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聖島國際法律事務所

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人體生物資料庫資訊系統

- LIMS
 - A laboratory information and management system (LIMS) is an IT application that supports laboratory operations with regard to the administrative and coordinative tasks of sample processing and with regard to the recording and evaluation of diagnostic analysis data.
- BIMS
 - A BIMS is a data management system dedicated to support the specific operations of a biobank.
 - A BIMS will have a strong focus on donor consent management, collection and sampling, preanalytical processing, storage, and access provision of samples.
 - https://online.medunigraz.at/mug_online/wbAbs.getDocument?pThesisNr=59535& pAutorNr=&pOrgNr=1#page17

人體生物資料庫資訊系統

- LIMS generally refers to a system for a wide range of laboratories, whereas a biobank information management system (BIMS) is designed for biobanks.
 Each biobank may have specific needs and functionalities from a system that fits their biobanking model and day-to-day operations.
 - Jacotot L, Woodward M, de Montalier A, Vaglio P. Utilizing Modular Biobanking Software in Different Types of Biobanking Activities. Biopreserv Biobank. 2022 Oct;20(5):417-422. doi: 10.1089/bio.2022.0076. Epub 2022 Oct 5. PMID: 36201224; PMCID: PMC9603250.
- Typical features of a biobank like donor consent management, long-term storage, or sample access are typically not in the focus of a LIMS
 - https://online.medunigraz.at/mug_online/wbAbs.getDocument?pThesisNr=59535& pAutorNr=&pOrgNr=1#page17

人體生物資料庫資訊系統

- Biobanks have been using **commercial LIM**S, **custom in-house databases** or **spreadsheets** for many years, but systems have evolved.
- A laboratory information management system (LIMS) **specifically designed for biobanking** is essential for the management and organization of the complete life cycle of biological samples and their associated data.
 - Jacotot L, Woodward M, de Montalier A, Vaglio P. Utilizing Modular Biobanking Software in Different Types of Biobanking Activities. Biopreserv Biobank. 2022 Oct;20(5):417-422. doi: 10.1089/bio.2022.0076. Epub 2022 Oct 5. PMID: 36201224; PMCID: PMC9603250.

人體生物資料庫資訊系統的重要性

- Such software has had to evolve to be sustainable and scalable as biobanks store more samples and more data.
- In addition, there has been more demand for **cloud-based options**, and data centers
- Specifically, for BIMS, functionalities have evolved during the course of many years to manage much more information such as patient clinical information, consent, analytical results, allowing different types of sample collections (longitudinal studies, cohorts, and clinical trials), batch work rather than small numbers of samples, as well as integration with new and changing robotics or other medical software.
 - Jacotot L, Woodward M, de Montalier A, Vaglio P. Utilizing Modular Biobanking Software in Different Types of Biobanking Activities. Biopreserv Biobank. 2022 Oct;20(5):417-422. doi: 10.1089/bio.2022.0076. Epub 2022 Oct 5. PMID: 36201224; PMCID: PMC9603250.

the International Society for Biological and Environmental Repositories (ISBER) Best Practices

- According to the International Society for Biological and Environmental Repositories (ISBER) Best Practices, a computer-based inventory system should be in place to track the location and pertinent annotation of every specimen in the Biobank
- Campbell LD et al. Development of the ISBER best practices for repositories: Collection, storage, retrieval and distribution of biological materials for research. Biopreservation and Biobanking. 2012;10(2):232-233

- IT 系統必須確實對應生物資料庫的營運流程
- The biobank informatics infrastruc-ture needs to contain **hardware and software** that are sufficient to **address the functional requirements** of the biobank, **record and store** the infor-mation acquired during **each biobank process**, and **pro-vide an electronic method** for records management.
- IT 系統必須確保檢體與資料的可追蹤性(traceability), 及資訊安全與機密性
- It is important that the hardware and soft-ware infrastructure is designed in such a way that it not only meets these **ca-pacity and traceability requirements** but also meets the requirements for **security, data protection, and privacy**.
- https://publications.iarc.fr/_publications/media/download/4492/b3c1b92bf3 005c6f3b939c65998e02b95007d90e.pdf

- 確保不同資料間進行串連的可用性
- Although it is not essential for the specimen-asso-ciated data to be in the same data-base as the biobank-specific data, it is important for the clinical data to be easily accessible via a link or a regular import.
- There may be logis-tic concerns in directly accessing hospital IT systems, and careful attention should be given to this during the planning of the biobank IT infrastructure.
- <u>https://publications.iarc.fr/_publications/media/download/4492/b3c1b9</u>
 <u>2bf3005c6f3b939c65998e02b95007d90e.pdf</u>

