Core Issue I :
Individual or Group Consent

Figure III: The Ideology of Group Consent

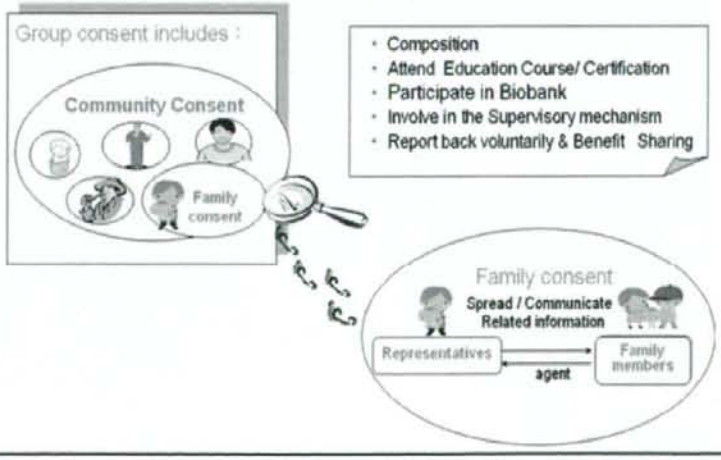
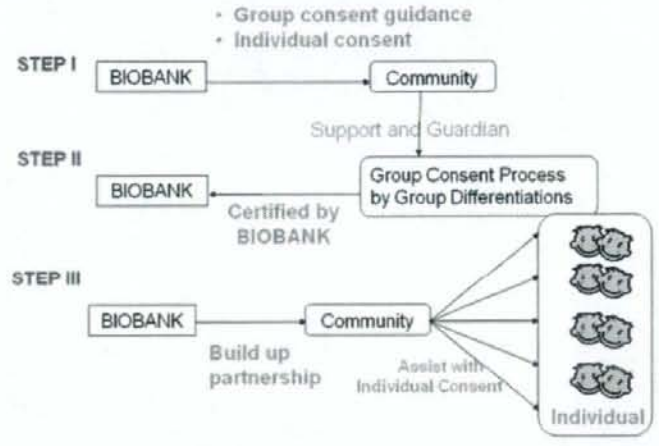
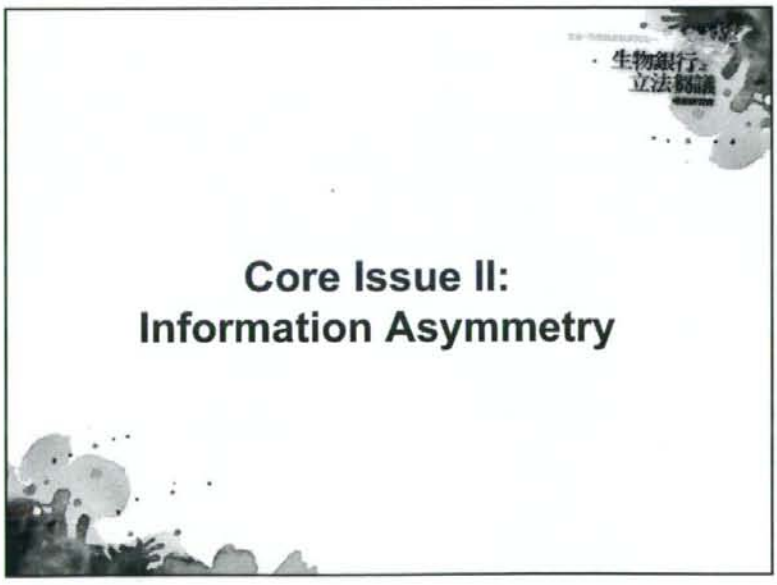


