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ARTICLES

Examining the Protection of Group's Interest under Taiwan's Human Biobank Management Act*

LIN JUI-CHU AND LIAO CHIA-CHENG

Background

A Brief Review of the Disputed Cases

The Collection of Aboriginal People's Salvia

In 2007, Dr. Marie Lin, together with the Mackay Memorial Hospital, was accused of violation of research ethics for collecting saliva samples from the Kebalan tribe. According to the Association of Kebalan Development, Dr. Lin collected saliva samples from 29 Kebalan people without completely informing the underlying purpose of research use. Despite Dr. Lin's and Mackay Memorial Hospital's response that consent was sought from the group leader and individual through tribal group meetings, they were still subject to ethical discipline for not duly disclosing their research purpose to the tribal meeting when collecting samples from the aboriginal people.[1]

The Uninformed Commercial Use of Research Outcome[2]

In 2010, Prof. Ying-Chin Ko was accused of violating research ethics for patenting his research outcome without prior consent from the Tayal tribe. By collecting blood samples from 1,500 aboriginal people, Prof. Ko was able to identify and locate the gene sequence that causes gout disposition. The

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alleged misconduct was that when seeking consent, Prof. Ko did not clearly advise the tribal group of the purpose to commercialise the result of the research in the future. After further investigation, Prof. Ko admitted that the filing of application for U.S. patent proceeded without prior knowledge and consent from the tribal group, and promised that if there would be any commercial profit derived from the research, it would belong to the aboriginal people. Also, Prof. Ko promised he would withdraw the patent application.

EGC's Resolution to Destroy the Collected Samples

Considering the importance of group interest and the compliance with the relevant laws, the Ethical Governance Committee (the "EGC") of the Pilot Study of Taiwan Biobank recently resolved that the research team must abide by the Aboriginal People's Fundamental Law (the "Fundamental Law") before beginning to collect samples in the area of tribal group. Pursuant to the requirement in the Fundamental Law, to collect samples from the aboriginal people, the research team must first call a tribe meeting with the targeted group members. Furthermore, as to the samples that have been collected to date, if there is any sample collected from aboriginals without full compliance with the requirement of the Fundamental Law, such samples must be destroyed under the supervision of EGC members.

Issues and Questions

Not only do the aforesaid cases heighten the tension between the research subject and researcher, the underlying disputes also trigger a wave of reflections on the topics of behavioural norm with respect to biomedical research. Despite the fact that all the preceding cases involved some degree of the informed consent process, sadly, none of them seemed to be satisfying. Furthermore, as held by the resolution of EGC, under some circumstances, consent may not only need to be sought at the individual level, but at the group level as well. So the question is: why is individual consent not enough? Especially, when a researcher targets aboriginal people, why must the consent be sought from the tribal group? Moreover, apart from research involving aboriginal people, is there any other occasion which requires a same or similar protection of group interest?

The above questions became more interesting after Taiwan's legislators passed the "Human Biobank Management Act" (the "Act"), which aims to regulate the establishment of a biobank, and ensure the protection of participants' interests.[3] According to the Act, the biobank is defined as for the purpose of biomedical research, the biobank contains participants' biological specimens,

natural persons' information and other related data and information based on human population or specific groups.[4] In a similar vein, one may further ask: in the context of biobank research, is it sufficient to seek consent at the individual level only? What is the Act's view?

This article intends to examine the abovementioned cases through the light of the newly enacted Act. Taking the disputed facts as background material, this article intends to clarify some ambiguities and disputes in the Act, and to provide a deeper insight in the construction and application of the Act.

Discussion of Group Consent

Before exploring the issue of group consent, it is necessary to revisit the origin and ethical base of the principle of informed consent. By having a clearer picture of the doctrine's mete and boundary, we can have a deeper understanding of its limit and scope, and therefore know the reason why we need group consent.

