

# Canadian Partnership for Tomorrow Project



## PRIVACY IMPACT ASSESSMENT

### BC Generations Project

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Conducted by the BC Cancer Agency  
in association with  
The Canadian Partnership Against Cancer

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*The consultant is not a lawyer and is not offering legal advice. It is understood that the BC Cancer Agency will seek legal advice as required.*

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## **Abbreviations**

The abbreviations that will be used throughout this document are outlined below:

<b>BCCA</b>	<b>BC Cancer Agency</b>
<b>CIHR</b>	<b>Canadian Institutes of Health Research</b>
<b>CPAC</b>	<b>Canadian Partnership against Cancer</b>
<b>CSCC</b>	<b>Canadian Strategy to Control Cancer</b>
<b>ELSI</b>	<b>Task Force on Ethics, Legal, and Social Issues</b>
<i>FIPPA</i>	<i>Freedom of Information and Protection of Privacy Act (BC)</i>
<b>GVRD</b>	<b>Greater Vancouver Regional District</b>
<b>IT</b>	<b>Information Technology</b>
<b>LHDB</b>	<b>Linked Health Database, University of British Columbia</b>
<b>LIMS</b>	<b>Laboratory Information Management System</b>
<b>OICR</b>	<b>Ontario Institute for Cancer Research</b>
<b>OIPC</b>	<b>Office of the Information and Privacy Commissioner (BC)</b>
<b>PHSA</b>	<b>Provincial Health Services Authority</b>
<b>REB</b>	<b>Research Ethics Board</b>
<b>UBC</b>	<b>University of British Columbia</b>

## Introduction and Overview: the Canadian Partnership for Tomorrow Project and its BC Component

- The Federal Health Minister, Tony Clement, and the Canadian Partnership Against Cancer (CPAC) launched a thirty-year cancer prevention study on June 11, 2008.<sup>1</sup> The federal government had announced the creation of CPAC in November 2007 as an independent organization funded by the federal government to accelerate action on cancer control.<sup>2</sup>
- *The Canadian Partnership for Tomorrow Project* will be a study of 300,000 Canadians that explores how genetics, environment, lifestyle and behaviour contribute to the development of cancer and other chronic diseases. The pan-Canadian study will track randomly selected Canadians (ages 35 to 69) for at least the next twenty to thirty years. It will gather information on health and lifestyle through surveys and the collection of blood and other specimens. The information will help researchers, policy-makers, and others understand how different combinations of risk-factors lead to cancer.<sup>3</sup>
- *The Canadian Partnership for Tomorrow Project* involves partner organizations in five regions: the BC Cancer Agency, the Alberta Cancer Board, Cancer Care Ontario, with the Ontario Institute for Cancer Research, Quebec's CARTaGENE project, and Cancer Care Nova Scotia, with Dalhousie University, collaborating for work in the Atlantic Provinces. Study funding comprises \$42 million in support from the Canadian Partnership Against Cancer, along with a regional commitment to the Ontario component to date of \$41 million. These committed funds will be leveraged to trigger further investment with an anticipated total of more than \$100 million by 2010.<sup>4</sup>
- The Canadian Partnership for Tomorrow Project is a prospective cohort study, meaning researchers will follow a large group of people over a long period of time. It is designed to regularly capture data from average Canadians who are randomly selected from a wide range of backgrounds and regions. The goal is to secure a more complete picture of people's health and habits, including what they eat and how much they exercise, as well as environmental variables such as where people work and live. The impact of screening and prevention programs will also be assessed. The goal is to enroll 300,000 people and follow them over the duration of the project.<sup>5</sup>
- Researchers will regularly examine the data and, in the short-term, expect to gather insight into how Canadians are responding to public health and prevention programs. Longer-term, researchers will be looking for patterns among people who develop cancer. Over the life of the study, researchers will be able to test theories about cancer risks and will be able to map the onset of factors responsible for other life-threatening and chronic diseases such as heart disease and diabetes.<sup>6</sup>
- The pan-Canadian project is built on the successful foundation of the Alberta Cancer Board's Tomorrow Project, which has enrolled 30,000 people. Useful insights into lifestyle factors that may contribute to cancer are already being generated from that

