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**Deliberative Public Engagement Related to
Governing Biobanks**

Final Report

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Deliberative Public Engagement Related to Governing Biobanks

Final Report

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Executive Summary

Deliberative democracy theory and practice has the potential to enhance other policy approaches to ethical and social issues related to biobanks. Current policy manifests democratic deficits, including a lack of representation of diverse public interests, input from publics that is informed about technical and other public perspectives, and policy advice that explicitly addresses trade-offs between public interests as evaluated by the public participants.

Collaboration with international scholars in deliberative democracy and ethics supported the research group design of a deliberative engagement on biobanks, emphasizing the province of British Columbia, Canada as the relevant population. A random-digit dialed demographically stratified sample of 21 participants participated in a two weekend deliberative event. Participants were informed via a booklet written specifically for the event; an annotated bibliography of reprints was available on- and off-line. There was a half-day of expert presentations at the event, followed by question and answer sessions. Participants also had the opportunity to receive answers to their questions on an ongoing basis during the event or via a private website in the 12 days between event weekends. A model of a biobank showing its relationship to research laboratories, health care facilities, the community and health related outcomes was constructed of Lego © and used by some presenters to explain biobanks and related issues.

Participants were paid \$200 for each weekend they participated to cover their time and miscellaneous expenses. Hotel, meals and transportation for out of town participants were provided. National and provincial biobanks, research funders and policy groups expressed interest and provided support for the event, providing some confidence to participants that the deliberations would be considered beyond the event.

It is a considerable challenge to promote deliberation that is respectful but engaged, motivated to find common values without being oppressive of disagreement, open to challenge without being intimidating, and reflectively inclusive of different styles of “warranting” claims. Moderated small groups of 6-7 participants enhanced participation and respectful engagement, while professionally moderated large groups provided a venue for the dissemination of specialized information. Large group discussions also provided a forum for presenting reports from small groups to enhance the diversity in subsequent small group discussions. The 12 day break between event weekends encouraged participants to reflect, gather their own information, talk to others, and consider the deliberation in the context of their own lives.

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There were several approaches to assessing the deliberative event. All sessions were audio recorded and transcribed, notetakers took notes, facilitators collected flip chart notes, and the large group sessions had additional observers. Participants completed evaluations at the end of each weekend deliberation and were interviewed by telephone in the month following the event. In addition, surveys of participants' ranking of policy options and statements were conducted on the first and last day of the event in collaboration with a group from Australia National University who have the most experience with this approach world-wide. Both quantitative and qualitative analysis of all of the data is underway, with completion anticipated by early 2008. Collaborators at the Mayo Clinic will be using this design as a basis for a deliberative public engagement in September 2007.

Initial impressions drawn from the event are that it is possible for members of the public who have not previously considered their interests in biobanks to learn the technical, stakeholder and various public perspectives and engage each other in respectful deliberation without succumbing to superficial consensus. Points of agreement, though often without unanimity, are identifiable; nevertheless, the basis for agreement is less clear than the basis for dissent. Small groups (6-7 participants) seem most suited to inclusiveness and deliberation. However, as the study design used here did not provide adequate time for large group (21 participants) deliberation to develop as fully, this finding may need further investigation. Small and large group reports, reviewed by the participants, are presented at the end of this document.

The deliberative democracy on biobanks research team is part of the Genome Canada and Genome BC funded project *Building a GE³LS Architecture* (PIs M. Burgess and P. Danielson). Research team members providing essential theoretical and logistical support for the event: Mike Burgess, Daniel Badulescu, Helen Davidson, David Hartell, Daisy Laforce, Holly Longstaff, Samantha MacLean, Kieran O'Doherty, Nina Preto, David Secko, Kim Taylor, Heather Walmsley and Elizabeth Wilcox. Additional valuable input on the project was received from collaborators, Barbara Koenig, Simon Niemeyer and Mark Warren and consultants Peter Abrams, Susan Dodds, Brian Evoy, Archon Fung, John Gastil, Janet Joy, Janet Wilson-McManus and Peter Watson.

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- BC BioLibrary: Banking for Health (a MSFHR Technology/Methodology Platform)
- BC Cancer Agency Tumor Tissue Repository
- Better Biomarkers of Acute and Chronic Allograft Rejection
- Building a GE³LS Architecture (Genome British Columbia/Genome Canada)
- Canadian Biotechnology Secretariat
- Canadian Tumor Repository Network (CTRNet)
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Deliberative Public Engagement Related to Governing Biobanks