The Principle of Informed Consent in the Context of Biobank Research

The principle of informed consent in human trial was first raised by the Nuremberg Declaration,[5] which did not specifically outline an overall model for human trials but has embodied some necessary requirements of this principle and laid the foundation for the follow-up ethical development.[6] With the efforts made by related scholars and activists in many countries, the principle has gained wide recognition. In 1979, the content of the informed consent doctrine was further codified in the famous Belmont report,[7] and was widely accepted and applied by European and American countries.

The aim of informed consent is to protect and ensure the respect of the human subject's autonomy.[8] According to this doctrine, physicians or doctors are required to advise the trial subject the nature of the experimentation, its potential risk and benefit, and its possible result. The idea behind this doctrine is that because the trial subject has insufficient information or knowledge to evaluate all the potential risks and interests, the doctrine requires a physician or doctor to inform the trial subject of the relevant information,[9] to make sure the trial subject can make an autonomous decision. Through the informed consent process, trial subjects will be in a better position to evaluate the potential harm and benefits, and thus his autonomy in making such decisions is warranted and respected.

In Taiwan, it has been emphasised by the government agency that collecting human tissue for research use requires that one obtains prior informed consent from the tissue provider.[10] After the enactment of the Act, it is statutorily affirmed that there is a "legal" duty to acquire participant's prior informed consent before collecting any human tissue, no matter if such collection is for establishing a population-based biobank or for other biomedical research use.[11] Any violation of such duty may be subject to a fine up to 2.5 million (when the collection is aiming at building a biobank)[12] or 1 million New Taiwan Dollars.[13]

The Limit of Individual Consent

Basically, the ethical basis of informed consent is to respect the independent choice made by an individual based upon his/her own interest. In other words, the respect and requirement of informed consent is somewhat based upon individualism.[14] However, individual autonomy shall be put into social context, and sometimes the cultural difference should be taken into account. When one's decision will have substantial impact upon another's interest or welfare, such as other group member's interest, the validity of one's individual consent may come under doubt.[15,16] As biobank research may create a serious and profound impact on both the participant and participant's group or family, the appropriateness of individual consent has been called into question.[17]

Group Interest Involved in Biobanking

Generally, concerns of group interest involved in a biobank may be invoked under the following two contexts:

1) When genetic information is sought from one person and such genetic information is shared among a group of people.[18,19] Because of the unique feature of genes, research conducted on one group member may reveal the health condition of another who happened to own similar or common genetic characteristics. For example, assume a researcher successfully located the mutations of gene that might cause increased risk of breast cancer, and was able to identify such mutation in women of a specific descent. The publication of such findings may have exposed women of this descent to discrimination in the employment and insurance markets.[20]
2) When genetic information is sought from a group of people who shared common value and culture, and have developed a decision-making process, such as the aboriginal people.[21] Under such a context, it is not because

genetic information is sought, but because whether to participate in such genetic research is a decision that should be discussed and made by the group as a whole, instead of being decided by one or two persons.

Given the fact that the outcome of genetic research may have a profound and potential impact at both the individual and group levels, some argue that there must be a mechanism, such as group consent, to make sure that human dignity is respected.[22]

However, before jumping to the concept of group consent, we shall first examine the definition of a group, i.e., what constitutes a group that calls for requirement of group consent.

The Definition of Group and Group Consent

Despite of the importance of group consent, the definition of "group" in the context of biobank research is not clear. According to the degree of complexity and sophistication, a group may be defined as: 1) people with a common interest; or 2) people with not only a common interest, but also with shared collective structure, including a common history, way of life, and/or living in a common geographical area; or 3) people with not only a common interest, and shared group structure, but who also share the same decision-making process or authority. [23]

We may note that the tightness and structure of a group may vary,[24] which increases the difficulty in deciding when the requirement of group consent will be invoked.[25] Some hold the view that the shared nature of genetic information can itself justify the need for group consent.[26] Some hold another view that group consent is required only when a group of participants in research may potentially be affected by the results of that study.[27] Still, others hold that group consent is needed only when the group can be clearly labelled and will face discrimination or stigmatisation as a result of the research.[28,29]

