

biobank and database

Current situation in Japan

- No national regulation on biobank so far.
Each so-called biobank has or has not its own regulation.
- Size, objective, scope of use and accessibility are diversified.
- Cooperation is not always assured among researchers. Small size biobank is in many cases closed to the third party researchers.

Elements to be included in the biobank regulation

- Informed Consent Procedure
 - Broad consent
 - good understanding on what is the biobank
- Linkable Anonymisation of samples
 - Protection of samples and personal information
- Samples and Data collection
 - Quality control needed
- Accessibility to samples and data
 - Openness is required. However, the data quality should be universally (nationally) uniform.
- Governance system more than ethical review system
 - Size, substantial elements and social impact are so important that traditional ethical review system may not be adequate or sufficient.

平成 20 年度

公開国際シンポジウム「バイオバンクとゲノム医療

—ゲノム医療の生命倫理—

資料

International Symposium
Biobank and Genomic Research
-Bioethics of Genomic Medicine -
10:00 –13:00 22nd March, 2009
Kyoto University Clock Tower
International Exchange Hall III



Biobank Japan and its Ethical Framework

Kaori MUTO, Ph.D.
Dpt. of Public Policy
Institute of Medical Science
The University of Tokyo

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Topics

- What is Biobank Japan?
- Ethical Framework?—Then and now
- Based on the critique “Governance by stealth” by Triendl and Gottweis
 - incld in “Biobanks—Governance in Comparative Perspective”, edited by H. Gottweis and A. Peterson, Routledge, 2008
 - Muto used to be a member of Bioethics Committee (Committee for ELSI) and a leader of the Ethics and Governance Working Group in the project.



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Biobank Japan Project

By any definition, Biobank Japan is among the world's largest and best-funded efforts to build a large-scale biorepository linking biological materials, DNA samples, and data on genetic variation and clinical information taken from actual patients. At the same time, Biobank Japan is one of the least debated or controversial of the large biobank projects currently being developed. [...] Biobank Japan stands out in terms of its size, overall budget, investment in facilities, and perhaps also the sheer speed [...]

(Triendl and Gottweis, 2008)



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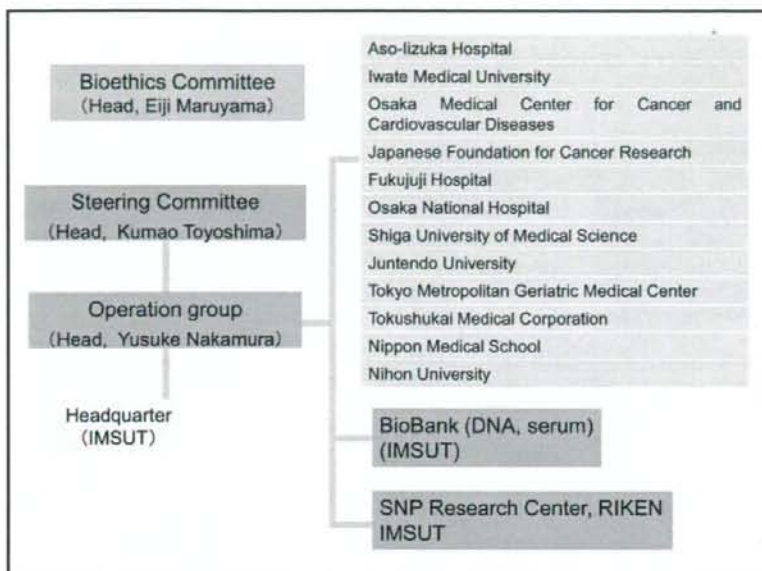
Biobank Japan Project

- 5 yr-project launched in June 2003 (First Term)
- Extended 5 more yrs in April 2008 (Second Term)
- Headed by Yusuke Nakamura (IMSUT)
- Supported by Ministry of Education, Culture, Sports and Technology (MEXT)