Figure IV Group Consent Process





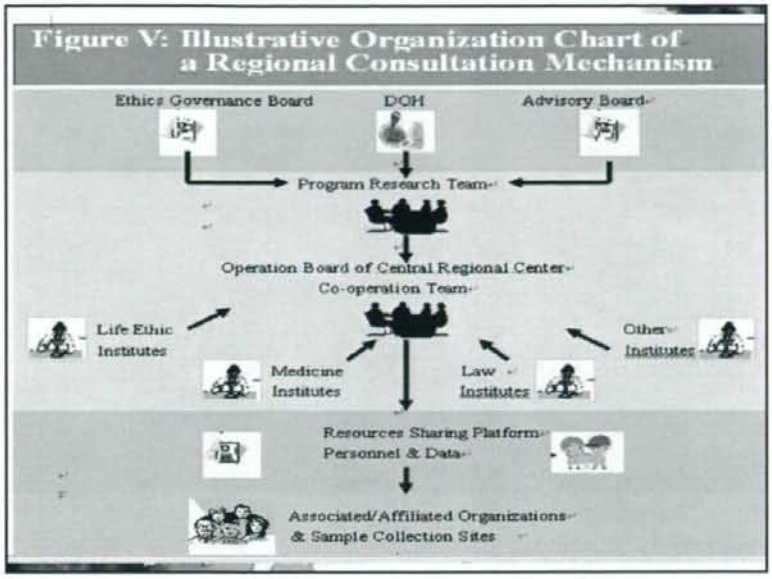
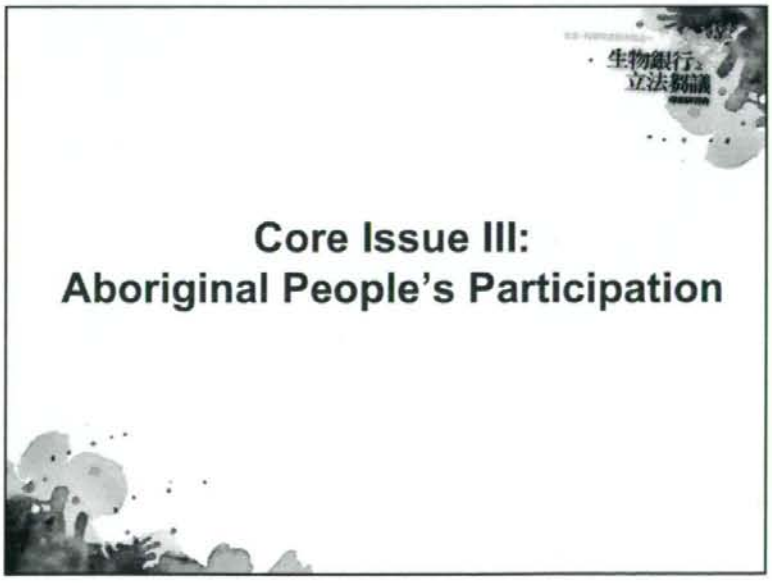
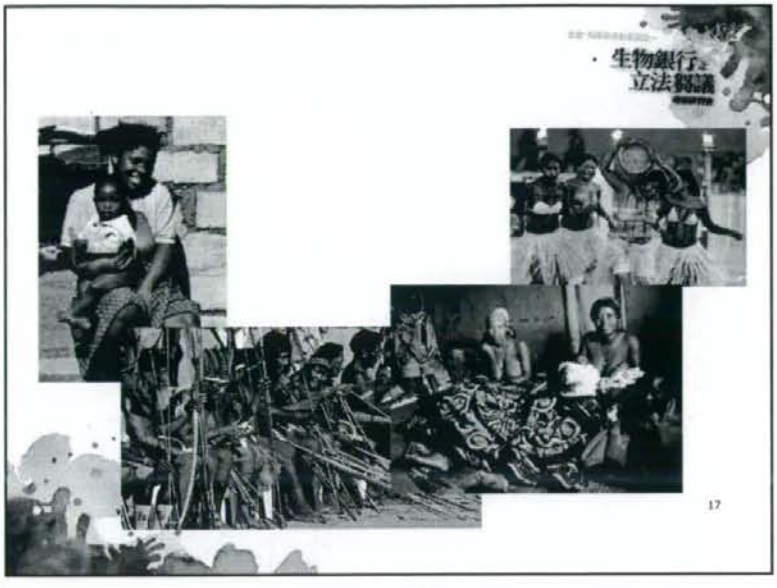