Likewise, the purpose and function of group consent may be different as well, depending on the tightness and structure of a group.[30] 1) As to a group who has shared culture, history, or way of life, and has developed some sort of decision-making authority, the expression of group consent reflect these groups' traditional norms, historical or cultural views.[31] Group consent under this context reflects strong image of group identity, and requires due respect to group autonomy. 2) As to a group who only has some sorts of shared interests, the expression of group consent may not necessarily reflect the group identity or shared culture, but instead be the cumulative consent of every

individual's own personal interest.[32] Group consent under this context may serve to prevent future disputes arising from potential conflicts between individual interests, and enhance the ethical ground of individual consent. 3) As to a group who not only has a shared interest, but also has detectable group structure, such as a common culture/history/way of living, group consent under this context may play a diverse role, which includes: facilitating the discussion within the group, promoting the understanding to the potential impact, balancing the asymmetry between target group and researcher, and further enhancing the appropriateness of individual consent.[33]

Therefore, it seems inevitable that whether and how to protect specific group interest will require a case-by-case judgement. To this end, a flexible and dynamic framework would be helpful.

Short Conclusion

After the above discussion, some observations may be concluded as follows: first, a less rigid ethical base for group consent is ideal. The difficulty in defining the scope and type of group renders a one-size-fits-all theory less suitable to support the development of a diverse framework for group consent in practice.

Second, because there is a variety of circumstances that may justify the requirement of group consent, we should note that group consent is not a topic that only arises from the context of indigenous people. What is important is to analyse the structure and constitution of the group, not simply trying to define if the group in question is an aboriginal group.

Third, to be feasible and practical, the focus of group consent has somewhat shifted, and its content is enriched. Researchers now focus on how to facilitate group discussion and involvement. Various approaches, including community consultation, community engagement, group meeting, collaborative research, etc., have been developed. What is essential is how, to the maximum, to promote group discussion and involvement. As a result, various terms are used in this respect, because the researcher's ultimate goal is no longer limited to seek rigid "consent" only, but to seek substantial group involvement and to build trust.

Fourth, the steps taken to get group involvement may be varied. As a regulatory strategy, a loose framework is helpful and more feasible because there must be flexibility reserved for the further adjustment or refinement.

With these background understandings in mind, we now take a deeper look into the attitude shown in the newly enacted Act.

The Attitude of the Act Regarding Group Consent

The View from the Scholarly Opinion

In Taiwan, there is strong urge to protect group interest involved in building a population-based biobank.[34] Among these opinions, some hold a strong view that without recognition and consensus on the protocol of group consent, researchers shall be prohibited from building a biobank;[35] while some others hold the view that although group consent is important, more discussion is required to clarify its relationship with individual consent, and for the approach to be adopted to fulfil group consent.[36] However, in the Taiwan Biobank Ethics Governance Framework, it is provided that the requirement of group consent is not to replace the requirement of individual consent; rather, it is a mechanism to promote the respect of individual interest, and to prevent potential conflicts between the individual and group.[37] In the Pilot Study of Taiwan Biobank, it is stated that group consent is a supplemental approach to protect individual participants from exploitation.[38]

The Passage of Administrative Acts Governing Human Biobank Management (the "Act")

Pursuant to Article 6 of the newly enacted Act, prior and explicit informed consent is required before the collection of biological specimens for biobank research.[39] Article 7 of the same further provides the information that shall be advised;[40] among them, one example is "possible impacts of the genetic information derived from the biological specimens on the participant, and his/her relatives or an ethnic group".

At first glance, it is unclear whether Taiwan's legislator has noticed the necessity of group consent during the stipulation of the Act. Under the literal meaning of the statute, it seems that a researcher is required to seek consent from an individual only. The legislator seems to be satisfied as long as the participant is advised of the potential impact to his family or ethnic group. Literally speaking, the Act leaves a great gap regarding the protection of group interest, and thus group consent seemed to be unnecessary.