文部科学省 リーディングプロジェクト
オーダーメイド医療実現化プロジェクト

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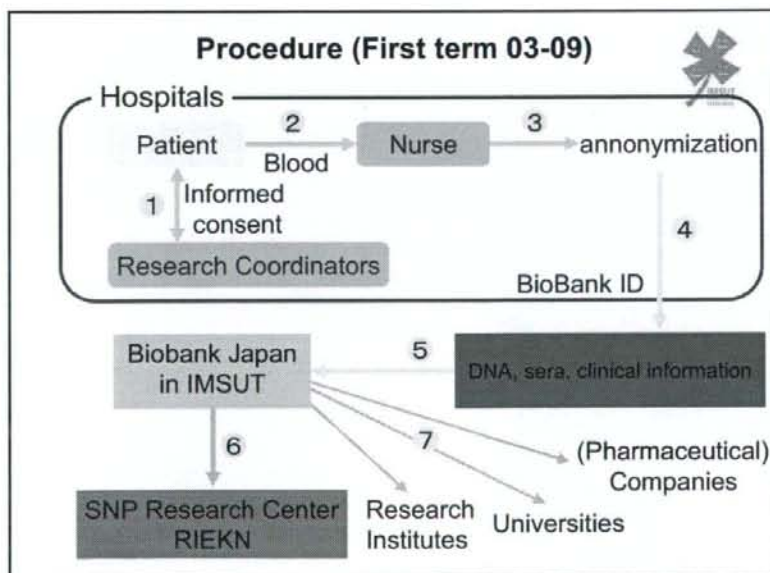


Registered diseases (47 common diseases)



Diabetes mellitus	Bronchial asthma	Hysteromyoma
Hyperlipidemia	Pulmonary fibrosis	Endometriosis
Cataract	Pollinosis	Uterine cancer
Glaucoma	Drug induced eruption	Ovarian cancer
Myocardial infarction	Tuberculosis	Breast cancer
Unstable angina	Atopic dermatitis	Esophageal cancer
Angina pectoris	Hepatitis B	Gastric adenocarcinoma
Arrhythmias	Hepatitis C	Colorectal cancer
Congestive heart failure	Liver cirrhosis	Prostatic carcinoma
ASO	Ureterolith	Hepatocellular carcinoma
Febrile convulsion	Nephrotic syndrome	Cholangiocarcinoma
Epilepsy	Basedow's disease	Pancreatic cancer
Cerebral infarction	Rheumatoid arthritis	Myeloproliferative diseases
Cerebral aneurysm	Keloid	Lung cancer
ALS	Periodontosis	
COPD	Osteoporosis	

Procedure (First term 03-09)



Biobank Japan Project

- First Term (2003-08)
 - Building basic structures: banking, anonymization, security and database
 - Collection of DNA, sera, and clinical information in four years from 199,742 patients with 47 common diseases (Recruitment period: 4.5 yrs)
 - Systematic genomics (mainly SNP analysis)
 - Identification of genes with medical importance



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Biobank Japan Project

- Second Term (2008-12)
 - Collection of sera and clinical information from some amounts of participants once a year
 - Systematic genomics (mainly SNP analysis) and proteomics analysis on cancer and heart diseases with broader research community.
 - Data cleaning of clinical information
 - Prognosis survey from all participants



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Biobank Japan Project

- Not designed as epidemiological cohort study based on community population.
- Neither an isolated project nor a national biobank.
- Built into the larger research infrastructure in genomics, followed by SNPs research at the IMSUT, in which MEXT had already invested.
- Thus, BBJP is also defined as an aspect of a large PGx project rather than a provider of biological resources to other scientists.



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Public consultation

Biobank Japan remains largely unknown to the Japanese public and [...] even to the country's medical and biological research community. [...] None of the ministry's advisory bodies had been consulted on the subject of the project, virtually no debate took place. [...] [It] was eventually selected by the finance ministry from around 40 "Leading Projects" at the MEXT.

(Triendl and Gottweis, 2008)



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Public consultation

- Very short preparation period after budget compilation
- No public consultation before launch
- Independent and ethical advisory board (Bioethics Committee) was established for the project, funded by the MEXT
- The committee's main agenda: monitoring of sample collection process



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Biobank Newsletter and Café Scientifique



- “Biobank Newsletter” (2007-) is quarterly newsletter for participants, coordinators and the public since 2007.
- Summary of latest scientific articles using samples and data from BBJ, voices from participants and commentary.
- We're planning to have a Café Scientifique this summer.