Figure V: Illustrative Organization Chart of a Regional Consultation Mechanism
Ethics Governance Board
DOH
Advisory Board
Program Research Team
Operation Board of Central Regional Center
Co-operation Team
Life Ethic Institutes
Medicine Institutes
Law Institutes
Other Institutes
Resources Sharing Platform
Personnel & Data
Associated/Affiliated Organizations & Sample Collection Sites


生物銀行立法芻議
Core Issue III:
Aboriginal People's Participation


生物銀行之
立法探討
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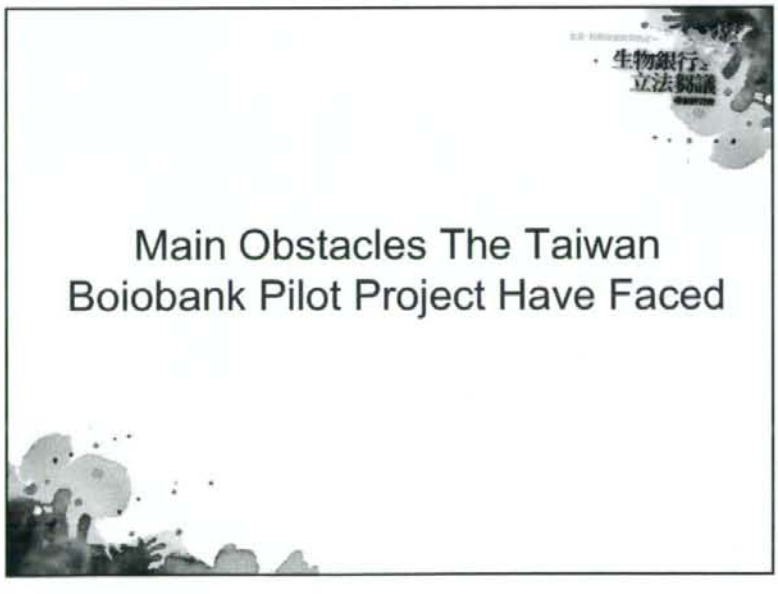

生物銀行之
立法探討
Main Obstacles The Taiwan
Boiobank Pilot Project Have Faced

- It takes more than 2 years before IRB may reach conclusion
- All the ELSI works turn out to be on the paper-based review, which cannot be substantiated.
- EISI section, as a part of the research project, was taken as an guardian to the bio section. (Conflict of Interest)
- Human right group insisted on the completion of legislation
- Reaching the end of Pilot Project, the result belonging, operation framework, the implementation of public goals, who should be held responsible for the project driving and how to promote the benefit sharing are all in issue.

Solutions Admitted by IRB at the End of 2008

Approval of Experimental Tissue Collection

- 以IRB既有的附條件同意爲基礎，以期限及檢體採集數量的雙門檻爲限，在IRB確認的程序下，在目前人員訓練及設備均較爲成熟的駐站實施試行收案。
- IRB負責全程監督，並由既有ELSI人員協力，一旦有所疑慮則可隨時停止試行。
- 以此試行經驗作爲未來EGC的監理基礎，以免EGC委員必須再重複紙上審理程序，並可提供公眾溝通的具體事證，減少假設性爭議。

Accelerating the EGC Establishment

- EGC顯爲當前各方認爲具獨立性，而較能爲社會信任的倫理治理機構，也是本計劃倫理治理規範及管理條例(草案)所要求設置者，應加速其建置。
- 惟一般的期待往往與現實有間，蓋我國的Biobank仍處研究計劃階段，實際上應以執行單位之IRB爲倫理治理單位爲是；爲避免EGC成立後與IRB之分際混淆，建議EGC的設置應配合後述籌備處的設計，使之成爲籌備處的獨立監理單位，真正擁有制度化的法律地位；並有別於原研究計劃的IRB。