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<sup>1</sup> See [http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/\\_2008/2008\\_90-eng.php](http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2008/2008_90-eng.php)

<sup>2</sup> See <http://www.partnershipagainstcancer.ca/inside.php?lang=EN&ID=48>; and <http://www.partnershipagainstcancer.ca/home.php?lang=EN>

<sup>3</sup> Cohort Press release final, June 4, 2008.

<sup>4</sup> Cohort Press release final, June 4, 2008.

<sup>5</sup> Cohort Press release final, June 4, 2008.

<sup>6</sup> Cohort Press release final, June 4, 2008.

work. Examples include determining factors that predict use of cancer screening tests and barriers affecting participation in physical activity.<sup>7</sup>

- Discussions are underway to secure the long-term viability of the BC component of the Canadian Cancer Cohort by making it a joint venture of the BC Cancer Agency, the Canadian Cancer Society (BC and Yukon Division), and the Government of BC.<sup>8</sup>

## **Description of the BC Generations Project**

### **1. General Goals of the Canadian Partnership for Tomorrow Project**

- The operational objectives of the Canadian Partnership for Tomorrow Project are:
  - To build a Canadian Cancer Cohort comprised of a confederation of provincial cohorts currently under construction, or underway, in Alberta, Atlantic Canada, British Columbia, Ontario and Quebec.
  - To enroll 300,000 Canadians in the Canadian Cancer Cohort over the next five years, beginning with the current provincial initiatives, including the potential for adding other provinces/territories.
  - To collect high quality lifestyle and environmental exposure information as well as high quality DNA and other biological samples (e.g. plasma, serum, and urine) from the enrolled cohort members.
  - To build the facility for use of data and specimens by scientists across Canada and potentially, through collaborations with other cohorts, to scientists around the world.
  - To make the links necessary to ensure the participation of the Canadian Cancer Cohort in international collaborative disease studies around the world. Only anonymized data on individuals will be shared with other cohorts.
  - To find sufficient financial backing to ensure good follow-up of the cohort over the twenty years following completion of recruitment and initial data/sample collection.
  - To undertake all activities within a clear and transparent legal framework of accountability and with the highest ethical standards.<sup>9</sup>
- “Through linkage to provincial health utilization data, a Canadian cohort also offers the opportunity to study chronic diseases which may not otherwise be recorded anywhere on disease registries or on death certificates. In addition, as the cohort design lends itself to administering repeat questionnaires and the collection of biological samples at regular intervals over many years, a complete picture of an individual’s health status and exposure data emerges. As new technologies, methods and information become available, additional layers can be added, resulting in a comprehensive characterization of the study population and their health outcomes. Furthermore, collection of biological samples, such as blood and urine, from participants before cancers occur, adds great value to the cohort resource.”<sup>10</sup>

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<sup>7</sup> Cohort Press release final, June 4, 2008.

<sup>8</sup> CPAC, “Canadian Cancer Cohort Proposal,” p. 13.

<sup>9</sup> BC Biobank V1.3, October 15, 2008; and Canadian Partnership against Cancer (CPAC), Research Action Group, “Canadian Cancer Cohort Proposal,” by the BC Cancer Agency, Alberta Cancer Board, Ontario Institute for Cancer Research, CARTaGENE Project, Cancer Care Nova Scotia, November 23, 2007 (105 pp.), p. 7. Hereafter cited as CPAC, “Canadian Cancer Cohort Proposal.”

<sup>10</sup> CPAC, “Canadian Cancer Cohort Proposal,” p. 3.