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Bioethics Committee and Biobank Japan

In many ways, the [Bioethics Committee's] reports read almost like summaries of a site review or an inspection. [...] [T]he issues raised by the committee are somewhat superficial and rather removed from some of the key questions facing a large biobank project. [...] While arguing the Bioethics Committee has followed a somewhat 'bureaucratic agenda' and is only limited use to the project, Nakamura also points out that individual members of the committee have helped considerably to finetune the sample collection process.

(Triendl and Gottweis, 2008)



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Bioethics committee and Biobank Japan

- The Bioethics Committee was inflicted with “information asymmetry”, which made the committee concentrate on the sample collection process.
- Little attention has been paid to issues of management, use, transfer and ownership of the resources collected for future change.
- Recently, project leader asks consultation on specific theme to the Bioethics Committee.



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Standard consent process of the BBJP

1. Physicians ask patients whether they are interested in details about the BBJP after their regular consultation.
2. If patients were interested in details, research coordinators show the DVD (10 minutes) and explain the overviews of the BBJP using special pamphlets.
3. Patients are asked whether to donate their DNA as well as sera and clinical information once a year.
4. They are also required to give consent to several conditions such that their personal genotyped data won't be disclosed, IP issues, rights to withdraw consent and so on.
5. They can give consent and blood right after this explanation; otherwise they can take time to think twice at home.
6. In total, it takes about 30 minutes in average.

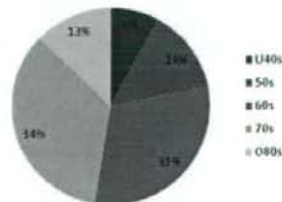


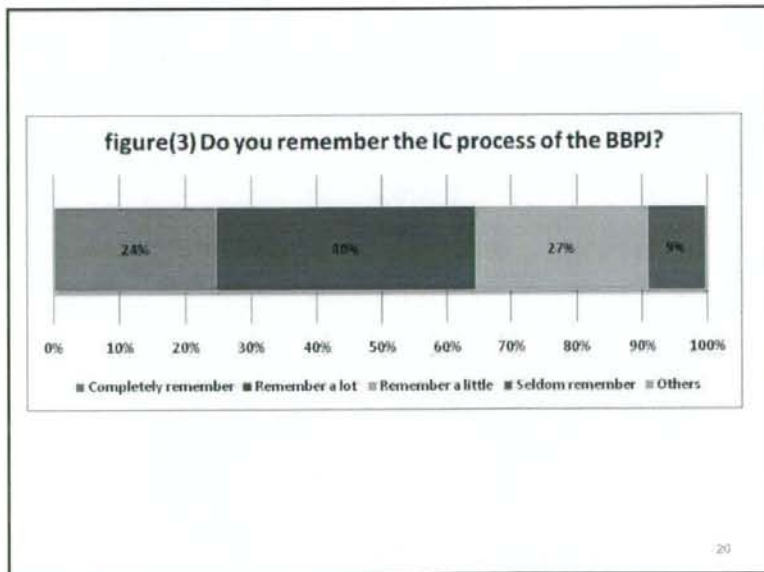
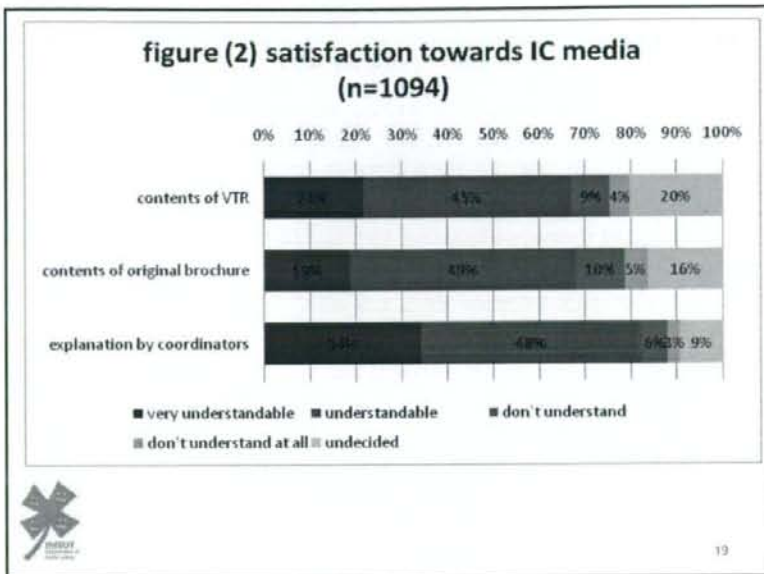
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Questionnaire survey to participants