Perfect the Legislation Work

- 人權團體與部份立委在此方面的期待已嚴重影響計劃的推動經費與時程，如何加速立法進程，攸關未來本計劃的能否續行；應優先推動。
- 執行上應有政府與產官學研的密切合作；以過去落實科技會議決議的法規調適經驗來推動有其必要。

Transform into an Legal Entity

- 將研究成果與採集的檢體交由制度化的籌備處負責管理，將能解決前述IRB與EGC的重疊問題必強化倫理治理機制的獨立性與可信賴性。
- 以具法律地位的籌備處來接手，將能區隔原計劃與執行單位間的法律關係，使參與者之權利義務更清楚，並在某種程度上受到現有法律的監督，有利於滿足社會所期待公共利益的落實。
- 以籌備處名義作業有利於Biobank制度化的先期運作經驗的累積、營運人才的養成以及後續營運模式的確立。

A Sketch on Auditing Report

1. Abstract

1.1 The Project Purposes

1.2 The Review on Designed Tissue Collection Process

1.3 Checking Points

1.4 Compliance with Related Rules

1.5 Conclusion

2. The Recruitment of Participants

2.1 Targeting & Acquisition of Participants' Contact Information

2.2 The management of Recruitment Operation

2.3 Q & A and Information Flow

2.4 Cooperative Medical Institutes' Questions and Responses

2.5 An Analysis on Reason of Participants' Refusal

3. Interview Conducted by Collection Sites

3.1 Collection Sites' Facilities and Related Arrangements

3.2 Contents & Time Schedule of Interview

3.3 Participant's Recognition & Opinion

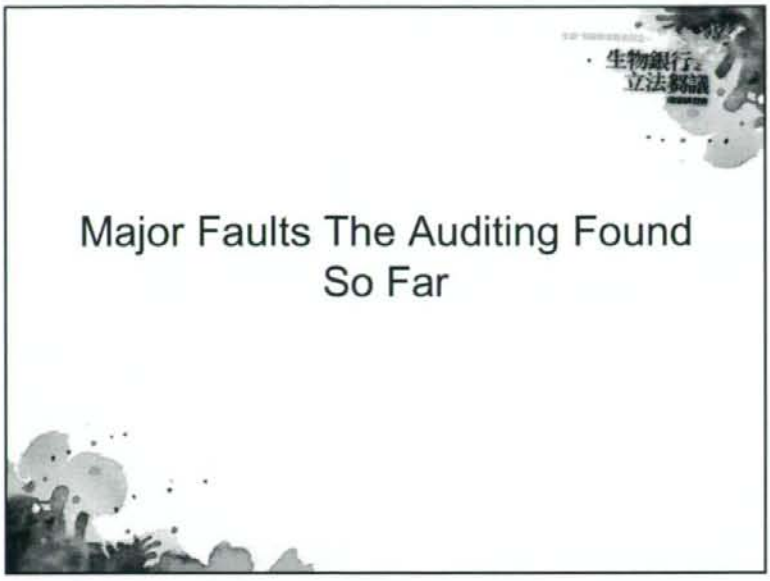
4. Management Proceeding of Collected Tissues and Personal Data