Some also hold the view that because there is no clear guidance given by the legislator, it would be inappropriate to recognise the existence of group consent,[41] and the establishment of a biobank may be based on individual consent only. For reasons explained in the next section, this article holds a different point of view.

Re-Construing the Meaning of Consent

As previously discussed, the collection of sample and data for a genetic bio-bank is a process that involves both individual and group interest. Thus, besides individual consent, the researcher should also notice if it is necessary to further inquire for group consent or take steps to protect group interest. As shown in the disputed cases, the lack of communication with group members or group authority may not only invalidate individual consent, but also render the whole research activity unethical or illegal.[42]

When construing the intent of the legislator, we should also bear in mind that sometimes it would be difficult and time consuming to identify a group, and the method to obtain group consent. The relevant process may involve a long investigation or burdensome inquiry. Hence, it is unavoidable that the requirement of group consent should be decided case by case, and discretion and flexibility should be reserved for the researcher, group member, and the ethic review entity. Based upon such understanding, a loose and broad statutory language is reasonable and inevitable, because it reserves more flexibility and possibility for different cases. To the contrary, it may be inappropriate to arbitrarily conclude that there is no requirement for group consent simply because the statutory language in the Act is loose and soft.

Such a conclusion is also supported by a systematic construction of the current legal regime. Despite the fact that there is no specific language in the Act, by taking a further look into other aspects of law in Taiwan, we can observe that similar rationale for protecting group interest has been shown in other statutes. For example, the Fundamental Law recognises the legal status of a tribal group, and thus confers certain degree of group autonomy in the form of decision authority.[43] When a researcher intends to conduct research activity in the land of aboriginal people, then, according to the Fundamental Law, the researcher must obtain approval from the tribal group.[44] As such, it should be undisputed that when there is noticeable cultural difference or shared nature presented, the legislator has recognised the need to protect group interest and ensure group involvement.

Besides, as stated above, the concept of a group may involve a wide range of group structures that called for specific protection, and the function and purpose of group consent may be different as well. It would be improper to try to address all these types of group interests by applying only one single model. To this end, the soft language adopted by the legislator in the Act seems to be reasonable. Requiring the legislator to lay out a detailed and feasible scheme for group consent would be extremely difficult. From this point of view, the approach held by the Act is not only acceptable, but is also reasonable.

For the aforesaid reasons, this article argues that the statutory requirement in the Act is only the starting point for seeking group consent and ensuring group involvement. Such initial inquiry aims to assess the background of a participant and to detect if there is any substantial group interest involved. By informing the potential impact on participant's group and family, the potential concern about group consent may be disclosed, thus triggering further steps to be taken.

How to Fill the Gap

Although a loose and soft framework is acceptable, questions regarding feasibility still remain unsolved. Basically, under current circumstances, except research involving aboriginal people,[45] whether to adopt group consent depends on the self-discipline of the researcher and supervision of ethics review institution.[46] To fill the gap between the norm and the practice, this article suggests the following.

First, the method and approach of group consent are diverse and complex. As a regulatory strategy, it would be better to let the researchers, ethics committee, and the interested parties work out the most suitable approach. To this respect, a model or principled guidelines issued by government branch, such as Department of Health, would be helpful as guidance for follow-up development.

Second, the formation of standard criteria and behavioural norms requires the accumulation of case materials and experience. Therefore, it may be more ideal to have a pilot study to assess the potential risk and obstacle, and to establish model protocol for follow-up study and refinement.[47]

Third, there are various groups that may invoke the requirement group consent. When research targets family, region community, or members of rare diseases, the group consent process may be necessary as well. Therefore, the focus is to get the entire community or group involved, not simply to obtain a formal consent.

Conclusion

After nearly 20 years, the importance of group consent has been widely acknowledged.[48] Through the effort and promotion of various activists and scholars, the importance of group consent has been well-established in Taiwan society. However, there are also some disputes and ambiguities left regarding its substance and process.