- IT系統須能妥善的紀錄、追蹤生物資料庫的各項作業流程
- It is fundamentally impor-tant that there is a method to **track** each sample throughout the bio-bank process and to **document the actions** that have been carried out on the sample.
- In addition to IT software to **re-cord the information** at each point of the biobanking process, there need to be software solutions **to docu-ment information** about monitor-ing of storage infrastructure and **to report alarms** about adverse events.
- https://publications.iarc.fr/_publications/media/download/4492/b3c1b9
 2bf3005c6f3b939c65998e02b95007d90e.pdf

- •預算、功能、維護、相容性等為主要考慮重點:
- As biobanking evolves in terms of the types of samples that are col-lected, archived, and stored and the downstream use of the sam-ples, **there continues to be a need to develop informatics tools for the management of biobanks**.
- On a larger scope, a laborato-ry information management system (LIMS) enables the management not only of the biobank but also of the entire sample life-cycle workflow.
- Options: Commercial, open-source, or developed in-house
- <u>https://publications.iarc.fr/_publications/media/download/4492/b3c1b9</u>
 <u>2bf3005c6f3b939c65998e02b95007d90e.pdf</u>

- 資訊管理系統應有助於資料的交流,以促進合作
- The facilitation of **scientific net-working** is an important aspect of IT infrastructure. Networking can increase biobank use and therefore is an important element of biobank sustainability.
- Publication of data on the Internet can greatly increase the visibility of the biobank and its ability to participate in biobank net-works. It is recommended that a biobank develop a website to pre-sent its operations to the scientific community, in addition to an online cat-alogue with information on the nature, characteristics, and quality of its biolog-ical samples.
- Networking to facilitate exchange and access to an increased number of samples requires that bio-banks adhere to standards for use of samples and data to ensure **seman-tic interoperability** between different systems and different biobanks, and this in particular presents a significant challenge for biobanking and IT sup-port
- https://publications.iarc.fr/_publications/media/download/4492/b3c1b92bf3005c6f3b939c
 <u>65998e02b95007d90e.pdf</u>

生物資料庫資訊化系統市場綜觀

- •疫情的催化下,需有更快速、更穩定的資訊系統,推動LIMS全球 市場穩定成長
 - The global **laboratory information management system market size** was valued at **USD 2.1 billion in 2022** and is expected to grow at a compound annual growth rate (CAGR) of 6.74% from 2023 to 2030.
 - During the COVID-19 pandemic, the demand for 24/7 laboratory testing services experienced a surge. Moreover, clinical laboratories were operating at full capacity, which resulted in significant stress for the laboratory personnel as well as the laboratory infrastructure. Such stressful environments are very undesirable, especially when laboratories are equipped with a large number of dangerous chemicals capable of causing biohazards every day.
 - This, in turn, is encouraging the implementation of LIMS solutions to streamline workflows by global benchmarks.
 - https://www.grandviewresearch.com/industry-analysis/laboratoryinformation-management-system-lims-market

AI + Cloud

- Cloud-based LIMS
 - 隨時、隨地存取
 - Perhaps the biggest benefit of having your lab information management system based in the cloud is ease of access.
 - 系統可靠性
 - Keeping up with software changes, patches, and bugs was never easy, and was often too much for organizations to do themselves, even with the best LIMS software on the market.
 - 安全性
 - Security may be the single most compelling reason to switch to a cloud-based LIMS. Hackers are constantly changing their tactics and it is almost impossible for an individual lab to keep on-premise software up-to-date with all the latest security fixes and vulnerability patches.
 - 成本效益
 - The cost of a cloud-based LIMS is normally less than an on-premise version.
 - This is because on-premise LIMS require you to purchase servers and other IT hardware to run the application. In addition, there are peripheral costs like IT staff, real estate, environmental monitoring, and more that have to be accounted for in the on-premise model. This makes the true cost of a cloud-based LIMS much lower than the on-premise alternative.

https://thirdwaveanalytics.com/blog/cloud-vs-on-premise-lims/

AI + Cloud

• Al-driven:

