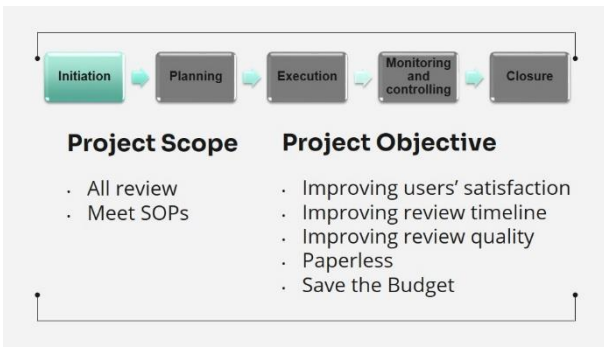
System's History timeline



1987, REC established <Paper work>	2011, Sponsor initial review <Paper & PTMS>	2012, All initial review <Paper & PTMS>	2013, All review <Paper & PTMS>
2018, All review <PTMS>	2020, Exempt review <e-REC> parallel with PTMS	2021, All review <e-REC> parallel with PTMS	2022, All review <e-REC>



**03
Product Development**



Make approval letter

QR CODE

國立臺灣大學醫學院附設醫院
研究倫理委員會

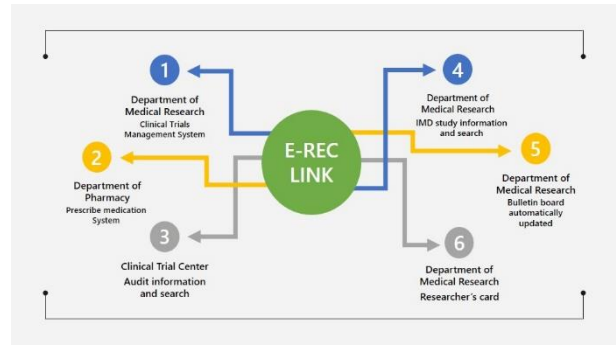
Resume

1. Automatically calculate training hours, e.g. GCP
2. Download the CV
3. ...

Reminder

Continuing Review
Before the study expiration date, "continuing review" automatically create in the system.

Training
You NEED to new training and tell you how many hours do you need.



05 Results or Services

Users' satisfaction for using the E-REC system

- "The E-REC system's friendly interface and system stability" satisfaction rate has 99%
- "Initial Review Service and Efficiency" satisfaction rate has 97%
- "Exemption Review Service and Efficiency" satisfaction rate has 100%
- "Amendment Review Service and Efficiency" satisfaction rate has 95%
- "For the Ethics Center Research Ethics Section overall services" satisfaction rate has over 95%

Length of time

Exempt Review: 13 days → 11 days

Get approval letter:

- Study team: 3 days (PTMS) → 1 days (e-REC)
- Sponsors/CROs: 5 days (PTMS) → 1 days (e-REC)

Review quality

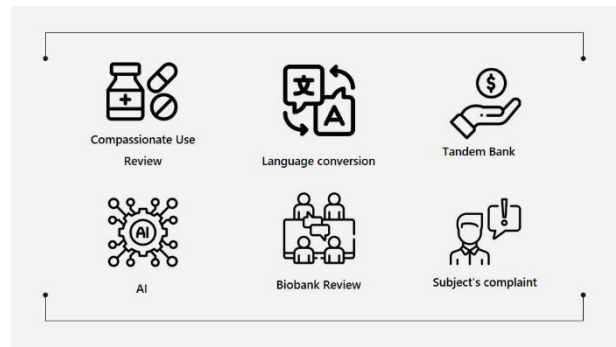
The members use the "review checklist" **NEVER** check the wrong.

