

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.	11.85	11.16	0.79	
male	mean	0.58	0.57	0.00	
	s.d.	0.48	0.48	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	1.26	0.06	
willing to participate in the future	mean	0.80	0.58	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.	0.16	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.

23

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.



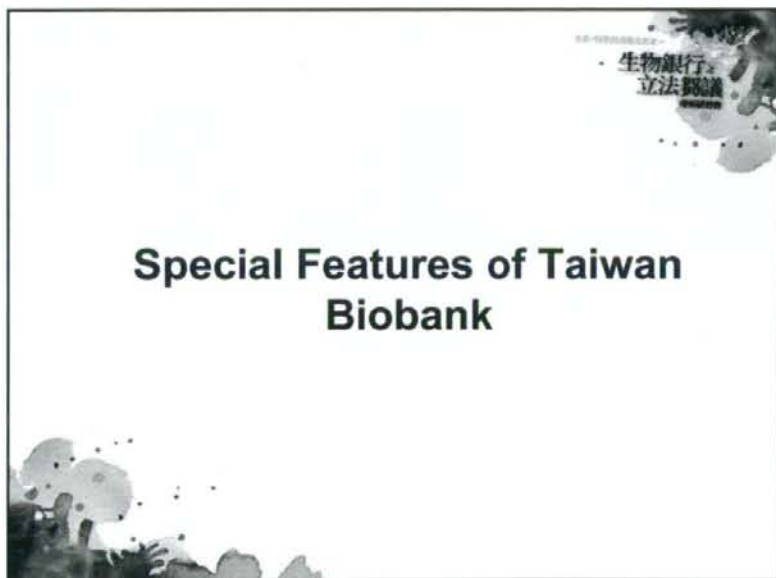
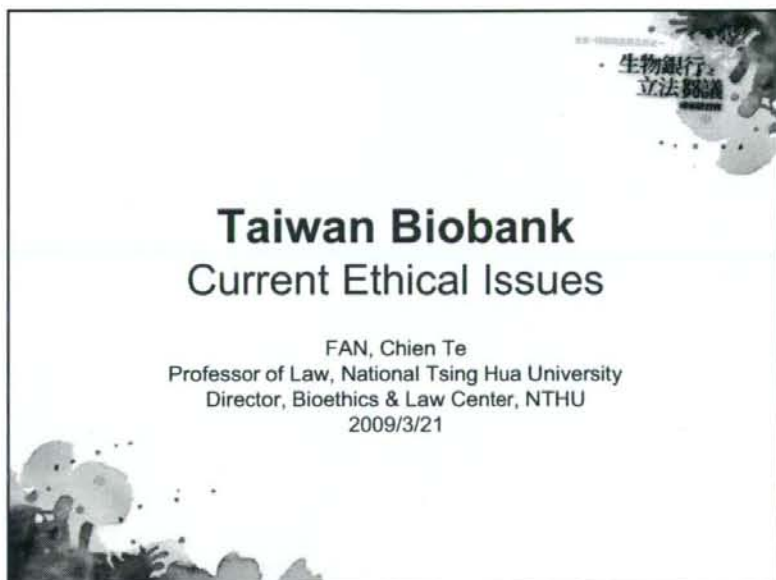
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Conclusion

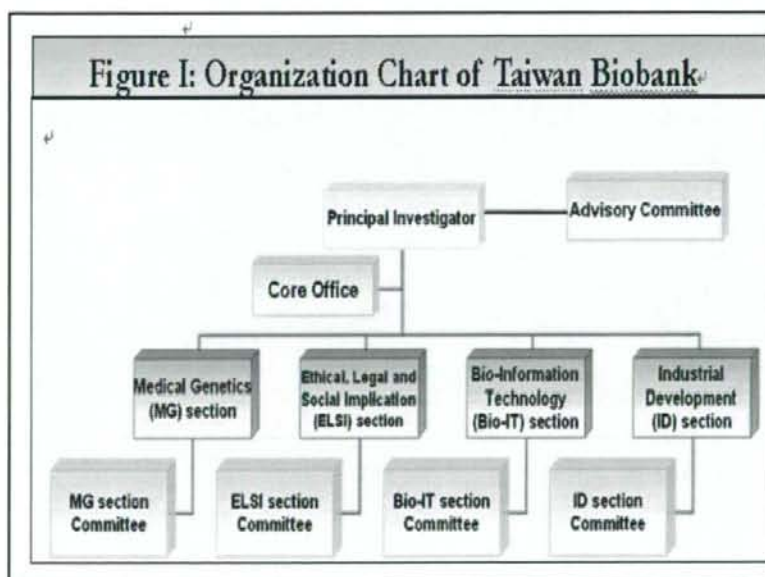
- Triendl and Gottweis's paper is almost correct.
- But, some critiques have been improved in BBJP2: transparency, openness and public dialogue