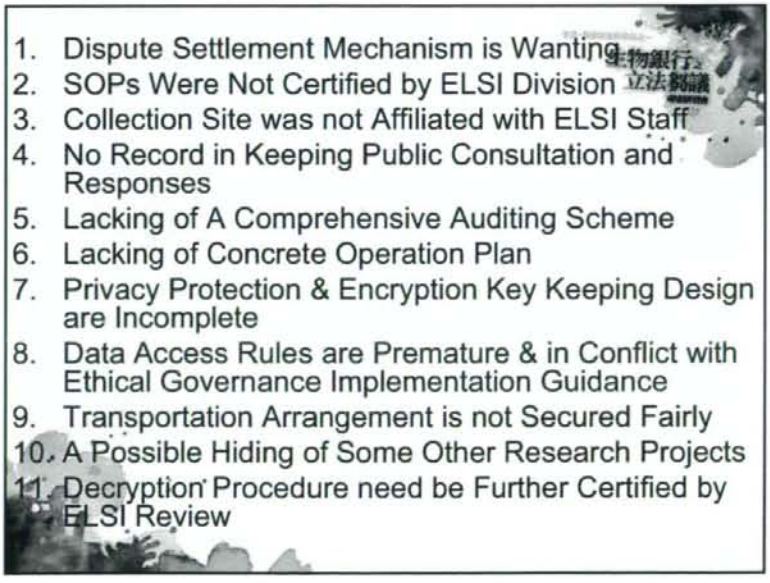
4.1 Establishment of Headquarter & Collection Sites

4.2 Transportation & Management of Collected Tissues & Personal Data

5. Collateral Documents

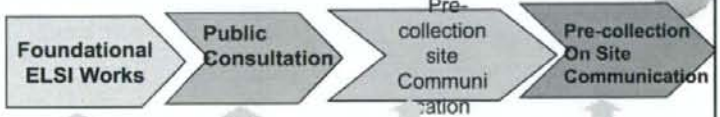
- Including All Forms, SOP Guidance, Protocol, and etc.


生物銀行。
立法探討
Major Faults The Auditing Found So Far


1. Dispute Settlement Mechanism is Wanting
2. SOPs Were Not Certified by ELSI Division
3. Collection Site was not Affiliated with ELSI Staff
4. No Record in Keeping Public Consultation and Responses
5. Lacking of A Comprehensive Auditing Scheme
6. Lacking of Concrete Operation Plan
7. Privacy Protection & Encryption Key Keeping Design are Incomplete
8. Data Access Rules are Premature & in Conflict with Ethical Governance Implementation Guidance
9. Transportation Arrangement is not Secured Fairly
10. A Possible Hiding of Some Other Research Projects
11. Decryption Procedure need be Further Certified by ELSI Review

Possible Corrective Efforts

Enhancing the Cooperation between BIO & ELSI Disciplines



ELSI
- Expansion of Networks
- Design of Special Consent Mech.
- Personnel Training (Nurses, Volunteers & Intellectual People)

ELSI + Bio
- Public Consultation for Recruitment

ELSI + Bio
- Tel Contact
- Other Supporting Channels for Conducting Informed Consent