Final Report

Introduction

The W. Maurice Centre for Applied Ethics at the University of British Columbia has been experimenting with different forms of public engagement in a Genome Canada and Genome BC sponsored research project, "Building a GE³LS Architecture" (Pis M. Burgess and P. Danielson). Online surveys (Ahmed et al, 2006; Danielson, 2007, Danielson, Mesoudi, Stanev, in press; Danielson et al, in press), focus groups (Burgess, 2005; Burgess, Tansey, in press) and large group discussions (Longstaff, Burgess, Lewis, 2006) have been used to explore the use of information and how publics define and assess topics as diverse as genomic research (Burgess, 2005), genetic testing (Danielson et al, in press), salmon genomics (Burgess, Tansey, 2006, in press a; Tansey, Burgess, in press b) and biobanks. Most recently, the research team led by M. Burgess conducted a pilot study in deliberative democracy to assess whether this approach could go beyond mere collecting of data about public perceptions to include participant deliberation based on access to information and a diversity of views. The goal was to use a stratified demographic sample of 25 people to identify the values that a deliberative and informed group of citizens believe should shape the governance of a British Columbia (BC) biobank.

The impetus for the event was based on the research team's assessment that current policy approaches manifest a "democratic deficit." It is necessary to find a way to enhance representation in biobanking policy that can challenge whether the appropriate values are being considered and how different publics would rank them (Tansey, Burgess, in press b). The task of designing a deliberative democracy event presented many challenges, including whether participants can be expeditiously informed, avoid "capture" by vested interests and premature consensus, engage across deliberative styles, and include the politics of social groups with special interests (e.g., indigenous peoples).

Recruitment

Collaborators from the field of deliberative democracy (A. Fung, J. Gastil, S. Niemeyer, M. Warren) assessed and helped design the event, advising that since the event could not be politically representative of the provincial population, recruitment should aim for diversity while minimizing selection biases to design the most deliberative and representative event on a "small" scale and with a "limited" budget. The final sample was large enough to begin to test both logistical and practical components of the event design, enrich the existing public and expert discussions, and evaluate whether it could be used in the future for a politically representative event.

Using the 2001 Canadian Census for BC, participants were random digit dialed and recruited to fill stratification for ethnicity, religion, occupational group and sex. A minimum of two participants were recruited from all five of the province's health regions. With oversampling to 34, 27 agreed to participate, 23 registered

for the first meeting, 22 completed the first weekend, and 21 participants registered for, and completed the second weekend (see Figure One).

Some participants reported initial suspicion about the telephone recruiting, but noted that they were reassured by a public website the recruiters directed them to that was designed by the research team (Figure Two), and by the project's university affiliation.

Gender	Female	12*	Income (21 responses)	Less than \$25,000	1
	Male	10		\$25,000-\$49,999	3
Health Region	Fraser	7		\$50,000-\$74,999	3
	Interior	2		\$75,000-\$99,999	1
	Northern	2		\$100,000-\$149,999	3
	Vancouver Coastal	9*		\$150,000 and over	0
	Vancouver Island	2		Undisclosed	10
Employment (20 responses)	Business - Finance - Administration	3*	Chronic illness/disability	Yes	4
	Chemical Engineering	1		No	18*
	Social - Education - Gov't - Religion - Health	4	Risk of inherited disease	Yes	8
	Trades - Transportation - Equipment	3		No	14*
	Unable to work	2	Religion	Atheist	1
	Looking for work	1		Buddhist	1
	Retired	5		Catholic	4*
	Other	1		Christian	6
Ethno-cultural	Caucasian	2		Muslim	1
	Chinese	3		Protestant	1
	Pakistan	1		Sikh	2
	Indian	3		Theist, no religion	1
	Anglo	1	None or other	5	
	Ukrainian	1	Number of children (17 responses)	none	6
	First nations	2		1	4
	German	1		2	3
	Filipino	1*		More than 2	4
	Other	7	Age (18 responses)	Under 30	3
Education	More than high school	20*		30 - 45	5
	Less than high school	2		45 - 60	4
				Over - 60	6

* Includes one person who only participated in the first weekend's deliberation

Figure One:
demographic stratification of participants



Figure Two:
Public website designed for the deliberative event (hyperlinked)
Informing Participants

The research team sought to identify arguments or ways of explaining values and positions that could be used to better inform and engage the public, generating several approaches to informing participants. Participants received an 18 page booklet including three pages of glossary in advance of the event (Figure Three). The materials were based on the team’s review of the relevant literature and media.