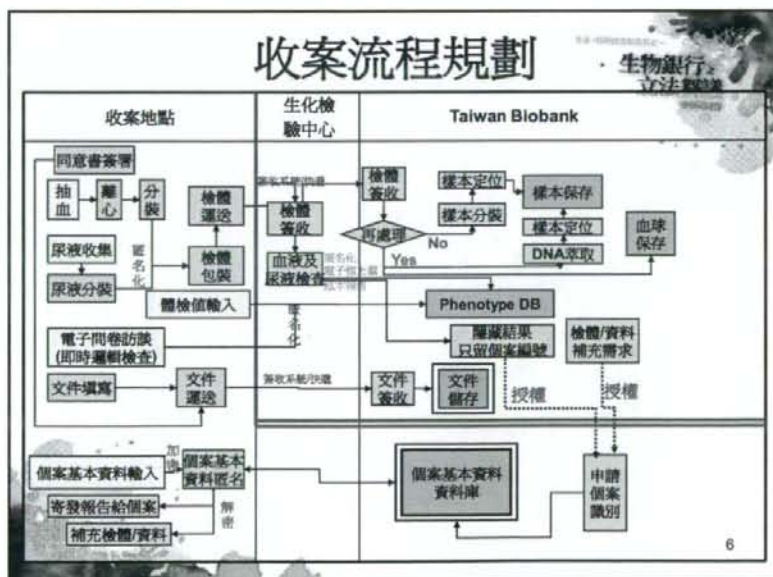
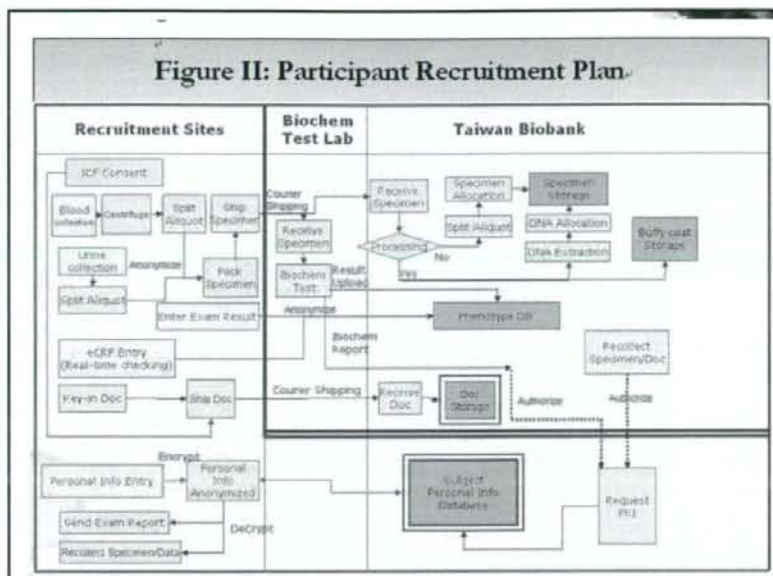
- How has the recession affected biobanks worldwide?