Bio
- Reconfirm before Participant's Signing on the Consent Form

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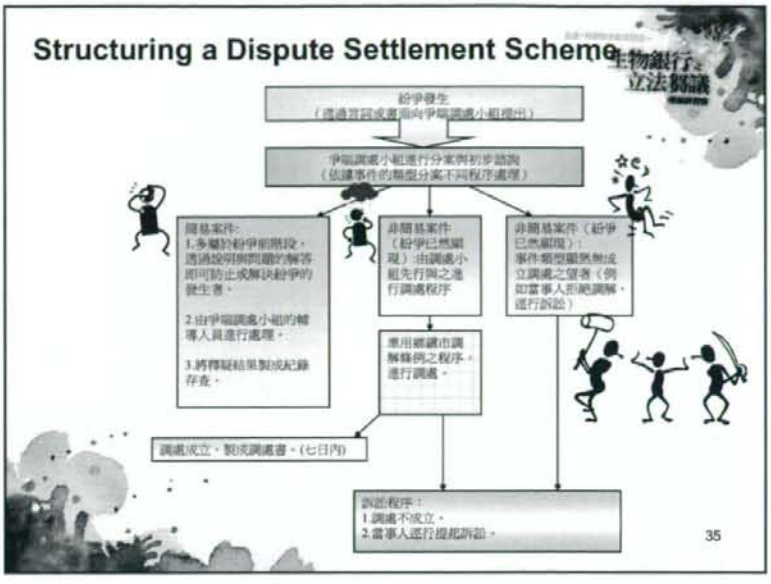
Structuring a Dispute Settlement Scheme
生物銀行立法芻議
爭議發生
（透過言詞或書面向爭端調處小組提出）
爭端調處小組進行分案與初步諮詢
（依據事件的類型分案不同程序處理）
簡易案件：
1.多屬於紛爭前階段，透過說明與問題的解答即可防止或解決紛爭的發生者。
2.由爭端調處小組的輔導人員進行處理。
3.將釋疑結果製成紀錄存查。
非簡易案件（紛爭已然顯現）：由調處小組先行與之進行調處程序
非簡易案件（紛爭已然顯現）：事件類型顯然無成立調處之望者（例如當事人拒絕調解，逕行訴訟）
準用鄉鎮市調解條例之程序，進行調處。
調處成立，製成調處書。（七日內）
訴訟程序：
1.調處不成立。
2.當事人逕行提起訴訟。
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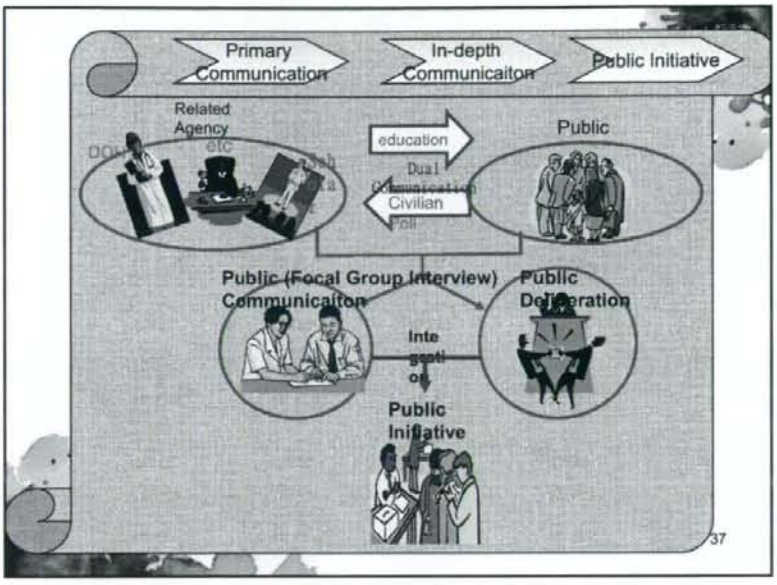
生物銀行立法芻議
Strengthen Public Communication


Primary Communication
In-depth Communicaiton
Public Initiative
Related Agency
education
Public
Civilian
Public (Focal Group Interview) Communicaiton
Public Deliberation
Public Initiative
37


Thank you for your attention

International Symposium
Biobank and Genomic Research
- Bioethics of Genomic Medicine

Ethics, Law and Governance of Biobanks

Professor Don Chalmers

KYOTO, 22 March 2009

UTAS

Centre for Law & Genetics

Overview

- Biobanks – Definition
- Biobanks – National and International
- Biobanks and Genomic science
- Research uses and Personalised medicine
- Technical challenges for Biobanks
- Legal and Ethical challenges for Biobanks
- Governance Principles
- Conclusions

1 Biobanks - Definitions

- Biobanks are specifically created collections of human tissue samples established with the specific aim of conducting **research**.
- UK "Biobank"; Latvia -"genebank"; French National Ethics Consultative Committee -"biolibraries"

1 Biobanks -Existing Collections?

- Existing collections of human tissue (eg Pathology samples; blood banks) with **primary** aim for diagnostic and clinical purposes
- These collections may be used for **secondary** purpose of research
- Are these Biobanks? Generally no but may be organised with proper governance arrangements.
- Existing collections have only specific and limited consent regimes.