- 自動化:
 - Logging samples into LIMS, for example, is generally a manual entry, with the exception of barcode scanners and pre-created sample templates, where possible.
- 更有效率的品質管理:
 - Stability studies are expensive to run and can take several years to reach final conclusions.
 - AI and ML could, with access to historical data, begin to be used to limit the size of studies so they can focus on a 'sweet spot' of critical study attributes. Ultimately, this could dramatically reduce study length by detecting issues earlier and predicting when failure will occur.
- 資訊完整性:
 - ML could be used to monitor the audit trails of informatics systems and instrument systems in real-time and AI could report any out of the ordinary actions or result trends that do not 'look' normal to managers.
- 設備維護的最佳化
 - Using ML to review each new run, comparing it with previous runs and correlating with system failures, could predict the need for preventative maintenance.

https://scimcon.com/2021/04/16/the-role-of-ai-and-ml-in-the-future-of-lab-informatics/



Method and system for implementing augmented reality (ar)-based assistance within work environment



Current Assignee: Agilent Technologies Inc; US20220351475A1, Filed: 2022.7.18

資訊系統對於生物資料庫的永續營運至關重要

Operational and Information Technology Costs

Years in operation	Average operational costs	Average IT costs	IT%
Less than 1 year		—	—
1–3 years	\$750,000	\$80,000	10.7%
3–5 years	\$250,000	\$57,500	23.0%
5–10 years	\$354,800	\$32,820	9.3%
Greater than 10 years	\$2,239,215	\$59,367	2.7%

<u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6479261/</u>

資訊系統對於生物資料庫的永續營運至關重要

- LIMS 4.0 有助於Biobank 永續成長
 - The foundation of Laboratory 4.0 is automation.
 - Once it is in place, it supports the elimination of tedious, error-prone manual tasks.
 - A LIMS should eliminate or automate as many manual tasks as possible so that sample entry, processing, retrieval, and shipping may proceed more quickly and reliably.

https://www.genengnews.com/resources/biobank-tailoredlims-to-track-precious-samples-and-manage-data/



https://www.ncbi.nlm.nih.gov/pmc/articles/PMC647 9261/

生物資料庫資訊系統的演進與重點



生物資料庫資訊系統在大數據時代應具備功能

- Scale:
 - 管理巨量資料的能力
- Speed
 - 快速、穩定的資料處理
- Scope:
 - 安全、相容的資料連結與傳輸
- Learning:
 - 人工智慧的加值、整合服務

全方位、客製化的生物資料庫資訊系統,為成功關鍵

	All Of Us	UK Biobank
收集	 結合mobile device 動態同意 Individual feedback 	Interactive consent
儲存/處理	 NIH-controlled cloud environments Mayo Clinic 	 Thermo Scientific Nautilus LIMS
利用/釋出	 Powered by Google 	Powered by DNAnexusBased on AWS

人體生物資料庫資訊安全規範

- 一、設置者訂定之資訊安全管理規定(以下稱資安規定),應包括下列事項:
- (一) 資訊管理單位之組織、權責及分工。
- (二)人員管理及資訊安全訓練。
- (三) 電腦系統安全管理。
- (四)網路安全管理。
- (五) 資訊系統存取控制管理。
- (六)資訊系統購置、發展及 維護安全管理。
- (七) 資訊資產之管理。
- (八) 實體及環境安全管理。
- (九)資訊安全事件發生之通報及保全處理程序。
- (十)業務持續及回復管理。

2023/8/16(十一)本規範與相關法令規定事項,及其他有關資訊安全事項。

國內人體生物資料庫管理系統

ې	收集。		儲存。		利用↩				
	E 化文件。	互動網頁。	動態同意↩	軟體↩	硬體↩	專責人員↩	E 化文件。	網路申請。	雲端
國泰綜合醫院人	٧		•	VVV ₄ 2	•	•	VV		•
體生物資料庫。									
三軍總醫院人體	V ⁴ 2			VVV ₄ 3		V			
生物資料庫。									
聯新國際醫院人	٧			VVV.			V ₄ ²		
體生物資料庫。									
長庚醫療財團法	٧			VVV.			V ₄ ²		
人嘉義長庚紀念									
醫院人體生物資									
料庫。									
美兆人體生物資	٧			VVV ₄ 2			V ₄ ²		
料庫。									
臺中榮民總醫院	V			VVV.			V ₄		
人體生物資料庫。									
國家衛生研究院	٧			VVV.			V ₄		
人體生物資料庫。									

人體生物資料庫管理系統發展程度

	Paper-Based	Computer- Based	Web-Based	Cloud-Based
收集				
儲存				
利用(釋 出)				