By reviewing the origin of group consent and examining the grounds of group consent, this article attempts to clarify the understanding to group

consent, and to build the bedrock to construe and apply such ethical norms under the context of the Act. To properly understand the flesh and bone of group consent and to apply such ethical norms, we shall be cautious and avoid making sudden and rushed moves. Otherwise, before obtaining group consent, we may inadvertently injure other related interests, such as individual autonomy.

As supra discussion, we may conclude that the concept of group consent has many perspectives and diversified meanings. Therefore, rather than having the legislator pass another law to provide clearer guidance, what is more important is to have more discussion and to involve more voices and perspectives into the formation of requirement of group consent. After all, the very purpose of group consent is to show our reflection on individualism and respect to cultural difference, not another legalese or slogan that is based upon pure legal vacuum.

Notes

1. Further detailed information about the dispute is available at http://www.abohome.org.tw/index.php?option=com_content&view=article&id=1792%22 [accessed 8 August 2011].
2. The related news report is available at http://www.abohome.org.tw/index.php?option=com_content&view=article&id=4580:2010-03-22-03-41-04&catid=73:2008-10-22-22-16-20&Itemid=132 [accessed 8 August 2011].
3. See Article 1 of the *Human Biobank Management Act*.
4. See Article 3, subparagraph 4 of the *Human Biobank Management Act*.
5. See Article 1 of Nuremberg Code, available at http://ohsr.od.nih.gov/guidelines/nuremberg.html [accessed 8 August 2011].
6. For example, the announcement of *Declaration of Helsinki* by the World Medical Association. Available at http://www.wma.net/en/30publications/10policies/b3/ [accessed 10 August 2011].
7. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979), available at http://ohsr.od.nih.gov/guidelines/belmont.html [accessed 10 August 2011].
8. Autonomy is perceived as a person's ability to make his own decision after weighing the pros and cons of the decision he is about to make. See *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Part C.
9. According to Belmont Report, this information generally includes: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.
10. See the Department of Health's *Guidelines for Collecting and Using Human Tissue For Research Use* (2006), and the *Ethics Guidance on Human Research* (2007). Available at

http://dohlaw.doh.gov.tw/Chi/FLAW/FLAWDAT0202.asp and http://www.doh.gov.tw/CHT2006/DM/DM2_p01.aspx?class_no=1&now_fod_list_no=4352&level_no=2&doc_no=50438 [accessed 10 August 2011]. See also C.-T. Fan and C.-C. Liao (2008) A Study on the Legal & Ethical Planning of a Population-Based Genetic Database Establishment in Taiwan, *Taipei University Law Review*, **68**, 95–149; J.-C. Lin and Z.-X. Liang (2009) A Study on the Informed Consent Principle and the Biobank — Taking Taiwan Biobank as Instance, *Chung Yuan Christian University Law Review*, **23**, 1–36.