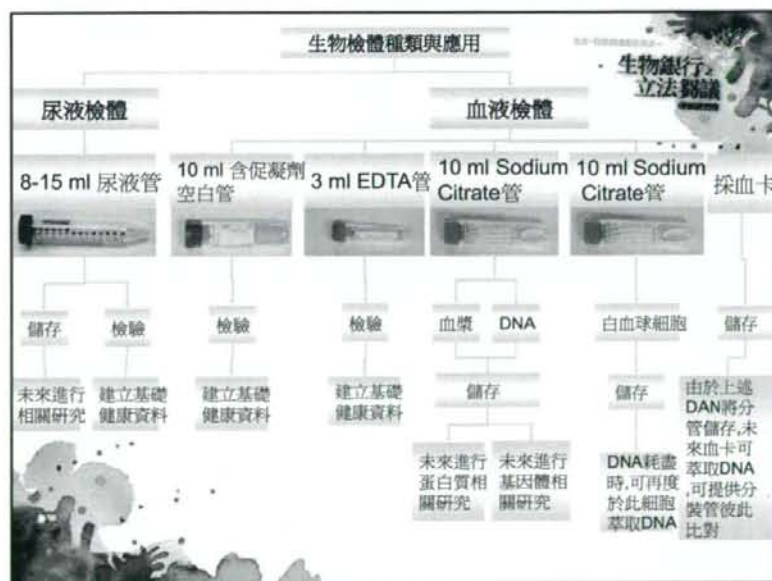


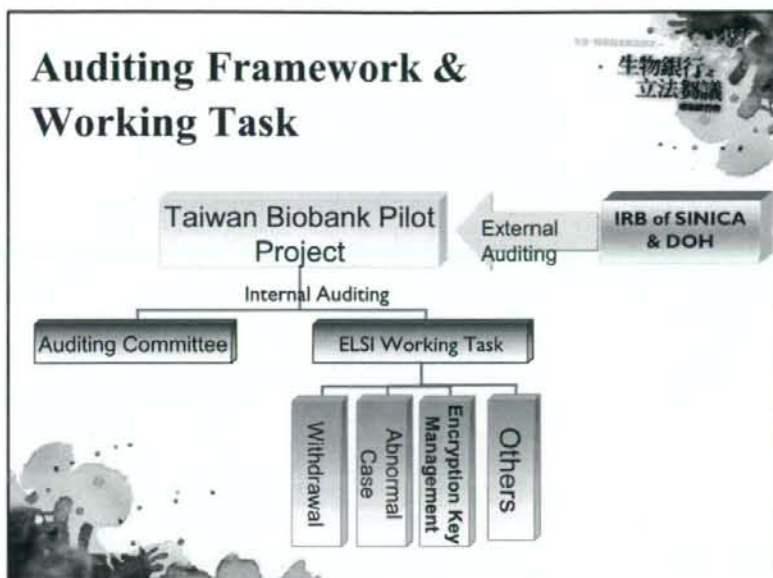


1. The participants will be recruited on the voluntary basis.
2. There are three collection sites evenly allocated in northern, southern and eastern Taiwan.
3. The participants are people of the age between 30 with no gender restriction.
4. People of foreign nationality, foreign ancestry and/or diagnosed 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.