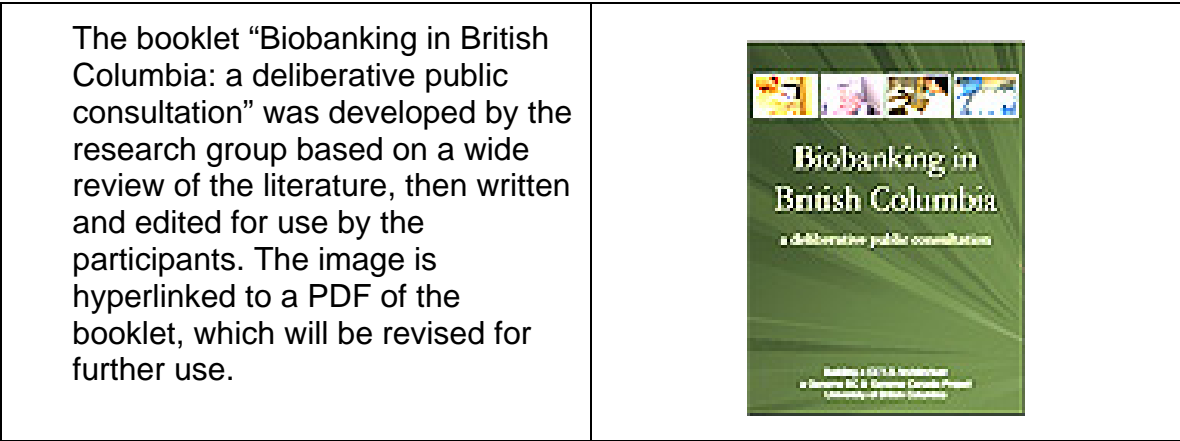
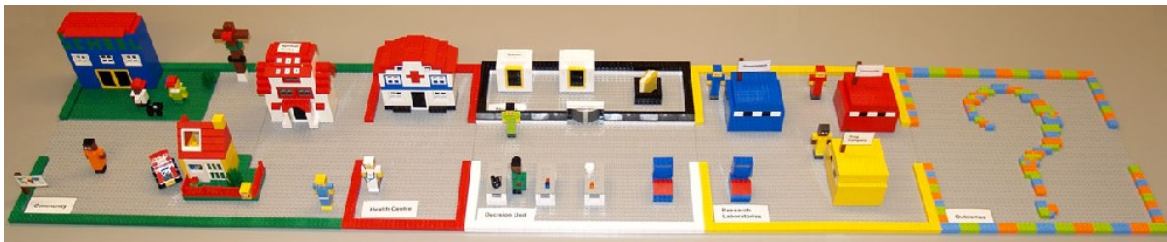


Figure Three:
Information Booklet Produced for Participants

These advance materials were supplemented by a Lego[®] model, an annotated bibliography with sample articles and media reports, five expert speakers, and information researched and introduced by participants.

The model (Figure Four) was designed and introduced by research team member E. Wilcox. A malleable and graphic illustration of the function and context of a biobank, the model showed how people, samples, information, research and funding moved across the community, health care settings, research laboratories, collections of data and samples to produce health and community benefits. Four out of five speakers made reference to the model, and some explanations in the large group by M. Burgess used the model to make otherwise abstract discussions more concrete. On the second weekend, the model was used to introduce possible components of a biobank, including oversight mechanisms such as research ethics boards, informed consent forms, benefits, and financing.



**Figure Four:
Physical Model of a Biobank**

The annotated bibliography (articles and summaries) was available for participants to take home in printed form, and was posted to a private website that also supported participants' "blogging" on topics they initiated. One research team member monitored the website for substantive questions from the participants, and collaborated with others to provide online responses.

The first weekend began with presentations and discussion from four "experts and stakeholders." Online discussions were printed for participants on the second weekend and were included in the introduction to the tasks for the second weekend.

The primary purpose of holding the event on two non-contiguous weekends was to provide an opportunity for participants to leave the intensity of the weekend discussions and return to their lives to consider and perhaps discuss the issues raised in the meetings with their friends, family and community.

Engaging and Motivating Participants

Motivating participants to participate appropriately is a complex and difficult task. Once recruited, participants must take the deliberation seriously enough to work hard to understand the substance of the discussion and each others' perspectives, to engage and present their own views, and to form consensus where feasible without ignoring persistent disagreements. Out of town participants were provided with travel and accommodation, and local participants with accommodation in a Vancouver hotel. Saturday dinners were arranged by

the research team and day time meals were provided at the W. Morris Wosk Centre for Dialogue, as were very comfortable settings for discussion. All participants received a stipend of \$200 per weekend of participation to cover incidental expenses.

A professional moderator (P. Abrams) ran the large group discussions. The professional moderator and the lead researcher provided facilitation instruction to the research team, selected three small group facilitators, and provided facilitation guides and facilitator support throughout the events. The primary focus was to enhance the ability of participants to comfortably contribute to the discussions in small (break away) groups. When the break away groups returned to present the results of their discussions to the large group, every individual was encouraged to contribute to the presentation.