- The Canadian Cancer Cohort has been designed with ultimate aims consistent with the prevention-related objectives of the Canadian Strategy for Cancer Control (CSCC), particularly “to reduce the expected number of new cases of cancer among Canadians” and “to lessen the likelihood of Canadians dying from cancer.”<sup>11</sup>
- The operational objectives of the BC Generations Project are:
  - To recruit a total of 40,000 BC residents aged 40 to 69 years into the BC component of the Canadian Cancer Cohort by collecting their personal information. Initial recruitment will be in the Greater Vancouver Regional District and then move to Vancouver Island, the Interior, and Northern areas. Up to four hundred thousand letters of invitation will be sent out to potential participants with the expectation that ten percent will agree to participate.
  - To acquire, process, and store DNA and blood fractions, as well as a urine sample, from all participants in the BC Generations Project.
  - To acquire participant consent for use of the data and specimens for cancer and other chronic disease research.
  - To acquire participant consent to access past health history information and to do follow-up through linkage to their health records.
  - To acquire participant consent for re-contact at intervals over the course of the project.
  - To ensure that data and specimen collection procedures and products are harmonized, under controlled conditions, with those used in other provinces in order to be able to maximize the value of the cohort for the study of disease, since many individual cancers are relatively rare, and the power to study diseases increases much more rapidly by combining such datasets.<sup>12</sup>

## **2. The Need for the Canadian Partnership for Tomorrow Project**

- *The Importance of Chronic Disease Prevention:* “What is known is that chronic diseases such as cancer are caused by a combination of lifestyle factors, exposure to environmental agents, and individual genetic make up.... Thus, for cancer prevention to have a significant impact at the population level, an understanding of the environmental risk factors involved, and the interplay between these factors and human genetic make-up, is needed.”<sup>13</sup>
- *The Need for ‘Big Science’ in Disease Prevention Research:* “The realization that there are more than 30,000 genes, with potentially millions of common variants, drove home the need for change in the cancer research paradigm; moving away from projects driven by single isolated investigators or small teams, and moving towards large interdisciplinary consortia of scientists working toward a common goal.... Recently, epidemiologists, biostatisticians, and population geneticists (the ‘basic scientists’ of cancer and chronic disease prevention) have also moved to the formation of large coordinated interdisciplinary groups to study environmental and lifestyle risk factors for disease.”<sup>14</sup>

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<sup>11</sup> CPAC, “Canadian Cancer Cohort Proposal,” p. 6. See <http://www.partnershipagainstcancer.ca/> [review]

<sup>12</sup> BC Biobank V1.3, October 15, 2008.

<sup>13</sup> BC Biobank V1.3, October 15, 2008.

<sup>14</sup> BC Biobank V1.3, October 15, 2008.

- "...the dramatic (and continuing) fall in genotyping costs over the past five years has made the 'full-genome scan' the method of choice over the 'candidate gene' approach in determining the effect of genetic variants on human disease. This in turn has further encouraged the need for the consortia approach in order to ensure the large numbers of subjects needed for hypothesis development datasets and independent confirmation datasets. A further benefit of these large scale datasets is that they minimize the problem of 'false positives' inherent in association-testing using literally hundreds of thousands of genetic variants."<sup>15</sup>
- The establishment of a Canadian Cancer Cohort in response to these global trends in research will ensure Canada has a key scientific platform necessary to take advantage of, and to be a full participant in, the emerging scientific revolution in determining the causes of cancer and chronic diseases. The BC Generations Project will be a key component of this initiative.<sup>16</sup>
- "The proposed Canadian Cancer Cohort study will accomplish what no other major international groups are doing: specifically building a prospective cohort platform that will focus primarily on the investigation of environmental and lifestyle risk factors for cancer and their interaction with genetic and epigenetic risk factors. Aspects of our environment and lifestyle, such as water quality, air quality and activity levels, have seldom been thoroughly evaluated in epidemiologic cohorts, because their measurement is problematic. However, a new Canadian Cancer Cohort would be ideally placed to take advantage of the emergence of new technologies, as well as the growing realization amongst epidemiologists that challenging issues can be addressed in innovative ways using trans-disciplinary approaches."<sup>17</sup>
- The Canadian Partnership for Tomorrow Project will include, for the first time in a national cohort, a major emphasis on the effect of environmental exposures on cancer risk. An innovative Environmental Exposure Task Force, intended to be convened in the first year of the study, will exhaustively examine the latest techniques for capturing environmental exposures of relevance to cancer, and will enable the Canadian Cancer Cohort to implement state of the art assessment tools.<sup>18</sup>