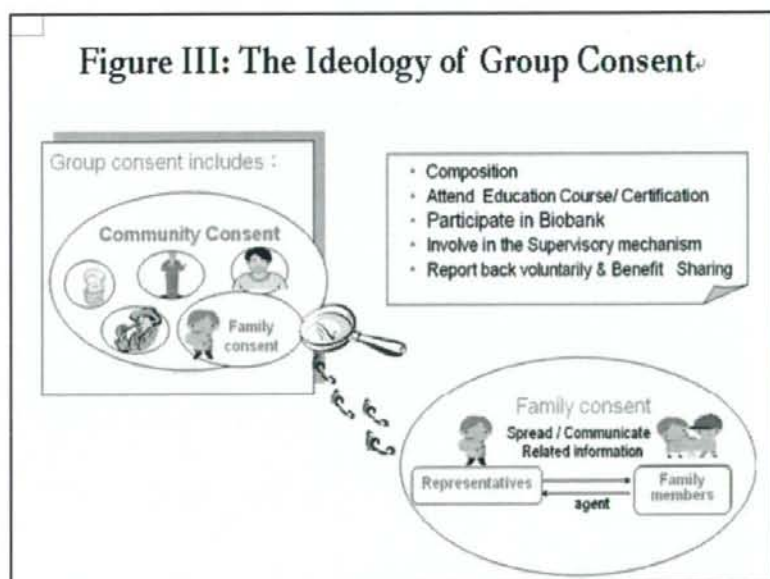
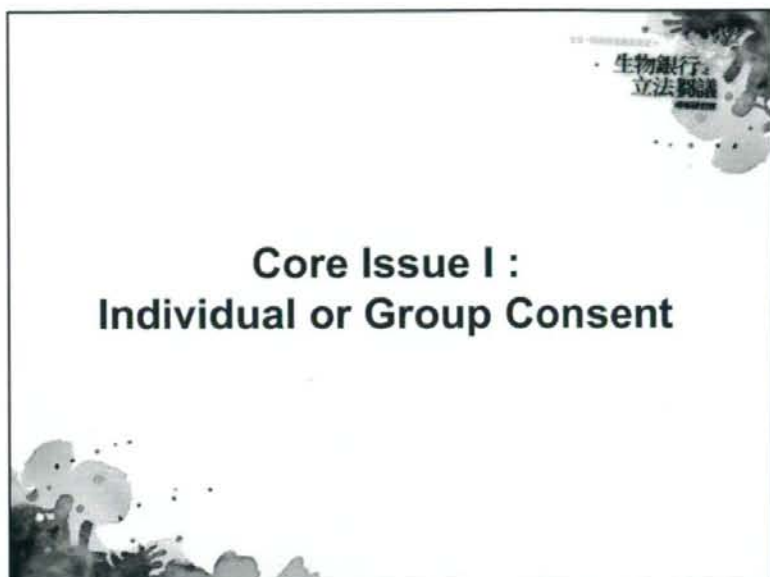
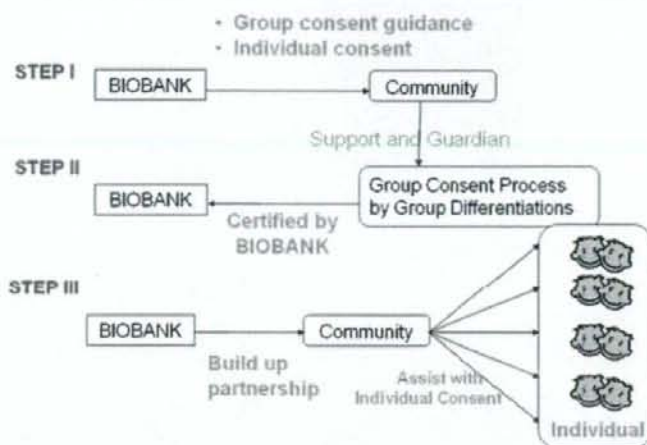
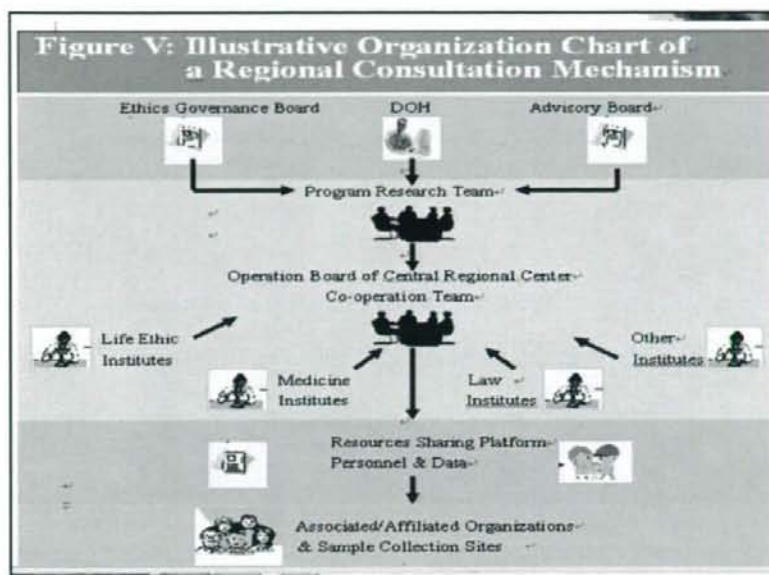


Figure IV Group Consent Process

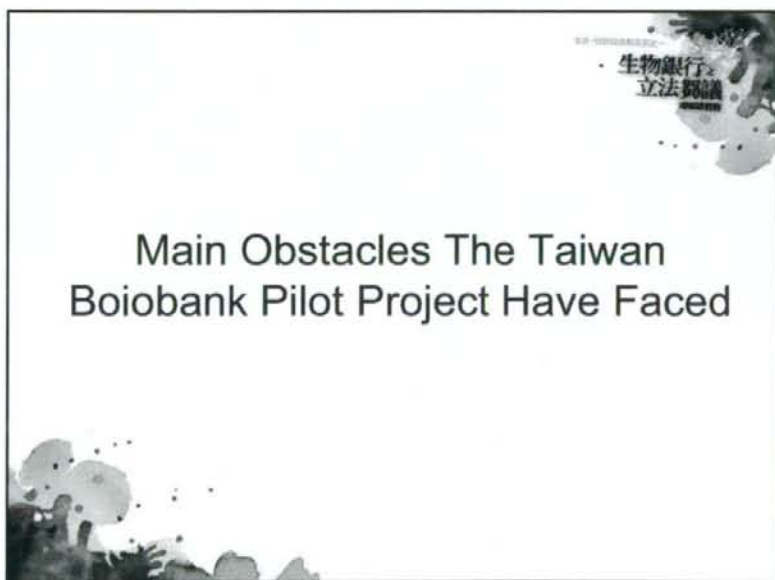


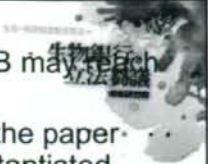
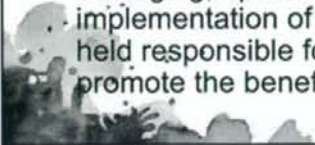
生物銀行
立法討論