There was a commitment at the outset of the deliberation from the leader of a proposed BC BioLibrary (now funded by the Michael Smith Foundation for Health Research) that the BioLibrary's policy discussions would consider suggestions from this deliberation. This commitment and the fact that the project's funders included several biobanks and federal agencies with an interest in the governance of research, seemed to have stimulated participants' dedication as measured by the return rate, the evaluation forms, and the intensity of discussion. The funders included the Canadian Institutes of Health Research Institute of Genetics and the Ethics Office, the Canadian Biotechnology Advisory Secretariat, the Canadian Tumor Repository Network, and local biobanks.

Promoting Deliberation

There is a considerable body of theory and practical discussion about the distinctions between "deliberation" and other forms of public engagement. The objectives behind deliberation as a goal have to do with participants being respectful of each other as equals, positions taken by participants being justified and challenged by others, and conclusions being a reflection of the deliberating groups' efforts to find common ground. In complex or technical areas, deliberation needs to be well informed about technical aspects of the topic without undermining the expectation that participants can redirect assumptions made by experts or stakeholders (see below).

Deliberation is difficult to define and evaluate, but several design features included in this project were intended to provide important support. Enhancing participants' confidence and knowledge was achieved by providing background materials and providing responses to technical questions through the research team, speakers, and extended resources. Encouraging diverse reasoning or explanatory styles was encouraged by recruiting for diversity of life experience, professional facilitation of the large group sessions, and facilitation of the small group sessions by team members as described above.

Each weekend served different functions (Figure Five). The first weekend was intended to provide background information, and develop a communication context that was respectful but would support disagreement on the second weekend. There were eight hours of large group discussions, including four

hours of speakers and the introduction of the physical model of a biobank. The large group discussions were intended to establish common understanding, whether of technical or stakeholder perspectives, or that of the participants. The small group discussions (two hours) were strategically organized to facilitate comfort and maximize participants' ability to participate and engage each other. The goal of the small group session was for the participants to identify their hopes and concerns about biobanks. The weekend concluded with a presentation of the small groups' hopes and concerns about biobanks.

The second weekend focused on the design of a BC biobank; participants spent six hours in small group discussions and six hours in a large group discussion. It was necessary to have a constructive, even consensus oriented goal to motivate participants to move beyond stating views and to begin to negotiate policy.

Potentially dominant individuals were identified by the confidence they displayed over the course of discussions and presentations in earlier parts of the deliberative event. The small groups were then constituted by distributing the most confident participants in the large group across the small groups, and breaking up the early friendships and cliques that had formed during the first day. The facilitators worked with the moderator to establish a common facilitation guide for each session.

<p style="text-align: center;"><u>AGENDA: APRIL 21</u></p> <p><i>Share knowledge about the operations of Biobanks and their possible roles in society</i></p> <ul style="list-style-type: none"> • Welcome – Introductions & Orientation – Large group • Survey & Website orientation • Introduction to Biobank Model – Large group • Speakers' Panel; discussion – Large group 	<p style="text-align: center;"><u>AGENDA: MAY 5</u></p> <p><i>Design a biobank Identify agreement & of persistent disagreement</i></p> <ul style="list-style-type: none"> • Recap: emerging ideas & information – Large group • Hopes, Concerns, Trade-offs – Large group • Designing a biobank – Breakout groups
<p style="text-align: center;"><u>AGENDA: APRIL 22</u></p> <p><i>Identify the values & interests we need to respect when determining the roles and operations of biobanks</i></p> <ul style="list-style-type: none"> • Key emerging themes – Large group • Open discussion – Large group • Identifying key values and interests – Breakout groups • Preparation for sharing results – Breakout groups • Sharing results – Large group 	<p style="text-align: center;"><u>AGENDA: MAY 6</u></p> <p><i>Design a biobank Identify agreement & of persistent disagreement</i></p> <ul style="list-style-type: none"> • Preparation for sharing results – Breakout groups • Sharing results – Large group • Designing a common biobank – Large group • Survey – individual work with assistance • Debrief and Closing – Large group

**Figure Five
Daily Agendas**

Data Collection and Analysis

There were notetakers in each room for large and small group discussions, and each room was audio recorded. Only the large group moderator interrupted the small groups (occasionally) to monitor their progress. The large group discussions had an average of 12 non-participating observers, including the research team members and collaborators, arranged behind tables at the back of the room behind the U-shaped participant table.

Evaluation of the deliberative event includes quantitative measures using a pre/post survey, narrative analysis of audio recorded sessions, participant evaluations and follow-up telephone interviews with each participant. Participants began and finished the event with a Q-sort. These exercises took about one hour on the first and last day of the event. Analysis of the data is in collaboration with S. Niemeyer and J. Dryzek of Australia National University. The Q-sort method employed in this study required participants to rank order 38 value-statements about biobanks and 8 policy based statements according to their personal beliefs and preferences. Rankings ranged from -5 (strongly disagree) to +5 (strongly agree) for value statements and from -5 (strongly against) to +5 (strongly in favour) for policy statements. The rationale for including Q methodology in the event was to incorporate a quantitative measure in the deliberation that is well recognised as a systematic tool for the study of subjectivity (Brown, 1993).