### 3. Current and Intended Scope of the BC Generations Project

- "The BC Cancer Agency (Cancer Control Research Program) has started recently to recruit a cohort of healthy women, aged 40-69 years, into a study known as the I-HELP Cohort. The long-term aim of this project is to establish a cohort of well women whose epidemiologic information and plasma can serve as a comparison group for researchers internationally who are developing new serum biomarkers for early detection of female cancers. The immediate objective of the I-HELP program is to obtain a blood sample, as well as lifestyle and other data, each year for five years from a group of women recruited through the Screening Mammography Program of BC.... Women who are joining the I-HELP biomarker discovery study are also being informed about and are being asked to participate in the BC component of the Canadian Cancer Cohort."<sup>19</sup>

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<sup>15</sup> BC Biobank V1.3, October 15, 2008.

<sup>16</sup> BC Biobank V1.3, October 15, 2008.

<sup>17</sup> BC Biobank V1.3, October 15, 2008.

<sup>18</sup> CPAC, "Canadian Cancer Cohort Proposal," p. 4.

<sup>19</sup> CPAC, "Canadian Cancer Cohort Proposal," p. 13.

- Privacy practices for the I-HELP initiative are outlined in the participant information and consent form that each individual entering the study signs at recruitment. Additional consent will be required to include these persons in the BC Generations Project, since it will involve collection of a urine specimen (which was not included in the original I-HELP protocol).
- The goal is to collect specimens and datasets from the vanguard group of 350 cohort participants by June 30, 2009 at an initial cohort assessment centre in the Greater Vancouver Regional District (GVRD).
- Year 3, 1<sup>st</sup> April 2009 to 31<sup>st</sup> March 2010, will see the recruitment of a further 10,000 cohort participants at one or more GVRD cohort assessment centres.
- Year 4, 1<sup>st</sup> April 2010 to March 31, 2011, will see the recruitment of a further 14,000 cohort participants from the GVRD area, and then a move to the Capital Regional District (Victoria) for recruitment in an assessment centre on Vancouver Island.
- Year 5, 1<sup>st</sup> April 2011 to 31<sup>st</sup> March 2012, will see the recruitment of 8,000 from Vancouver Island plus the initiation of a special program to recruit a further 8,000 participants, including people from small towns and rural areas of the province, in collaboration with the BC and Yukon division of the Canadian Cancer Society.<sup>20</sup> During this phase a special attempt will be made to recruit Aboriginal peoples into the cohort. The process will involve a traveling assessment centre. Any such collaborations will be on behalf of the BC Cancer Agency's Cancer Control Research Program, which will retain control of the personal information collected, used, disclosed, and retained.<sup>21</sup>
- The assessment centre will function like a community clinic with separate semi-private stations for taking informed consent, completion of questionnaires, taking of blood pressure and other measurements, and blood taking.
  - For completing the questionnaire, participants will be screened on either side by partitions. When completing the physical measurements, they will be taken individually into a separate room or cubicle. Similarly, for blood taking they will be screened on 3 of 4 sides by a cubicle. Private washrooms will be provided for urine taking.
  - A small 'laboratory section' will be attached to the assessment centre to do preliminary sample processing, such as centrifugation of serum separation tubes and temporary refrigeration of blood and urine samples.
  - The centre will be located in a medical/dental building or other conveniently accessed facility, close to transportation and adequate parking, and will include disabled access. The assessment centre will move locations from time to time as recruitment in a particular area reaches target levels.<sup>22</sup>
- Major health research resources in BC include the BC Linked Health Database (LHDB) at the Centre for Health Services and Policy Research (CHSPR), University of British

