



生醫大數據資料治理研討會

-資料整合、商業應用與日韓經驗

主辦單位：國家衛生研究院

群體健康科學研究所 / 生醫資源中心

國立陽明交通大學 科技法律研究所

國立陽明交通大學 /

韓國梨花女子大學 生醫法律研究中心

計畫支持：衛生福利部衛生福利資料科學中心

國衛院研究分中心

衛生福利部健康大數據永續平台計畫

時間：2021 年 5 月 13 日(星期四)

地點：國家衛生研究院竹南院區行政大樓

第一會議室(苗栗縣竹南鎮科研路 35 號)

議程

頁碼

13:30-13:45 開幕致詞

梁廣義院長 國家衛生研究院

邱弘毅所長 國家衛生研究院群體健康科學研究所

陳鈺雄所長 國立陽明交通大學科技法律研究所

Session 1: 生醫資料庫法規與商業應用

Moderator: 張新儀主任/研究員

國家衛生研究院生醫資源中心/群體健康科學研究所

13:45-14:30 生醫健康資料之整合與應用規範

何之行副研究員 中央研究院歐美研究所.....3

14:30-15:15 健康資料大數據與公私協力

陳鈺雄所長 國立陽明交通大學科技法律研究所.....5

15:15-15:30 Break

Session 2: 日韓生物資料庫建置經驗

(Moderator: 陳鈺雄所長 國立陽明交通大學科技法律研究所)

15:30-16:15 The current status of KBN (Korea Biobank Network)

(中文同步口譯)

Dr. Sang Yun CHO Deputy Scientific Director, Division of Biobank,
National Biobank of Korea.....8

16:15-17:00 Current status of clinical research regulation in Japan

(英文演講)

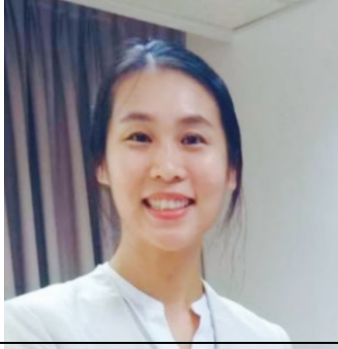
Prof. Masayuki YOSHIDA

Tokyo Medical and Dental University.....11

17:00-17:20 Panel Discussion

All speakers

注意事項: 視訊連線、線上提問及防疫措施.....13



何之行博士

學歷

英國倫敦政治經濟學院法學博士
美國史丹福大學法律科學碩士
美國哥倫比亞大學法學碩士
國立臺灣大學法學士

專業經歷

中央研究院歐美所副研究員 (2/2021~迄今)
中央研究院資訊科技創新研究中心合聘副研究員 (2/2021~迄今)
中央研究院資訊科技創新研究中心合聘助研究員 (1/2020~2/2021)
中央研究院歐美所助研究員 (4/2014~2/2021)
香港大學醫學倫理與法律研究中心研究主任 (1/2013~4/2014)

專業服務

衛福部中央健保署健保資料人工智慧應用管理審議會委員(2/2021~迄今)
臺北市立聯合醫院資通安全諮詢小組委員 (1/2021~迄今)
衛福部人體生物資料庫審查小組委員 (8/2019~迄今)
國家級人體生物資料庫整合平台諮詢暨審查委員會委員 (6/2019~迄今)
衛福部人體生物資料庫查核委員 (3/2019~迄今)
醫策會人體生物資料庫查核制度專家諮詢小組委員 (3/2019~迄今)
臺灣人體生物資料庫倫理委員會委員 (3/2019~迄今)
中央研究院醫學研究倫理委員會委員 (10/2018~迄今)
中央研究院歐美所歐盟重點研究計畫召集人(2017~2019, 2019~2020)
Frontiers in Genetics- ELSI 期刊編輯審查委員會委員 (2016~迄今)

生醫健康資料之整合與應用規範

摘要

生物資料庫在生醫研究上扮演重要的角色，若能與其他不同類型之建康數據資料庫做聯結，形成建康大數據基礎，對 AI 生醫研究將更形助益。生物資料庫之整合，以及與其他建康數據資料庫的合作與共享，已成為建構大型數據平台與智慧醫療的未來發展方向，然而在整合過程中仍有規範與實作上的挑戰，尤其是資料庫串聯中相關適法性基礎以及資料治理規範、隱私保護等問題仍待克服。此一演講將探討這些挑戰並提出可能的規範回應。



陳鈺雄所長

THOMAS CHIH-HSIUNG CHEN

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學歷

- 2002 - 2007 美國聖路易華盛頓大學法學博士
- 2001 - 2002 美國聖路易華盛頓大學法學碩士
- 1993 - 1996 國立臺灣大學法學碩士
- 1988 - 1993 國立臺灣大學哲學學士（法律系輔系）