Participants completed event evaluation forms at the end of each weekend. These forms helped the team and moderator to ascertain how well the participants reported being supported for informed, respectful deliberative discussion. On both weekends the global satisfaction was over 4.6 out of 5, with the main critical comments having to do with fatigue and the amount of information.

The audio recording taken in large and small group sessions were transcribed and are being analyzed with the support of Atlas.ti software. Notes from note takers and flip charts created during the discussions are also being used in the analysis. Members of each of the small group discussions have reviewed the summaries of their conclusions, and all participants have reviewed the summary of the final large group discussion. Nineteen of the 21 participants completing the event have been interviewed over the telephone (one is on vacation and one has asked to postpone the interview). Final analysis will be completed by early 2008.

The reports from the small groups and large groups are presented in the Appendix. Small group reports were sent back to the participants who contributed to each report, and they have agreed that the reports can be circulated as a summary of their conclusions. An earlier draft of the large group report was circulated to all participants for their response and suggestions: only modest revisions were necessary.

Conclusion

Although analysis is ongoing, it is possible to offer some preliminary impressions. The following points summarize the large group report, itself based on a

summary of the small group reports prepared by M. Burgess and reviewed by the participants in oral and written form:

- In principle support for biobanks.
- Standardization should enhance efficient research use and privacy.
- Governance should be independent of funding sources.

Small groups achieved agreement on more issues than could be resolved in the time given to the large group discussion. For example, two of the three small groups reached consensus on making provision for 'blanket consent' (i.e., donor consent that is not specific to a particular use but open with regards to all potential research uses approved by the biobank). However, it was not clear in the large group discussion whether all participants meant anonymous or identifiable samples. There were some participants who maintained that the risk of illegitimate use of samples, even with independent oversight, justified requiring informed consent for each research use. Payment of sample donors and benefit sharing was another topic that was raised by some participants, while others were concerned about the increased cost of research and applications. (See the small group reports—Appendix: Reports from participants—for a more detailed description of the groups' conclusions, as well as disagreements that they identified as irresolvable within the group.)

It seems very possible for diverse members of the public to engage in moderated, informed, deliberative engagement on topics of considerable technical complexity. Participants reported that it is valuable to be informed and engaged in respectful discussion with people who have different views.

Small group discussions were successful in stimulating all participants to engage with one another, with only one person dropping out during the first weekend. Some participants who expressed hesitation about speaking in earlier large group discussions strongly voiced minority opinions in the final large group discussion, suggesting that moderation and their involvement in the small groups built their confidence. Although the moderator kept open the possibility that biobanks could be eliminated (the "no biobanks option"), this was never actively considered. However, during follow-up interviews one participant thought that this option was not made sufficiently evident in the discussion.

Initial analysis of the quantitative surveys suggests some changes in individual participants' preferences, but little reduction in the overall complexity of the range of participants' orientations towards the issues (as measured by a factor analysis of responses across participants). As this contrasts with other deliberative events that report reduced complexity of participants' orientations post deliberation, it could be argued that the failure to reduce complexity is a sign of unsuccessful deliberation. However, given that reaching consensus was prioritised at an equal level with identifying persistent disagreements in the tasks given to participants, we interpret the lack of a reduction in complexity in this case as an indicator of successful deliberation because it suggests that individual participants were not 'captured' by dominant voices or paradigms. That is, although individual participants changed their preferences owing to deliberation, and consensus was

reached on several dimensions, they did not 'lose themselves' to dominant discourses.

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Appendix: Reports from the Participants

The question “What values should guide a BC Biobank?” was the focus for participants on the second weekend. They were asked to identify persistent disagreements as well as agreements. A consensus-oriented discussion was important to encourage deliberation, but the emphasis on persistent disagreements was intended to relieve some of the pressure to conclude agreement prematurely. On the final day the small groups were asked to prepare and present small group presentations to the large group. Little time was available for a large group discussion, so the large group discussion is less of a deliberative output than a summary across the smaller groups’ more deliberative reports that was briefly discussed and then reviewed by all participants.

Small group reports

The small groups were asked to spend about an hour summarizing their discussion of the design of a BC biobank for presentation to the large group. The small group reports here are based on those oral reports and flip charts, summarized by the small group moderators and notetakers and reviewed and approved by the small group members. The report, (not the small group discussion), was put into printed format by the moderators in the week following the event, and circulated to the participants from the corresponding small group. Clarifications received in response to the reports only clarified personal positions. No corrections were returned by email, phone or mail.