數位資料飛快成長

- 95% of businesses cite the need to manage unstructured data as a problem for their business.
 - In a digitally powered economy like ours, only those with the right form of data can successfully navigate the market, make future predictions, and adjust their business to fit market trends.
 - Unfortunately, most of the data we generate today is unstructured, which means it comes in different <u>forms</u>, <u>sizes</u>, and even <u>shapes</u>.
 - Hence, it is difficult and costly to manage and analyze, which explains why it is a big problem for most companies.
- In 2020, every person generated 1.7 megabytes per second
- https://techjury.net/blog/big-data-statistics/#gref

更快速的資料交換才能加速生醫大數據的利用

- •病毒變異非常快速,醫學研究必須跟上腳步、超前部署
 - 生醫研究中相關研究數據與資訊的【傳遞】與【分享】,成為生醫 研究加速進展的關鍵。
 - Nature Medicine | VOL 26 | December 2020 | 1808–1809
- •生醫研究所產生的資料量,已遠遠超過資料解譯的速度:
 - 根據NIH評估,到2025年,待處理基因體資料的資料量,將大於社群巨頭YouTube、Twitter資料量的總和。
 - •研究學界表示通常耗費在【收集】、【整理】*既有資料*的時間(約 占80%),遠超過【資料分析】與【探勘】的時間(約占20%)
 - 顯見生醫大數據時代下學術社群的資料處理量能已較難跟上研究所需處理的【資料規模】。
 - https://datascience.nih.gov/sites/default/files/NIH_Strategic_Plan_for_ Data_Science_Final_508.pdf

資訊系統須具備數位整合功能

- The fragmented way in which health data is acquired and held makes it difficult for academia or industry to access and work with health information.
- Different organizations each hold different layers of data, with variable linkage across the full continuum of care. It's a major challenge to find out where relevant data presides and who to ask to get hold of it.
- https://home.kpmg/xx/en/home/insights/2018/11/four-lessons-thedigital-health-data-race.html

資訊系統須具備數位整合功能

NEWS 16 February 2022 Correction 16 February 2022

NIH issues a seismic mandate: share data publicly

The data-sharing policy could set a global standard for biomedical research, scientists say, but they have questions about logistics and equity.

Max Kozlov

https://www.nature.com/articles/d41586-022-00402-1

- In January 2023, the US National Institutes of Health (NIH) will begin requiring most of the 300,000 researchers and 2,500 institutions it funds annually to include a datamanagement plan in their grant applications — and to eventually make their data publicly available.
- The mandate, in part, aims to tackle the reproducibility crisis in scientific research. Last year, a US\$2-million, eight-year attempt to replicate influential cancer studies found that fewer than half of the assessed experiments stood up to scrutiny. Efforts to tally the cost of irreproducible research in the United States have found that **\$10 billion to** \$50 billion is spent on studies that use deficient methods, a cost that is mostly fronted by public funding agencies. 30

NIH Policy for Data Management and Sharing

- NIH Policy for Data Management and Sharing
 - Scientific Data: The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data <u>do not include</u> laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens.
 - Data Management and Sharing Plan (Plan): A plan describing the data management, preservation, and sharing of scientific data and accompanying metadata.
 - https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html#:~:text=October%2029%2C%202020-,January%2025%2C%202023,-Related%20Announcements

不僅能處理巨量資料資料,速度亦須提升

- UK Biobank:
 - 2006-2010: 500,000人收案
- All OF US: (目標: 1,000,000人)
 - 2018:開始收案
 - 於2019: 共230,000人完成收案
 - 於2021:共387,000人完成收案
 - 於2023: 共683,000人完成收案

https://www.nejm.org/doi/full/10.1 056/NEJMsr1809937

https://www.sciencedirect.com/scie nce/article/pii/S2666389922001817 https://www.researchallofus.org/

- Our Future Health
- 英國最新國家型生物資料庫計畫, 目標收案規模達500萬人。
- 於計畫啟動的11個月內,收案人數
 即達50萬人。
- 一個月處理高達10萬名參與者的收 案。
- 一個星期內處理高達1萬名參與者的 收案。

https://ourfuturehealth.org.uk/news/our -future-health-reaches-500000volunteers/

不僅能處理巨量資料資料,速度亦須提升

UK Biobank 核准釋出案





Ethics

The new UK Biobank Ethics Advisory Committee supersedes the Ethics and Governance Council

Anneke Lucassen, a professor of clinical genetics at Southampton University with extensive ethical expertise, has joined the Board of UK Biobank and will Chair its new Ethics Advisory Committee (EAC). Anneke will be joined on the EAC by Nick Ross, a well-known broadcaster, who has been involved in national bioethics and who has been closely involved with UK Biobank since its inception. Dr Susan E Wallace, Lecturer of Population and Public Health Sciences in the Department of Health Sciences at the University of Leicester, also joins the Committee.