Core Issue II:
Information Asymmetry



Core Issue III: Aboriginal People's Participation



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- 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.
 - ELSI 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.
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Solutions Admitted by IRB at the End of 2008



Approval of Experimental Tissue Collection

- 以IRB既有的附條件同意為基礎，以期限及檢體採集數量的雙門檻為限，在IRB確認的程序下，在目前人員訓練及設備均較為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。
- 以此試行經驗作為未來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

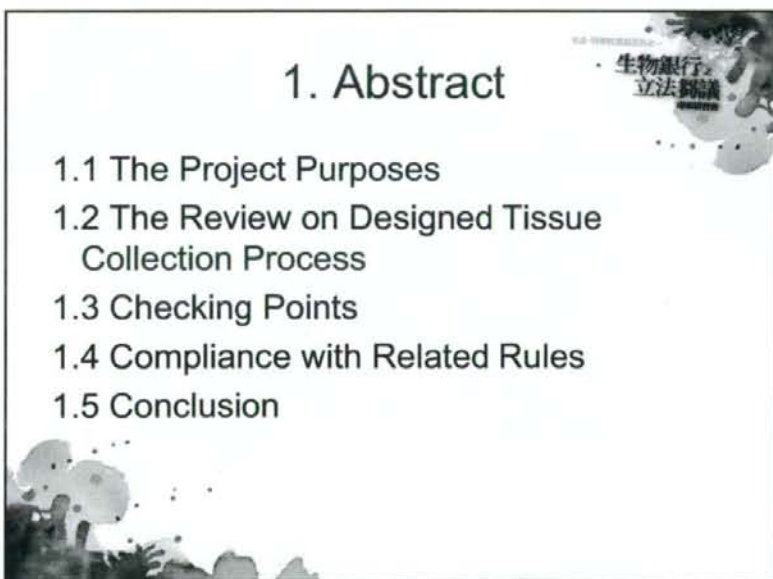
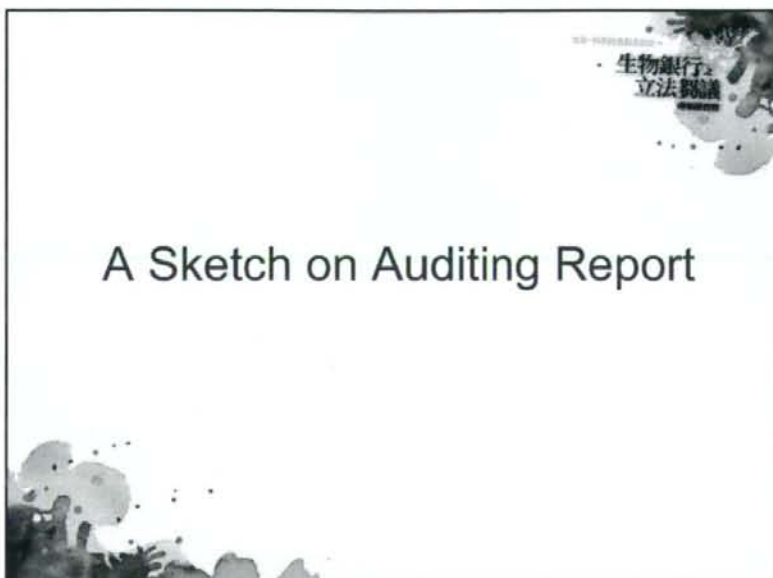
- EGC顯為當前各方認為具獨立性，而較能為社會信任的倫理治理機構，也是本計劃倫理治理規範及管理條例(草案)所要求設置者，應加速其建置。
- 惟一般的期待往往與現實有間，蓋我國的Biobank仍處研究計劃階段，實際上應以執行單位之IRB為倫理治理單位為是；為避免EGC成立後與IRB之分際混淆，建議EGC的設置應配合後述籌備處的設計，使之成為籌備處的獨立監理單位，真正擁有制度化的法律地位；並有別於原研究計劃的IRB。

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。



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.