#1 Participant small group report

Agreed design elements

The facilitator asked the group to focus their discussions by imagining a biobank specifically in British Columbia. They chose to focus on a medium-sized biobank in Prince George, located in a hospital. They reached consensus on a number of design elements:

- The biobank would be networked to other biobanks around BC – to enable streamlining of research.
- It should be provincially funded, with researchers paying a fee to access samples.
- There should be a tiered access fee – researchers for profit would pay more than non-profit researchers.
- Donors could be ‘paid’ for contributing to the biobank with tax credits.
- Research access fees should go back to fund the biobanks.
- Donors should be told any relevant health information resulting from research on their samples.
- There would be different fees for different samples – according to access, storage and processing costs.
- Some of the fees coming from researchers should be invested in research for rare diseases (e.g. by setting up a research grant).

- There should be one main consent form offering the option of blanket consent for either anonymous and/or linked samples. Those who rejected blanket consent could sign a customised form to indicate more specific consent preferences for different research uses. Donors under the age of 18 would need parental consent.
- Standards need to be set for quality control.
- There should be a governing body (with a variety of board members) and a tiered review system. Some projects would have to go through several levels of review, some just one.

Persistent disagreements

These were also issues that the group deliberated over at length, but without reaching consensus of opinion.

- Access to medical records by the police? The group explored potential benefits of linking biobanks to police databases (for example helping to solve crimes) and risks (for example it could lead to a 'police state').
- Review board members should be paid? Or offer volunteer services?

Members of the group disagreed as to whether governing body members should be paid for full time work, or should be made up of working professionals who donate several hours a week.

The group also discussed the possibility of constructing environmentally friendly biobank buildings – as a way of attracting donors, researchers and investors. Some members of the group felt this would be unnecessary as biobanks would normally be housed in existing buildings. There were diverse opinions within the group as to whether this classified as a persistent disagreement or was irrelevant to the discussion.

Outstanding issues to bring to the large group

The group deliberated over these issues at length during the weekend. But due to lack of time the group did not reach conclusions about how to incorporate them into the design of a BC Biobank.

- The need for education and awareness (e.g. through pamphlets, workshops or catalogues).
- The need for insurance and protection (for researchers, the biobank and for donors).
- Should the biobank be regulated by law, by guidelines or by standards?

#2 Participant small group report

Biobank Design Choices

The group approached the challenge of designing a biobank by first focusing on the **information entering** the biobank and then focusing on regulating how the **information leaves** the biobank and who has **permission to access** the data. Each design element was evaluated independently and justified and the following design choices are the ones that the group agreed were important components

when seeing to establish a biobank. The group looked at public and private biobanks, and these recommendations apply equally to both.

Mission Statement:

The most important aspect in the design of a biobank is its mission statement. The mission statement represents the biobank's reason for existence and articulates what the biobank does and how it carries out its functions. The mission statement is available to aid donors in their decision whether to donate to that particular biobank and to allow researchers to determine if their tissue request is in accordance with the purpose of the biobank.

Standardised Collection of Information Across Biobanks:

All biobanks should have a standardized method of collecting and annotating the collected samples. This will make it easier to share samples across researchers and across biobanks.

Privacy and Security:

Our group emphasised that privacy and security are both important in protecting the donors, and yet the group recognized that having a system that allows sharing of information across various levels would also be beneficial. The group was very cognisant of protecting privacy and yet at the same time recognized the benefit of coding a secure system that allows access to further information. The group explored the idea of coding the donated samples to remove all personal information, while allowing the possibility of contacting the donor if necessary.

The Consent Form:

The group agreed that the consent form should allow the donor to be as flexible as he or she wished to be when donating their sample. In other words, the donor should have the option to specify the conditions under which they feel comfortable with donating their sample. At the same time, the group felt that donors who were not that particular about restricting their information and were willing to have their tissue available as widely as possible should have the option to simply check a box that says "use my sample for any purposes". If the consent form is properly drafted, many in the group believed that it can take care of most, if not all, of the concerns of the donors.

The group discussed whether or not it was appropriate for a patient who is about to receive surgery to consent to donating their tissue to a biobank for research purposes. The group agreed that he or she may not be in a position to provide consent and properly digest the information. In this case, consent is to be provided simply for the use of the tissue for therapeutic purposes only. If the tissue is to be used for research purposes, the patient would need to be contacted at a later time.

Accreditation System for other Biobanks, Hospitals, Universities:

The group was very conscious that we had to be very careful with how the information emanating from the biobank was used and who had access to it. Many participants raised the concern that they do not want our samples and

personal information to be freely available to anyone upon request. By ensuring that only accredited organizations and individuals can apply for access to the samples, it ensures a means of safeguarding the source of the information from the source of the request to the biobank.

The Governance of the Biobank:

Each Biobank would be governed by a governing body. This group would be responsible for evaluating, approving and controlling access to the stored samples. The composition of the board would include (but not be limited to): a doctor, lawyer, layperson, technical experts, public relations, ethicist and economic experts.