專業經歷

- 2019 - 迄今 交通大學科技法律研究所教授
- 2017 - 迄今 交通大學科技法律研究所所長
- 2016 - 2016 交通大學科技法律學院推廣教育學分班主任
- 2012 - 2019 交通大學科技法律研究所副教授
- 2009 - 2011 交通大學科技法律研究所副所長暨在職專班主任
- 2007 - 2012 交通大學科技法律研究所助理教授
- 2000 - 2001 律師，福田法律事務所，臺北

專業參與

- 20201-2021 衛生福利部單次使用醫療器材重處理審議小組委員
- 2020-2021 衛生福利部優生保健諮詢會委員
- 2019-2020 衛生福利部全民健康保險資料人工智慧應用管理審議會委員
- 2018-2020 台灣醫事法律學會副理事長
- 2018- 台北市衛生局食安消費爭議調解庭
- 2018- 桃園市衛生局食品違規廣告專家學者會議
- 2018-2020 衛生福利部食品廣告標示諮議會委員
- 2015 交通大學人體與行為研究倫理治理中心主任
- 2013 美國加州柏克萊大學東亞研究中心訪問學者
- 2011~2016 高雄義大醫院人體生物資料庫倫理委員會委員

2010~2016 高雄義大醫院人體試驗委員會委員
2003 美國哈佛大學法學院東亞法研究中心訪問學者

健康資料大數據與公私協力

摘要

生醫大數據平台之建構與利用，透過公私協力（Public-Private Partnership）方式可加速進行。公私協力は各國推動生醫研究日趨常見的作法，我國討論尚少。本文將介紹公私協立在生醫領域的運用態樣，並以歐盟、英國等國家之實際案例，說明公私協力運作上考量的要點，包括智慧財產權、安全性、公益性、透明化、人權考量等要件之討論。



Dr. Sang Yun Cho

學歷

1988. 3. ~ 1994. 2. B.S. in Biochemistry, Hanyang University, Korea
1994. 9. ~ 1996. 8. M.S. in Biochemistry, Yonsei University, Korea
1997. 9. ~ 2002. 8. Ph.D. (Thesis: An integrated proteome database for 2-DE data analysis and laboratory information management system, Advisor: Prof. Young-Ki Paik, Department of Biochemistry, Graduate School of Yonsei University, Korea)

專業經歷

1999. 11. ~ 2002. 8. Staff Research Associate (responsible for MALDI-TOF operation and proteome database construction, management of projects) at Yonsei Proteome Research Center
2002. 8. ~ 2003. 8. Postdoctoral Fellow (Proteome Informatics Team Leader, Yonsei Proteome Research Center)
2003. 9. ~ 2009. 12. Research Assistant Professor (Yonsei Proteome Research Center)
2003. 9. ~ 2009. 12. General Manager of Yonsei Proteome Research Center / Biomedical Proteome Research Center
2005. 7. ~ 2006. 7. Visiting Researcher (Proteomics Services Team, Sequence Database Group, EMBL-EBI (European Bioinformatics Institute), Cambridge, UK)
2010. 3 ~ 2014.3. Principal Researcher, National Biobank of Korea
2014. 3 ~ Present Scientific Deputy Director, National Biobank of Korea

專業經驗

1999. 11. ~ 2009. Lecturer and Coordinator, Yonsei Proteomics Workshop (1st ~ 29th).
2000. 7. ~ 2003. 6. Managing Leader, Identification of possible biomarker candidates

- of hepatocellular carcinoma with proteomic approaches (FG-1-4-1, Supported by MOST: Annual budget, 0.4 million USD, total 3 years project).
2001. 6. ~ 2006. 3. Managing Leader, Construction of Proteome Informatics in Korea (01-Da-02, Supported by MOCIE: Annual budget 0.2 million USD, total 5 years project).
2001. 12. ~ 2003. 11. Managing Leader, Construction of Proteome Database System and Related Data-Mining System for Development of Automated Proteome Analysis and Clinical Sample Management (01-PJ11-PG9-01BT04-0009, Supported by MOHW and MOIC: Annual budget 0.5 million USD, total 2 years project).
2002. ~ 2005. Lecturer, Short Course of Latest Molecular Biology and Medical Science (at KNIH).
2003. 7. ~ Present General Manager, Korea Human Plasma Proteome Team and Biomedical Proteome Research Center (A030003, Supported by MOHW: Annual budget, 2.1 million USD, total 8 years project).
2004. 9. ~ 2004. 12. Course director and lecturer, Functional Genomics, Graduate Program in Functional Genomics (NU501), The Graduate School of Yonsei University
2007. 5. 27 ~ 6. 2 Coordinator and Lecturer, 30th A-IMBN/AMBO International Training Course
2006. 10. ~ 2008. 2. Administrator of HUPO 2007 World Congress, Seoul, Korea (COEX, Korea: 2007. 10. 1 ~ 5, Total number of attendance: 2,400, Total number of foreign attendance: 1,400)
2009. 4. ~ 2010. 3 Organizer / Coordinator of HUPO-PSI 2010 Seoul Meeting (KIST, Korea: 2010. 3. 28~30: Expected number of attendees: 50 foreign and 30 domestic researchers (<http://www.psudev.info>))
2010. 3. ~ Present Planning and Managing of 'Korea Biobank Project'
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The current status of KBN (Korea Biobank Network)