The function of the EGC was to:

UK Biobank組織架構之調 整一 1. EGC由EAC取代。 2. 倫理治理必須跟上日漸 龐大、複雜的資料庫營運 事務與效率要求

-act as an independent guardian of the UK Biobank Ethics and Governance Framework (EGF) and advise on its revision; -monitor and report publicly on the conformity of the UK Biobank project with the EGF;

-advise more generally on the interests of research participants and the general public in relation to UK Biobank.

Over the intervening years, the EGC has discharged this role and has made a considerable contribution to the UK Biobank resource.

It became apparent that <u>during this period UK Biobank had developed at a considerable pace and, as a consequence, the</u> <u>EGC recommended that its oversight role would be more effectively discharged by better integration within UK Biobank as</u> <u>an advisory committee of the UK Biobank Board</u>. This recommendation has been accepted by the UK Biobank funders and by the UK Biobank Board. <u>https://www.ukbiobank.ac.uk/learn-more-about-uk-biobank/governance/ethics-advisory-</u>

<u>committee</u>



因應雲端運算的規範調適:UK Biobank

- Cloud Computing Policy(2017)
 - In contrast to traditional computing undertaken on local servers and infrastructure directly owned and managed by a research organisation, cloud computing often entails the transfer and storage of data on systems managed by a third party. Security controls are required to protect against unauthorised access, data loss or theft, and these need to be proactively managed between a research organisation and their cloud computing provider.
 - UK Biobank would expect that a research organisation's intended use of cloud computing services be reviewed by a senior representative of their internal IT organisation and who can certify that security, privacy and all other IT management requirements will be adequately addressed by the cloud computing provider.
 - UK Biobank holds the research organisation fully responsible for any failure in oversight of using cloud computing services for storing or processing UK Biobank data.

因應雲端運算的規範調適:UK Biobank

- Cloud Computing Policy (2017)
 - UK Biobank expects a minimum set of controls to be in place at the research organisation, based on a security in-depth model, that includes (but is not limited to):
 - 3.7.1 preventing unauthorised access and sharing;
 - 3.7.2 monitoring and audit of the infrastructure and employee access;
 3.7.3 encryption of data both at rest and in transit (AES256 recommended);
 - 3.7.4 conducting regular risk/vulnerability assessment and analysis.
 - UK Biobank would expect any reputable cloud computing services provider to be certified to information security industry standards, including (but not limited to) ISO27001, ISO27017 and ISO27018.

因應雲端運算的規範調適:UK Biobank

- •雲端運算儼然成為發展生醫大數據的基本裝備
 - 使用者透過第三方提供的雲端運送資源進行分析研究,已屬普遍
- 生物資料庫作為參與者個人資料的管理者,自然必須對於隱私與 資訊安全嚴格把關
 - UK BIOBANK在2017-2018年透過制定雲端政策和修訂MTA的做法,規範使用者在委託第三方進行雲端運算時,應該具備的基本保護措施,包含:
 - 第三方服務者的資格與能力
 - 與該第三方服務者簽訂的合約的必要內容
 - 資料提供的比例性與必要性
 - 連帶責任。
 - 但是將雲端運算的規格主導權放在個別研究使用者之手,難免仍會發生因為服務提供者不同,導致不同使用者的運算成果或安全性存在差異
 - 何況,每個服務業者提供的運算資源和條件可能皆有不同,生物資料庫 在有限的資源下,又如何能有效的稽核個別使用者的委外使用情形?