2 Biobanks- National

- *National* UK Biobank (**500,000**) DeCode (Iceland);Estonian Genome;Karolinska Institutet (Sweden); CARTaGENE (Quebec); GenomEUtwin (Finland); Danubian Biobank Foundation (six countries in Central Europe); KORA-GEN(Germany); LifeGene (Sweden); Generation Scotland; INMEGEN (Mexico); LifeLines (Netherlands); National Heart, Lung and Blood Institute (NIH USA); Centre for Integrated Genomic Medical Research (UK).
- Japan and Taiwan
- *Australia*: WA Genetic Health project (Busselton);Victoria cancer consortium;Tasmania Menzies Centre

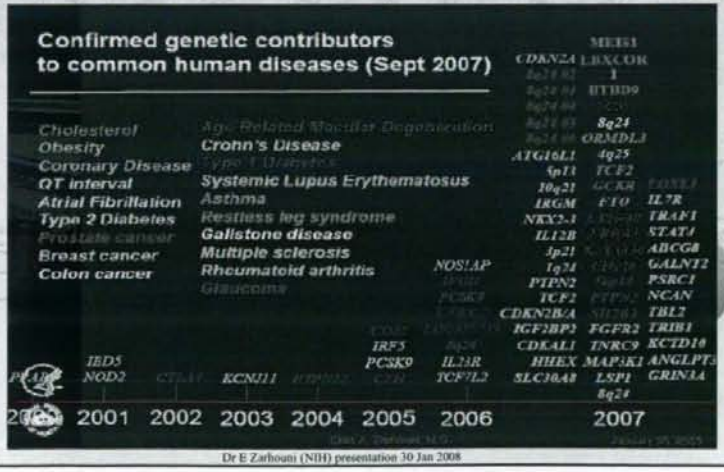
2 Biobanks:International

- *International Haplotype Mapping Project:* USA, UK, Japan, Nigeria, China and Canada collaboration after Human Genome Project to study/find genes that affect health, disease and medication responses
- *Public Population Project in Genomics* (P3G); genome Canada not-for-profit public database for biobank/genomics community, (motto - *transparency and collaboration*)- Consent forms; Guidelines; P3G Observatory; 22 Charter; 13 Associate; 152 members (41 countries, **10.5 million participants**
- PHOEBE (Promotion and Harmonization of Epidemiological Biobanks in Europe)
- Translational Genomic Research in the African Diaspora (TgRIAD)

3 Biobanks and Genomic Science

- Francis Collins NHGRI "The Genome Era"
- Exponential increase in 2007 in information about genes implicated in complex genetic disorders.
- New paradigms are emerging how genes and gene-gene interactions (e.g. networks in obesity) might function.
- New analytic research platforms allow multi-centre collaborative "blockbuster" type association studies to identify even more about gene activity

3 Biobanks and Genomic Science



Dr E Zarhouni (NIH) presentation 30 Jan 2008

3 Biobanks and Genomic Science

- Example of blockbuster study: breast cancer susceptibility genome-wide association study involving 28 centres in 12 countries and 50,000 samples
- 'The detection of further loci will require….larger numbers of cases and controls…[and] results across multiple studies"(Easton)-from *individual* to *population*

3 Biobanks and Genomic Science

- Taichi Sakaiya – *Knowledge-Value Revolution*
- Convergence of technologies -HGP and collaborations; computers and bioinformatics; microarrays; new tests; proteomics and metabolomics; national biotechnology policies; increased funding (eg President Obama in USA $20 billion); Commercialisation and Partnerships

3 Biobanks and Genomic Science


GEN
Genetic Engineering & biotechnology News
Biotechnology from bench to business
Liquid Chromatography
OMICS | Drug Discovery | Translational Medicine | Bioprocessing | Biobusiness
Pushing Toward a $1,000 Genome
Stepwise Technological Evolution Will Continue, but Disruptive Spurts Are Also Forecast

4 Research Uses of Biobanks

- Large scale research and biobanks and rising health costs (cancer, diabetes, heart diseae).
- Large scale genetic epidemiology studies; Disease gene/proteomic discovery studies
- "Biobanks are increasingly seen as an essential tool in translating biomedical research into real improvements in healthcare" (*Genetic Engineering News* , 2005)