11. See Article 6, 7, and 29 of the *Human Biobank Management Act*.
12. See subparagraph 2 of paragraph 1 of article 24 of the *Human Biobank Management Act*.
13. See paragraph 2 of article 25 of the *Human Biobank Management Act*.
14. See World Health Organization (2007) Ethical Challenges in Study Design and Informed Consent for Health Research in Resource-Poor Setting, available at http://apps.who.int/tdr/publications/tdr-research-publications/ethical-challenges-study-design/pdf/ethical_challenges.pdf [accessed 5 August 2011].
15. See A. Ganguli-Mitra (2008) Collective Consent, *Ethical Issues in Governing Biobanks: Global Perspectives*, ed. B. Elger, N. Biller-Andorno, A. Mauron, and A.M. Capron, Ashgate, Farnham, UK, 121–31, at 121.
16. See World Health Organization, note 14 above, at 27. See also the *National Statement on Ethical Conduct in Human Research* (2007), s 2, ch 2.2, Guidelines 2.2.13, which reads: "Within some communities, decisions about participation in research may involve not only individuals but also properly interested parties such as formally constituted bodies, institutions, families or community elders. Researchers need to engage with all properly interested parties in planning the research". Available at http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72.pdf [accessed 8 August 2011].
17. See C. Blohm and J. Simon (2008) Group Consent in Population Based Research, *International Journal of Bioethics*, **19 (3)**, 49–67.
18. Due to the biological feature of gene, the result of a specific genetic research or tests may have a strong impact on family members. For example, when conducting genetic testing among family members, some may show concerns over the potential impact of the results of tests upon other family members, and some participants' motivation may be to help other family members, or be influenced by other family members' needs. See N. Hallowell (2009) Consent to Genetic Testing: a Family Affair?, *The Limits of Consent: A Socio-Ethical Approach to Human Subject Research in Medicine*, ed. O. Corrigan, J. McMillan, K. Liddell, M. Richards, and C. Weijer, Oxford University Press, Oxford, 185–95, at 189.
19. Similar situations may also occur during genetic research targeting groups with a specific disease. See B. Schrag (2006) Research with Groups: Group Rights, Group Consent, and Collaborative Research Commentary on Protecting the Navajo People through Tribal Regulation of Research, *Science and Engineering Ethics*, **12**, 511–21, at 512.
20. Ibid., 512.
21. Under such circumstance, "to enter a community you need to carry that community along with you. There are imperatives … [You must communicate] with the Chief and his council and some others leaders from the community. The individualism that exists in the West does not exist here". See World Health Organization, note 14 above, at 28.

See also Human Genome Diversity Project, *Model Ethical Protocol* (1997), available at http://hsblogs.stanford.edu/morrison/files/2011/03/model-ethical-protocol.pdf [accessed 10 August 2011].

22. See C. Blohm and J. Simon, note 17 above, at 56.
23. See B. Schrag, note 19 above, at 515. See also World Health Organization, note 14 above, at 28. One should also note that when speaking of issues of group or group consent, various terms are used. For example, some use "community/community engagement", some use "group/group consent", still others use community permission or agreement. See C. Blohm and J. Simon, note 17 above, at 50.
24. A discussion of different moral weight of group consent, see B. Schrag, note 19 above, at 517.
25. See A. Ganguli-Mitra, note 15 above, at 126.
26. Ibid.
27. Ibid.
28. Ibid.
29. When seeking consent for participation from member of a specific or rare disease, especially disease triggered by malfunction of genes, there may be concerns if only individual consent is acquired, and no contact or explanation is made to other group members. Under such circumstances, the research outcome may affect the welfare of those who did not attend the research. For example, the testing of African Americans for sickle cell anaemia reportedly led major airlines to the grounding or firing of employees who tested positive for sickle cell anaemia and led Dupont Corporation to restrict workloads of employees who tested positive. See B. Schrag, note 19 above, at 512.
30. See B. Schrag, note 19 above, at 516.
31. See B. Schrag, note 19 above, at 516–7. See also See C. Blohm and J. Simon, note 17 above, at 49.
32. See B. Schrag, note 19 above, at 516–7.
33. See World Health Organization, note 14 above, at 28. See also J.G. Allen (2009) Group Consent and the Nature of Group Belonging: Genomics, Race, and Indigenous Rights, *Journal of Law, Information and Science*, **20** (**2**), 29–66, at 41.
34. For example, see M.-L. Lin (2007) The Establishment of a Population-Based Biobank — Review on the Principle of Informed Consent, *Central Police University Law Review*, **12**, 1–48. D.-J. Cai (2007) A Guiding Suggestion to the Ethical, Legal, and Social Implications of Taiwan Biobank on the Base of Community, *Taiwan Journal of Biomedical Ethics and Social Welfare*, **1**, 9–23. S.-Y. Yan, G.-X. Chen, and S.-M. Tang (2005) Informed Consent in UK Biobank, *Tsing Hua Journal of Law and Technology Policy*, **2**(**2**), 189–224.
35. The discussion between individual and group consent, see C.-C. Ho (2008) An Ethical, Social, and Legal Research of the Issues of Taiwan Biobank: Review and Policy Analysis, *Taiwan Journal of Law and Technology Policy*, **5** (7), 119–66, at 150.
36. Ibid.
37. See C.-T. Fan, J.-C. Lin, and C.-His Lee (2008) Taiwan Biobank: A Project Aiming to Aid Taiwan's Transition into a Biomedical Island, *Pharmacogenomics*, **9** (**2**), 235–46, at 243.
38. See the Protocol of Pilot Study of Taiwan Biobank. Available at http://www.twbiobank.org.tw/DOH_Pilot1/document/implement.pdf [accessed 10 August 2011].