Paperless ~ Environmentally friendly

-3200kg CO₂

\$5,000,000up

Save the Budget for the New System of NTUH



三、口頭報告

會議中透過現場提問與討論，促進不同的觀點互動與深度交流。



圖一 陳依煜管理師口頭報告臺大醫院專案開發成果



圖二 陳依煜管理師現場回覆問題



圖三 由主席頒發口頭演講獎項

參、參與心得／年會之過程與見聞

臺灣臨床研究倫理審查學會 (Taiwan Association of IRBs, TAIRB) 西元 2009 年成立，由研究倫理委員會/人體試驗委員會、臨床醫師、臨床試驗研究專家、藥師、社會工作師、律師等組成，會員分布地點包含全臺灣(機構為團體會員，臺大醫院為團體會員)，其成立主要宗旨係以提升國內研究倫理審查水準，促進國內外學術交流，同時，提升研究倫理審查品質、提出政策建言、舉辦研究倫理相關之學術演講及教育訓練，協助聯繫國內外相關團體。本次由 TAIRB 轉知 FERCAP 年會相關訊息，邀請全臺灣研究倫理領域相關同仁，一同至尼泊爾參與 FERCAP 年會，並分享各機構之研究成果。



圖四 臺灣研究倫理領域相關同仁與 TAIRB 學會合影



圖五 臺灣研究倫理領域相關同仁與 Cristina Torres 合影

今年新光醫療財團法人新光吳火獅紀念醫院及佛教慈濟醫療財團法人花蓮慈濟醫院獲得 FERCAP 評鑑認證，因此上台授獎。新光醫院楊凱琳主任委員、鄭文斌執行秘書邀請臺灣同仁一同上台領獎合照。



圖五 新光醫院授獎合影



圖六 臺灣 FERCAP 年會演講者合影

左一國泰綜合醫院護理部李惠珍副主任

左二國泰綜合醫院人體試驗審查委員會徐翠文執行秘書

中一三軍總醫院婦產部生殖不孕科張芳維主任（TAIRB 理事長）

左一國立成功大學醫學院附設醫院總務室何建良主任（外科部醫師）

左二陳依煜管理師

本次會議主題為「透過負責任地進行研究實現最大化的效益」(Maximizing Benefits through Responsible Conduct of Research)，內含現今研究倫理的挑戰與創新實踐，此主題強調「研究」不僅是推動知識發展之方式，更是服務社會、改善全體人類生活品質的行為，因此，「研究」整體過程，從研究設計、研究執行至研究成果公開，皆須符合國際標準的倫理規範，保障每一位受試者的權益，以利提升「研究」對於社會的正面影響，會議亦有舉辦工作坊，討論標準作業程序(Standard Operating Procedures, SOP)的執行、研究倫理審查程序的品質保證、各國研究倫理指引等，提供許多學術交流機會。

臺大醫院於研究倫理及研究誠信皆有明確的規範，且符合國際標準。在易受傷害族群的部分，於研究倫理查時，委員須詳細檢核其風險及必要性，在資訊安全與資料隱私的部分，請資訊安全專家進行相關審查，審查階段，本院要求嚴謹且符合國際標準。研究成果發表後，本院有相關學術倫理的審核流程。在研究執行部分，臨床試驗、前瞻性研究的稽核機制完善，然而，在回溯性研究、資料保護等方面卻未有相關稽核機制。

肆、建議事項

本次最大的啟發，是以發展人工智慧技術（Artificial Intelligence, AI）協助研究倫理審查，能有效減少主持人詢問時間、行政人員工作時間及委員審查時間。

本院研究倫理審查後續可考慮的發展方向：

一、拓展專屬臺大醫院「研究」宇宙

- （一）研究相關系統進行串聯，並加強自動化運行，有效減少行政人力。
- （二）臺大醫療體系皆使用相同模式運行，避免發生倫理或法律問題。

二、發展人工智慧技術

- （一）通過自然語言處理技術，辨別研究案件屬性，協助主持人送件審查。
- （二）發展規則行政審查邏輯，協助行政人員給予建議，提升倫理審查的效率。
- （三）與其他單位/機構合作，以利開發模型與邏輯。

三、系統再優化

- （一）加入商業智慧（Business Intelligence, BI），透過資料分析改進決策。
- （二）強化系統對數據隱私的管理能力。