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<sup>20</sup> The BC and Yukon Division of the Canadian Cancer Society (CCS) has initially approved the use of volunteers from the CCS to organize community 'assessment fairs' for invited rural participants in local school gymnasiums and community centres. The use of 'volunteers' is a reminder of the importance of privacy training for them. This process will entail CCS volunteers initiating community recruitment drives in their areas based on lists of names randomly generated from provincial databases and provided by the BC cohort study centre in Vancouver. [??] CPAC, "Canadian Cancer Cohort Proposal," p. 54.

<sup>21</sup> All of this information in this section is from BC Biobank V1.3, October 15, 2008.

<sup>22</sup> All of this information in this section is from BC Biobank V1.3, October 15, 2008.

Columbia.<sup>23</sup> The LHDB has the capability to create longitudinal health histories of all residents of the province back to 1985. Included in the resource are hospitalization and procedures, physician visits, prescription information, cancer diagnoses, long term care, and birth deaths and marriage data.<sup>24</sup> The LHDB is now part of Population Data BC. Linkage of information from cohort participants (with their written consent) with information from the linked health database will allow useful research to be immediately conducted on how previous medical history impacts on the chronic health conditions present in participants at the time of recruitment. This will ensure value to the BC Generations Project data long before the resource ‘matures’ in 7 to 10 years time.

#### 4. Architecture and Data Flows for the BC Generations Project

- Recruitment for the BC Generations Project will eventually involve a cooperative program between the BC Ministry of Health Services and the BC Cancer Agency to identify an appropriate sample of respondents. It is anticipated that the Ministry will play the lead role in this process of sampling and sending out the letters of invitation. See below.
- Up to 400,000 BC residents age 40-69 years will be invited by letter to come to a Generations Project assessment centre for an appointment.<sup>25</sup> The goal is to have a pool of 40,000 that are willing to participate. The letter to each potential subject will contain a unique but meaningless cohort identification number. These numbers will be generated and printed on letters as they are sent out.
  - Based on 2005 BC census data indicating a population of 1.7 million aged 40 to 69 years, one in four in this group of adults may receive an invitation to participate over at least a three-year period.
- As negotiations with the Ministry concerning sending out letters on behalf of the BC Generations Project are still underway, and milestones for continued funding by CPAC must be met, initial recruitment of subjects will proceed using direct mailing and random digit dialing.
- Direct mailing: Letters addressed to individuals resident within the 16km diameter catchment area of the assessment centre will be sent out in batches of between 500 and 5,000 depending on response rates from this technique. The initial mailing will be to 500 people. The letter will include a brief description of the project, and an invitation to either call or e-mail the BC Generations Project to join. Participants will be able to find out more information either by contact with Generations, or by looking up more on the website. The website is under construction ( [www.bcgenerationsproject.ca](http://www.bcgenerationsproject.ca) ). If individuals are age-eligible and are interested in joining the project they will be invited to come to the assessment centre at a booked appointment time. Names for direct mailing are provided by Info Canada Ltd directly to PDQ Print Solutions Ltd, who package and mail invitations to potential participants.
- Random digit dialing: telephone calls to residences within roughly 16km of the assessment centre will be made by eNRG Research Group Ltd in Vancouver. A

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<sup>23</sup> See <http://www.chspr.ubc.ca/node/3> CHSPR is currently merging with Population Data BC.

<sup>24</sup> CPAC, “Canadian Cancer Research Proposal,” p. 13.