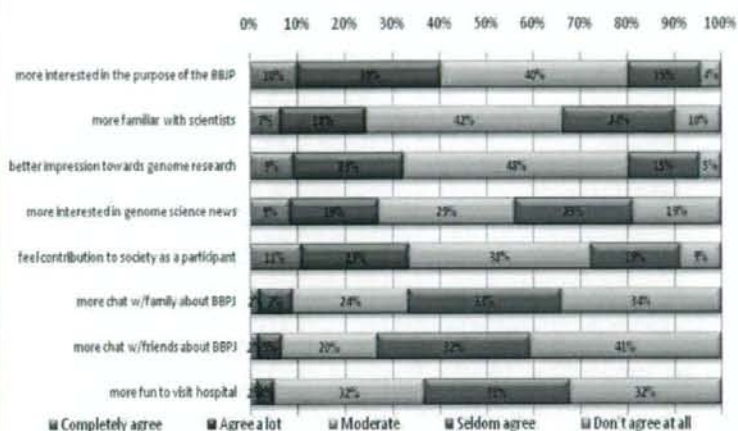
- We conducted self-reported questionnaire (4 pages) survey to research participants at one hospital of the BBJ project. This study was approved by the IRB of the IMSUT.
- Study period: 2007.10.23-2008.10.22
- Male 792:Female 584
- 1,378 samples
- Respond Rate=70.2%

figure(1) agegroups

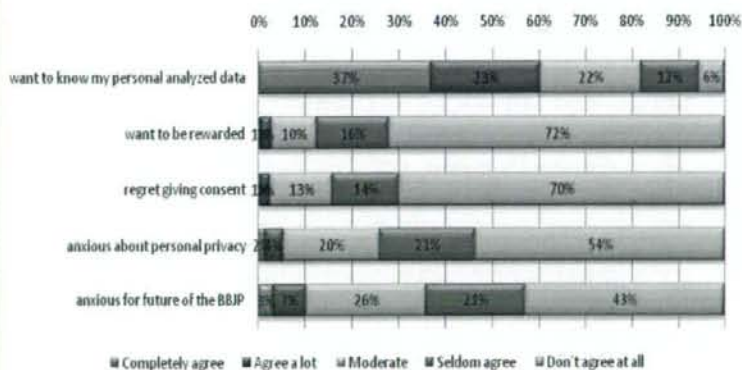




**figure (4) attitude change after participation in the BBJP
(n=1172)**



**figure (5) attitude change after participation in the BBJP
(n=1172)**



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Table (1) Statistical test of mean difference for "disclosure of personal analyzed data"

		yes	others	difference	
age	mean	84.83	89.58	-4.75	**
	s.d.	11.95	11.16	0.79	
male	mean	0.58	0.57	0.00	
	s.d.	0.49	0.49	0.00	
remember the consent process	mean	0.70	0.56	0.14	**
	s.d.	0.46	0.50	-0.04	
satisfactory towards IC media	mean	1.90	1.52	0.38	**
	s.d.	1.33	1.28	0.06	
willing to participate in the future	mean	0.80	0.59	0.21	**
	s.d.	0.40	0.49	-0.09	
burden for participation	mean	0.00	0.01	-0.01	
	s.d.	0.05	0.10	-0.05	
regret giving consent	mean	0.03	0.01	0.01	
	s.d.	0.18	0.12	0.05	

** indicates mean difference is significantly different from zero at 1 percent level.

Trend for "disclosure of personal analyzed data" relates to younger age, good memory and satisfaction towards the consent process, and willingness for future participation.

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New ethical challenge: Prognosis survey

- 5-10% of participants had already passed away.
- 20-25% have been missing from the original hospitals and not traced anymore.
- Prognosis survey is necessary to complete the BBJ's samples and data because its sole endpoint is "death".
- Can we know participants' survival and cause of death without re-consent?
- Ethical issues regarding prognosis survey using residents' cards must be discussed immediately.