2021翻修了MTA之後,2022 UK Biobank也重新修訂了ACCESS POLICY



Enabling scientific discoveries that improve human health

UK BIOBANK

ACCESS PROCEDURES

Application and review procedures for access to the UK Biobank Resource

Version 2.0

(March 2022)

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2023/8/16

當 Biobank本身就具備雲端運算的能力,自然能更直接規範雲端運算伴隨的風險

- UK Biobank 於2021針對生物資料庫的資料釋出與使用制定的MTA:
 - •明文化使用者資訊安全義務(4.2)
 - 使用者的申報義務(5.2)
 - 資料規格的相容性與完整性(5.7)
 - 具體化UK Biobank的稽核權(7)
 - 資料保護法的遵循(9)
 - 責任限制(10)
 - 第三方資料處理者之責任(14.5~14.10)
 - UK Biobank的安全措施(Annex 2)

All Of Us

Bring researcher to the data

- Advantages of this approach include:
 - 1. Security: Significant centralized resources can be brought to bear to secure copies of the data, and access can be more easily monitored and tracked by removing data "handoffs"
 - 2. Cost: This approach avoids the need to store multiple copies of the massive dataset
 - 3. Accessibility: Few groups have the infrastructure needed to support data on this scale, limiting its utilization
 - 4. Elasticity: provide a pool of compute resources for needs that vary over time

https://www.cell.com/patterns/pdfExtended/S2666-3899(22)00181-7

Authorized User

- Initially, a data user's institution must enter into an institutional data use agreement with the All of Us Research Program for an individual to become an authorized user.
- Once their institution has entered into the agreement, the individuals must take the following steps to become authorized data users:
 - Provide their identity to the *All of Us* Research Program.
 - Provide consent for public display of their name and affiliations along with plain language descriptions of their research projects.
 - Provide consent for public release of name and affiliation if the RAB finds that they have violated the DUCC.
 - Complete the *All of Us* Responsible Conduct of Research Training, including modules on data security and participant privacy awareness, and renew this training on an annual basis.
 - Provide a signature that codifies that the user has read, understood, and agrees to abide by the DUCC, and has completed the requisite training.

Data User Code of Conduct

• As an "Authorized Data User" of the All of Us Research Program data, I will:

- read and adhere to the All of Us Research Program Core Values.
- follow all laws and regulations regarding research involving human data and data privacy that are applicable in the area where I am conducting research.
- conduct research that follows all policy requirements and conforms to the ethical principles upheld by the All of Us Research Program.

https://www.researchallofus.org/faq/data-user-code-ofconduct/

行為準則違反的制裁

• 4. Violations of the Data User Code of Conduct

- The DUCC Compliance Review Policy lays out the process by which the RAB will evaluate violations of the DUCC and recommend penalties. This process includes, but is not limited to, such stipulations as:
- The RAB will determine whether a data user or group of data users have violated the DUCC and will notify the *All of Us* Research Program of the violation.
- The RAB may: O Notify the data user(s) of any violation of the All of Us DUCC.
- O Determine whether any action by the data user is required to remedy the violation, and ensure that the data user has taken the recommended actions.
- C Recommend that the Data and Resource Center (DRC) revoke and/or deny access of the data user to all non-public All of Us data.
- Recommend that the Data and Resource Center (DRC) post the name and affiliation, if applicable, of the data user on a public All of Us Research Program webpage.
- Based on the scope and impact of the violation, the *All of Us* Research Program may choose to employ additional sanctions against the authorized user who has violated the DUCC.

https://www.researchallofus.org/faq/data-user-code-ofconduct/

All Of Us v. UK Biobank

	All of Us		UK Biobank
契約當事人	Biobank (Vanderbilt Univ Center (VUMC))與機構	versity Medical	UK biobank與機構
實際行為人	直接拘束(須遵守行為 否則直接受到All Of U	為準則DUCC, Us制裁)	間接拘束(機構須確保PI與相關研究人員 遵守使用規定,並負連帶責任)
使用者權限	每年更新/需受訓	的使田式運	Bona fide researcher 無特定機制
對於第三方資料 處理者的規定	未有專章規定 算智計的 資料	皆在All Of Us設 的雲端環境, 科不得攜出, 较無委託第三	專章規定
資訊安全措施	未有專章規定 方通	運算的需求	專章規定

進化的生物資料庫資訊系統,對達到永續經營屬不可或缺

- 隨著生物資料庫的使用者越來越 多、使用量越來越高
 - 生物資料庫可以更了解每個使用者 的個人偏好,提供相對應的資料或 研究工具
 - 生物資料庫可以更有效率的管理個 別使用者的研究活動
 - 例如:是否准予研究展期
 - 不久的將來,生物資料庫可能預測/ 判斷
 - 生醫研究的整體趨勢
 - 個別研究案進行的效益(避免重複研究)
 - 個別研究的成功可能性/可行性

Different Stages of Biobanking



Daniel Simeon-Dubach Peter Watson, **Biobanking** 3.0: Evidence based and *customer focused* biobanking

謝謝聆聽!