摘要

Human bio-resources to support the health care industry and research are secured ethically and stably, and it is essential to link standardized clinical epidemiological information and related information. Biobank is an institution that systematically secures, manages, and distributes human resources.

In 2008, Korea launched the “Korean Biobank Project (KBP)”. Through the first phase (2008~2012) of KBP, the National Biobank of Korea (bio-resources from cohorts and other national research projects) and 17 regional biobanks (bio-resources from disease patients) organized ‘Korea Biobank Network, KBN). Through KBP second phase (‘13~‘15) and third phase (‘16~‘20), bio-resources of approx. 1 million Koreans have been secured and supported approx. 3,000 tasks.

To establish a system for securing advanced human bio-resources necessary for future health care industry and research such as precision medicine, 'KBP 2030' as a mid- and long-term plan was established in 2020. We have selected 10 sub-networks (10 hub-biobanks and 24 partner biobanks) and formed ‘new KBN’.

In today's presentation, I would like to share a brief introduction to the composition and operation of KBN. And I would like to present types and conditions of bio-resources necessary for future health care industry and research, and how to secure them ethically based on current legal matters.

In addition, I would like to explain the activities of the National Biobank of Korea and other bodies of Korea government to establish and maximize the use of a standardized information system at the national level, such as the “National Bio - Big data Project” for compiling big data from the clinical and genome information of 10,000 people.



MASAYUKI YOSHIDA, MD PHD

Masayuki Yoshida, MD PhD

Director, Life Science and Bioethics Research Center,
Professor, Department of Life Science and Medical Ethics,
Chief, Department of Medical genetics,
Tokyo Medical and Dental University

Masayuki Yoshida graduated from Tokyo Medical and Dental University (TMDU) School of Medicine in Tokyo and completed a residency in Internal Medicine and Cardiology at TMDU hospital. After his post-doctoral research fellowship at Department of Pathology, Harvard Medical School, he went back to TMDU School of Medicine to work as an instructor in Molecular Medicine and then promoted to an Associated Professor in Medical Biochemistry. He then appointed as a Director of Bioethics Research Center and Chief of Medical Genetics, where novel genetic testing and counseling are provided. His main research field includes vascular biology, atherosclerosis, and medical genetics and also devoted himself in clinical research management system in nationwide with contribution to develop new guidelines in clinical and genetic research in Japan.

Current status of clinical research regulation in Japan

摘要

Recently there have been numerous updates to regulations and guidelines of clinical research in Japan. These updates were taken in accordance with global environmental change in the view of private information. Moreover, recent emerging progress in human genetics research also prompt us to shift our view of personal information including genetic data and potential health care service under both healthy and disease condition. Polygenic risk scores and/or cancer genome analysis have been at most studied clinical genetic testing both of which accelerated by biobank archives.

In this talk, I will overview the current status of clinical research regulation and biobank network system in Japan and would like to discuss related issues.

注意事項

一、配合防疫·歡迎視訊參加!

Webex 視訊連線資料

<https://nhri-meet.webex.com/nhri-meet/j.php?MTID=me5bd0b5afcdc7cac9c94b3eef07b9758>

Thursday, May 13, 2021 1:00 pm | 5 hours | (UTC+08:00) Taipei

Meeting number: 184 553 8560

Password: pNvC7u5gMb3

二、線上提問：手機掃描 QR code 輸入問題

網址: [slido.com](https://www.slido.com)

會議代碼 #700 093



三、入場指引：為響應中央流行疫情指揮中心「防疫新生活運動」，本活動實施以下措施

1. 實名制入場：參加學員簽到入場。
2. 現場工作同仁全面配戴口罩，活動前後量測體溫自主管理。
3. 保護自己，同時也是保護他人，進入會場一律全程配戴口罩。
4. 門口備有酒精消毒，入場時請配合現場工作同仁進行額溫測量，並請提早進場，以免延誤入場時間。
5. 若有呼吸道症狀或額溫超過 37.5 度以上，將建議就醫，婉拒入場。
6. 若有提問或發言，仍應配戴口罩。
7. 活動結束後，必須確實執行手部清潔，以除去手上可以沾染之病源。

聯絡人：侯小姐; 037-206166 ext.33605 ;ylhou@nhri.edu.tw

2021/5/10 製作