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Conclusion

- Triendl and Gottweis's paper is almost correct.
- But, some critiques have been improved in BBJP2: transparency, openness and public dialogue

- How has the recession affected biobanks worldwide?





Taiwan Biobank Current Ethical Issues

FAN, Chien Te
Professor of Law, National Tsing Hua University
Director, Bioethics & Law Center, NTHU
2009/3/21



Special Features of Taiwan Biobank



1. The participants will be recruited on the voluntary basis.
2. There are three collection sites evenly allocated in northern, southern and eastern Taiwan.
3. The participants are people of the age between 30 with no gender restriction.
4. People of foreign nationality, foreign ancestry and/or diagnosed with cancer are excluded.
5. Collected samples include venous blood of 33 ml and urine of 15 ml
6. Other data to be collected include the health condition, history of diseases, lifestyles of the participants, and the personalized information about their living environment as well as samples of the environment.
7. The health condition of the participants will be retrieved for a longer period of time, so that researchers can embark on examining the interaction between gene and environment (including life habit, food, behavior and occupation etc) for the cause of common chronic diseases, which is beneficial to the further study in finding the solutions to improve the condition of preventing, diagnosing and treating these diseases.

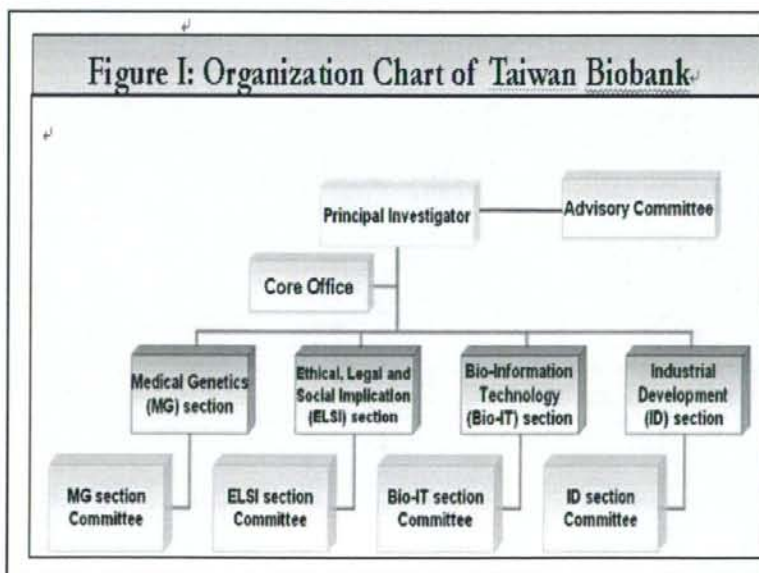
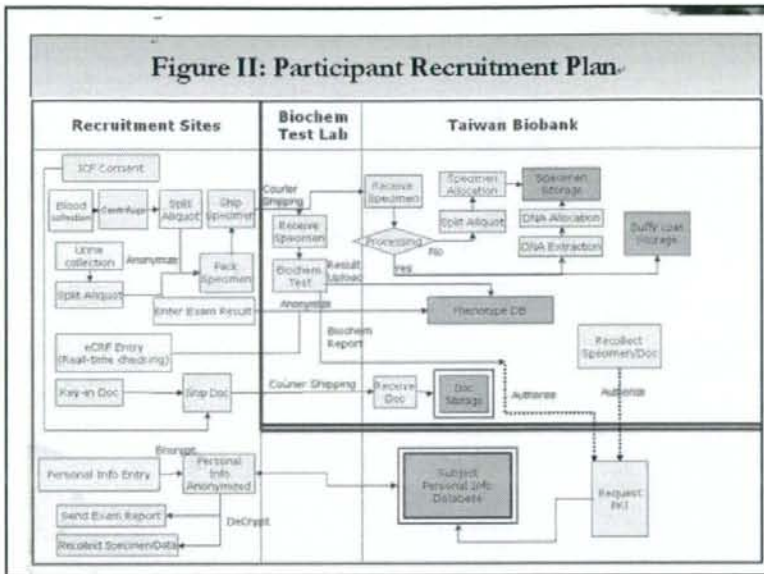
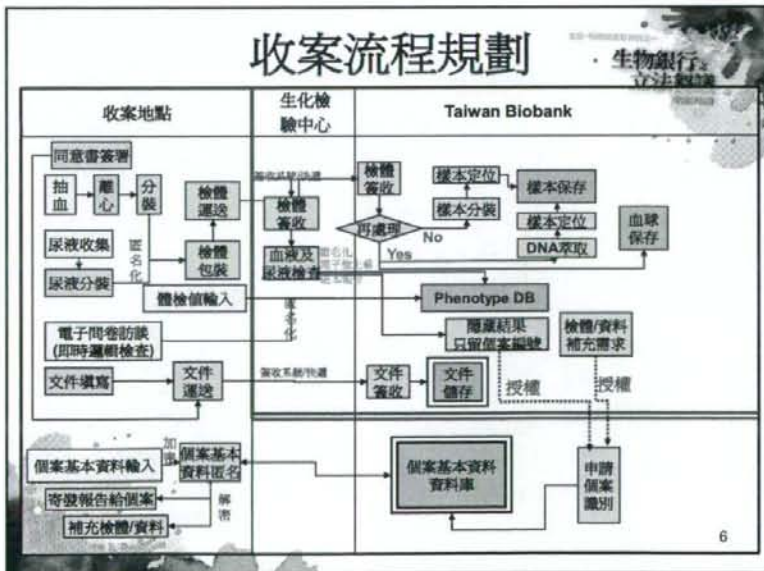