<sup>25</sup> Data from Statistics BC will be used to determine the best locations for the Cohort Recruitment Centres.

recruitment script has been written which interviewers will use to describe the purpose of the project and ask whether age-eligible respondents within the residence would be interested in participating in the project, and whether an information package could be sent to the home. The telephone interviewer will have access to answers for frequently asked questions, and will be referred to the BC Generations Project Director (Dr. Marilyn Borugian) for answers to more complicated questions, or to verify the legitimacy of the invitation. Random digit dialing of residences is expected to begin in June 2009.

- When individuals receive the invitation letter (direct mailing) or the information package (random digit dialing), they may choose to call or email to book an appointment; at that point, staff at a “back office” call centre will collect their data and then send them a confirmation letter, which will contain the unique cohort number, appointment date and time, directions, etc.<sup>26</sup>
- When participants arrive at the assessment centre with their letter of confirmation, they will be asked to identify themselves, and their unique cohort number will be confirmed, as well as their name, address, and telephone number, on the assessment centre server. Each will be asked to sign an informed consent forms, will be asked to complete an etiologic questionnaire, on a touch-screen computer, have several physical parameters measured (sitting height, standing height, weight, waist and hip measurements, blood pressure, bone density, lung function, body composition, grip strength), and have a 40 ml blood specimen and a urine specimen taken. The Generations Project may also ask that participants bring a toe nail sample with them and may ask for a saliva sample. The UK Biobank has successfully used an analogous process with a mean appointment time of about 90 minutes per subject.<sup>27</sup>
- Questionnaire information collected at the BC Generations Project Assessment Centres will be entered directly in electronic form in order to minimize paper-based instruments and to promote data quality. Paper-based collection will occur only as a back-up procedure in the rare occurrences in which electronic collection breaks down.<sup>28</sup>
- Personal information will be stored in secure electronic form at the assessment centre and transferred to the BC Cancer Agency daily in password protected and encrypted files. Personal identifying information (name address and phone number) will then be stripped off; only the participant’s unique cohort identification number will be maintained on the file containing questionnaire responses and physical measurements. Consent, participant name, address, and phone number, along with the cohort identification number, will be stored in an encrypted form in a separate password protected file on a different server at the BC Cancer Agency. This key file will be transferred to a separate zip drive, which will be kept temporarily in a safe within the BC Cancer Agency with extremely limited access to it.<sup>29</sup> In order to facilitate follow-up activity, a separate copy of the identifiers, information, and linkage key will be made with each submission of data to Population Data BC on a password protected and encrypted flash drive, which will be stored in a secure vault by Iron Mountain Ltd. or an equivalent escrow agency.

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<sup>26</sup> There is no room to house the actual study at the BC Cancer Research Centre.

<sup>27</sup> BC Biobank V1.3, October 15, 2008. See [www.ukbiobank.ac.uk](http://www.ukbiobank.ac.uk)

<sup>28</sup> BC Biobank V1.3, October 15, 2008.

<sup>29</sup> BC Biobank V1.3, October 15, 2008.

- Agreement has been reached in principle with Population Data BC to enable information from cohort participants to be stored permanently at its secure long-term storage site at the University of British Columbia. See below.

## Personal Data Collection for the BC Generations Project

### 5. Statutory Authorities for the Collection, Use, and Disclosure of Personal Information for the BC Generations Project