When researchers request access to the donated tissues, there needs to be a comprehensive agreement specifying what a researcher can and cannot do with the samples. To access the samples, the research applicant must:

- Meet our mission statement, i.e. the purpose or outcome of their research must be in accordance with the intent of the biobank.
- The applicants must be accredited to ensure legitimacy.
- The research proposals need to be approved by the biobank governing body.

Each research proposal that seeks access to the samples will be considered and evaluated by three subcommittees within the biobank (technical, ethical and economic). Each committee would evaluate the proposal from their own perspective to help determine whether this is a viable and authentic request. Each of these recommendations would then go forward to the board for final approval.

Periodic Review:

Each research project would agree to a review process that would periodically evaluate the approved research projects that use samples and information from the biobanks. The purpose of the review is to ensure that:

- The research is being performed for the purpose for which it was approved
- The research is in line with the biobank's mission statement and to ensure that it is being done ethically.

Persistent Disagreement

During the course of our discussions, the group arrived at two persistent disagreements. In these areas of disagreement, each group member understood the reasons supporting each position, however remained at a disagreement.

The first is whether researchers should have full unrestricted access to authorised samples or whether donors should be able to specify conditions on the use of their sample.

The second is whether the individual should have full control over whether they wish to receive personal health information that is discovered about them or

whether a governing body can control which personal health information that is discovered about an individual should be shared with members of his or her family.

Outstanding issues to bring to the large group

Our group did not have the opportunity to discuss the following outstanding issues pertaining to the use of biobanks:

- Ownership
- Benefit Sharing
- Profits
- The federal and provincial laws governing the use of biobanks

#3 Participant small group report

The following report provides an overview of the presentation that Holly's small group gave to the rest of the participants on Sunday May 6th as part of the 2007 deliberative event on biobanks. Participants were asked to present materials on banners that addressed the following three categories: persistent disagreements (see Section 1.0); questions for the group (see Section 2.0); and agreed upon design choices (see Section 3.0). Keys representing access to biobank materials were also presented (see Section 4.0).

Section 1.0 Persistent disagreements

Participants in this group disagreed on the amount of privacy protection that would be necessary for biobanking operations. Some reported that they saw no need for strong privacy protection explaining that such rules were not important, could lead to too much government involvement, or even impede research. These participants agreed to have their information shared publicly. Alternatively, others argued that there was good reason to support privacy protection when crafting biobanking procedures. They discussed many different ways of protecting personal information including anonymized, identified, or double coding data, and thought that donors had a right to expect privacy. They also pointed out that results emanating from donor information could lead to problems gaining employment and insurance coverage if privacy is not protected.

A second disagreement concerned whether the concept of stewardship should be a guiding principle for biobanks. One participant argued that stewardship, or the idea that an individual retains ownership of their information throughout the biobanking process, was integral. Others in the group understood this line of reasoning but asserted that such demands were impractical, unenforceable, and potentially restrictive to research.

All participants in this group agreed that some kind of research ethics board (REB) should govern biobanks but disagreed about who should sit on such a board. While there was agreement that representatives from the legal, medical, ethical fields, and those with proportional expertise should be present, there was disagreement about whether or not community involvement was required. Some argued that community member involvement was integral to the process while others believed that such individuals should be present as observers only.

Participants also disagreed on whether REB members should be elected or appointed. The group believed that they would need to examine a range of sample REB's before any final decisions could be made.

The group had a long discussion about the concept of consent. While some believed that individual consent could override group consent, others believed the opposite. A few argued that in some cases, individuals should be obliged to participate in biobank research (for example, if an individual has a rare genetic condition). There were additional disagreements regarding the issue of blanket consent. While some believed that it was their right or their own business to give blanket consent, others wanted to limit this right because they were concerned that blanket consent could result in research that has negative outcomes for society.

As for approving research, a few participants asserted that even unethical research should be allowed, given that it could potentially yield important knowledge. In this case, negative outcomes for society could be avoided if the results of such research were controlled. Most disagreed however, stating that unethical research should not be approved in the first place.

Participants could not agree on the issue of payment. Some asserted that all researchers should pay to access biobank materials. Free access to everyone was discussed, but the option of a sliding scale (i.e., that research should be free for some types of research/researchers but not others) was more favourably discussed.

All agreed that it was acceptable to patent drugs. However, participants could not agree if life forms or sequences should be patentable. The group ultimately decided that they would need additional information to discuss the problem of patenting any further.

Section 2.0 Questions for the group

Items in this category were divided into two sections: ideas for Barbara (Principle Investigator replicating this event at Mayo Clinic) and questions to foster large group discussion.