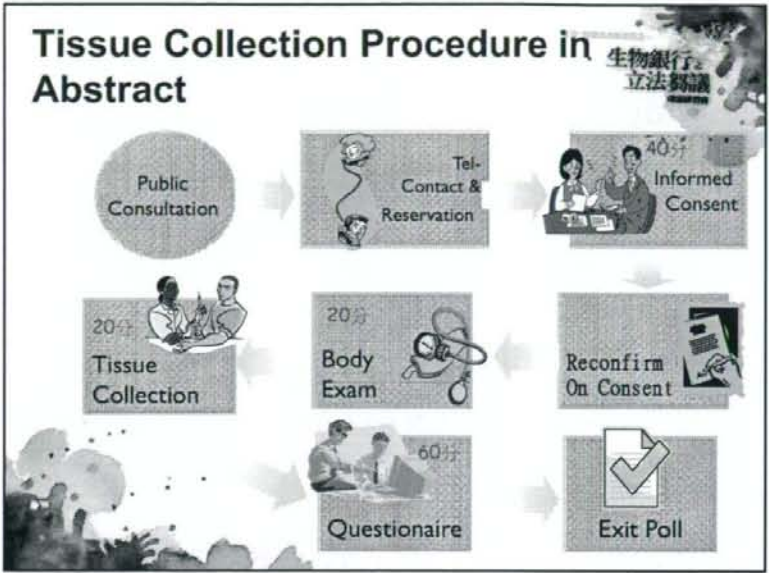
Figure II: Participant Recruitment Plan.



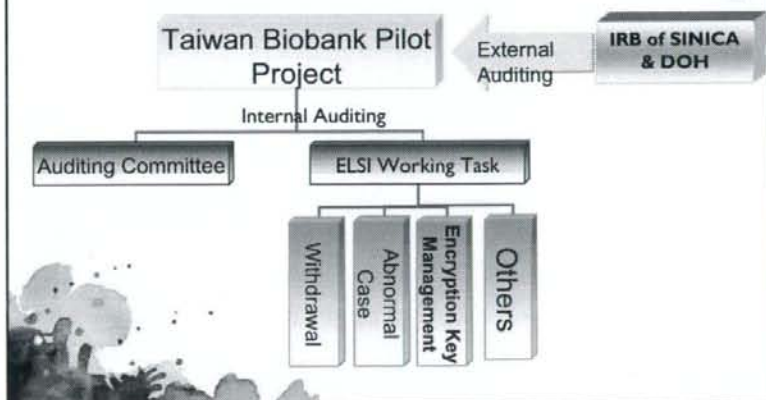
收案流程規劃

生物銀行
立法建議





Auditing Framework & Working Task



ELSI & Public Trust Building