39. See Paragraph 1 of Article 6 of the *Human Biobank Management Act*.
40. The Information that shall be advised are as follows: "(1) The legal authorities and their contents governing the establishment of the Biobank; (2) The identity of the Biobank Operator; (3) Information regarding the identity and the service unit of the biological specimen collectors; (4) The reasons why a particular participant was selected; (5) The rights and direct benefits to which the participant is entitled pursuant to these Administrative Human Biobank Management Acts; (6) The purposes of collection and the range and duration of the use of the collected biological specimens, collection methods, types and quantities of specimens to be collected, and regions where specimens are collected; (7) Any complications and hazards that might possibly occur during and as a result of the collection(s); (8) Any possible impacts of the genetic information derived from the biological specimens on the participant, and his/her relatives or an ethnic group; (9) Any reasonable risks or inconvenience which the participant may anticipate; (10) The rights which are excluded by these Administrative Human Biobank Management Acts; (11) The mechanism designed to safeguard personal privacy and other rights and benefits of the participant; (12) The Operator's organizzational structure and operating principles; (13) Specific type of health information of the participant that is expected to be linked in the future; (14) Relevant Human Biobank Management Acts governing the applications of the Biobank; (15) Anticipated commercial applications; (16) The participant may choose whether upon his/her death or incapacity, his/her biological specimens and related data and information will continue to be stored and used; (17) Other important matters related to the Biobank."
41. C.-C. Ho, note 35 above, at 151.
42. Such as in Prof. Ko's case.
43. See Article 21 of the *Aboriginal People's Fundamental Law*. See also J.-C. Lin and Z.-X. Liang (2008) Group Consent in the Genetic Research Involving Aboriginal People, *Taiwan Journal of Law and Technology Policy*, **5 (1)**, 87–118; C.-H. Lee (2007) The Ethical and Regulatory Framework for Genetic Research on Indigenous Peoples: A Preliminary Analysis, *National Taiwan University Law Review*, **36 (3)**, 465–518.
44. Under Article 21 of the *Aboriginal People's Fundamental Law*, when a researcher intends to conduct research activity in the land of aboriginal people, then according to the Fundamental Law, the researcher must obtain approval from the tribal group.
45. Some hold the view that the *Aboriginal People's Fundamental Law* does not adopt group consent, due to the poor statutory language and lack of clear guidance on how to enforce the requirement. See C.-C. Ho, note 35 above, at 151–2. For a different view, see J.-C. Lin and Z.-X. Liang, note 43 above.
46. See C.-C. Ho, note 35 above, at 153. See also Z.-L.Chen (2008) Comment on the Draft of Taiwan Biobank Act, *The Journal of Law and Bioscience*, **5**, 23–33, at 28.
47. For example, in the Pilot Study, the research team planned to build three to four model communities to promote the concept and framework of group consent. See http://biobankforum.blogspot.com/2009/06/36.html [accessed 10 August 2011]. For the development strategy of group consent under the framework of the constitution and the *Aboriginal People's Fundamental Law*, see J.-C. Lin and Z.-X. Liang, note 43 above, at 117–8.
48. See A. Ganguli-Mitra, note 15 above, at 122–3.