Section 2.1 Ideas for Barbara

Participants agreed that if this event was to be replicated in some form in the future, it would be helpful to have heard from an expert on patents and investors. Investors could provide the participants with accurate information regarding how much money was actually involved in the drug approval process, the steps involved when creating a new drug, and the responsibilities or liabilities that may be involved for investors if a drug incurred some sort of negative social outcome (i.e., deaths).

Section 2.2 Questions to foster large group discussion

One of the topics that participants wanted to discuss in the large group setting was the issue of standardization across a variety of biobanks. They wanted to

know if the others thought it was possible to develop criteria capable of being applied to different types of biobanks and biobanks in different regions/countries.

Section 3.0 Agreed upon design choices

Participants agreed that all biobank donors should receive a copy of their consent form for their records. It was agreed that before a child may participate in biobanks and biobank research, both parents and an REB would have to approve that child's participation. However, children could offer their own consent at a certain (yet undetermined) age. All believed that biobanks should seek to standardize processes and technical language to foster cooperation between research projects. They also agreed that projects could not be approved by an REB unless the motivation and/or purpose of the research project was known and that the project must agree to promote some type of benefit sharing. That said, although participants agreed that there should be some sort of benefit sharing, questions regarding who should receive benefits (community, researchers, industry?) and of what type (proportional expenses, information?) remained unresolved.

Participants suggested that it might be helpful for biobanks to incorporate information centres into their design to create transparency, and foster trust and public support. These centres would produce pamphlets and posters, hold press conferences, and address issues /concerns on a website (www.biobank.com) or through a toll free telephone number (1-800-askbiobank).

Section 4.0 Keys

During the small group discussions, three Key Masters volunteered to keep track of items for the red key, which constrained access to biobanks, the green key, which gave permission to access biobanks, or the yellow key, which represented tradeoffs. These participants were asked to write down agreed upon relevant items on little tabs attached to their key. Items that were not already covered above are discussed below.

Yellow key items

- wider access to biobanks versus restricting third party access
- using moral grounds for approving research conducted by biobank (produce health benefits for those who need it most) versus benefits to majority (studying cancer)
- *Green key items*
- funding for biobanks must come from a variety of sources (i.e., private industry, public sector, government)
- biobanks are the way to go. We should have one in BC.
- a body is needed to govern biobanks
- biobank creators must budget for public consultation

Red key items

- no access to biobank materials unless motivation and research purpose is approved by REB

- privacy concerns cannot be too restrictive. We want research to be facilitated
- we are concerned about price control for drugs. Drug companies make exorbitant profits. But how do you operationalize this? How can biobanks help?
- no access to biobanks materials without benefit sharing
- if something sounds fishy, the REB should probe further

Large Group Summary

The large group discussion was based on the large group discussion of the small group reports. The large group discussion was 90 minutes, compared to the 5-6 hours of discussion in the small groups on the second weekend. The topics raised or omitted, from the reports are a function of the discussion by the participants. To respect the deliberative context and competence of the participants to draw on the materials presented, the moderator and facilitators did not intervene to assure more complete consideration, or to initiate discussion of topics they thought were important issues that the participants were omitting. This would have been disrespectful of and the provision of a wider range of information on the first weekend and through the print and online resources.

The large group summary was initially composed by M. Burgess during the small group presentations, then presented for discussion to the large group. The summary was circulated to research team members for revision, then to all participants for their review, revision and approval. No corrections were made by the participants in response to the mailed out report. Comments from interviews are still being analyzed.

A. Design elements of a biobanks

“Support for biobanks to produce health related benefits”

First, based on the fact that all discussion emphasized tuning access and consent, it seems that there was in principle support for biobanks. This seems significant since we explicitly provided the option of concluding that biobanks should not be allowed, or should be restricted from particular uses.

“Standardization”

Biobanks should be standardized to enhance the ability of researchers to use biobanks to provide health benefits. This might include standardization of procedures to protect privacy or of record keeping so there is similarity between biobanks.

Responsible independent governance

Biobanks require administration that is responsible to evaluate requests for research, perhaps to ensure beneficial purpose and motivation of the researchers (although there was recognition that “unethical research” could have benefits). This administrative body should be independent of funders, whether public, private or government.

B. Persistent Disagreements

“Blanket consent”

The notion of consent to donation of tissue and information to biobanks without information about the specific use was widely, but not unanimously supported.

Participants who objected to consent that did not specify research purposes emphasized the right of individuals to refuse to be involved in research even if it is approved by the independent governing body. Some were concerned that despite all protections, samples could be used for illegitimate purposes. It was recognized that this might reduce the efficiency and effectiveness of biobanks to provide health benefits, but some participants found this insufficient reason to reduce the requirement for informed consent to specific research.

Payment of sample providers was promoted by some participants but others were concerned about increasing the costs of research and applications. Also, benefits to communities in addition to research outcomes may be appropriate, but these need to be further considered.