- As a public body, the BC Cancer Agency will collect, use, disclose, and retain personal information for the BC Generations Project under the protective umbrella of the BC *Freedom of Information and Protection of Privacy Act (FIPPA)* and subject to the independent oversight of the Office of the BC Information and Privacy Commissioner.<sup>30</sup>
- The BC Generations Project will collect personal information on the basis of section 26(3) of FIPPA.<sup>31</sup>
  - A Research Information Regulation for the BCCA under Section 9(1) of the BC *Health Act* lists the information that it may collect “relevant to medical research into the prevention, causes, diagnosis, treatment and outcomes of cancer or its precursor lesions and includes records containing that information.” Broad categories include personal identifiers; family identifiers; health identifiers; records from medical laboratories, imaging services, hospitals and other health facilities and physicians; mortality and morbidity data including autopsy reports; and factors which influence the occurrence of cancer in human populations (ethnicity and medical history).<sup>32</sup>
- The BC Generations Project will disclose personal information only as authorized under sections 33.1 and 33.2 of BC *FIPPA*.<sup>33</sup> Almost none of these detailed provisions authorizing disclosure will apply to the deidentified, linked data held for the Generations Project by Population Data BC, which are intended only for research and statistical uses authorized under section 35 of BC *FIPPA*. The Generations Project will never disclose identifiable personal information.
- The Generations Project will always act as if the data in its custody and control are potentially identifiable and will thus take all reasonable and prudent precautions to protect the security of the data at all times, especially through the highly-secure premises of Population Data BC on the campus of UBC.
- For the BC Generations Project, participants will have consented to the collection, use, disclosure, and retention of their personal information in both identifiable (solely and exclusively for purposes of re-contact) and anonymized form (with a unique identifier permitting ongoing linkages of relevant personal information about the individual under strictly controlled conditions).

<sup>30</sup> BC Biobank V1.3, October 15, 2008.

<sup>31</sup> “No personal information may be collected by or for a public body unless ... (c) that information relates directly to and is necessary for an operating program or activity of the public body.” See

<http://www.oipcbc.org/legislation.htm>

<sup>32</sup> [http://www.qp.gov.bc.ca/statreg/reg/h/health/286\\_91.htm](http://www.qp.gov.bc.ca/statreg/reg/h/health/286_91.htm)

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[http://www.oipcbc.org/legislation/FIPPA/Freedom\\_of\\_Information\\_and\\_Protection\\_of\\_Privacy\\_Act\(May\\_2008\).htm#section33.1](http://www.oipcbc.org/legislation/FIPPA/Freedom_of_Information_and_Protection_of_Privacy_Act(May_2008).htm#section33.1)

- Recent amendments to *FIPPA*, which are not yet in force, permit contact and re-contact with individuals.

## 6. Consent, Recruitment, and Re-contact Issues for the BC Generations Project

- Within the larger centres (Vancouver and Victoria), initially using direct mailing, or random digit dialing techniques as described above invitations to join the BC Generations Project will issued. Once negotiations are concluded it is hoped that the BC Ministry of Health Services will use one of its registration databases to identify a sample of potential participants within a 16 km diameter circle of the assessment centre.<sup>34</sup> This practice will require the review and agreement of the BC Information and Privacy Commissioner. The Ministry will be asked to mail invitations (or to release information under secure conditions to an organization, such as MAXIMUS BC Health, which will mail invitations (and then destroy the names) to participate to potential participants aged 40-69 years in batches of up to 4-5,000 letters weekly.<sup>35</sup>
- The letter of invitation will outline the purposes of the BC Generations Project and describe what would be required of the participants (Invitation to Join a Medical Research Project-Appendix 1). An Information and Consent Pamphlet will describe, in a transparent way, how data and specimens would be taken and used, the risks and benefits involved, the privacy and ethics oversight in place, and invite the potential participant to come into the local assessment centre. (See appendix 1 below). If the potential participant needs further information or wishes to discuss the project prior to making a decision as to whether to come in, he/she is invited to call the assessment centre.<sup>36</sup>
- The contact mailing will include a reference to the Generations Project's website for additional information. Interested parties will be asked to contact the project office by telephone (toll free for those outside the local area) or email to make an appointment to come to an assessment centre.<sup>37</sup>
- The letter of invitation will say that the invitation is random and not based on access to any health information of the recipient.
- The potential participant will not be asked to mail back the consent form. It will be completed electronically when the participant comes to the centre for an appointment. This process will involve both "consent to treatment" and information consent.<sup>38</sup> At that time a barcoded unique (but meaningless) cohort identification number will be issued to identify participants as they move through the assessment centre if they choose to participate.
- Discussion of consent at the national level included the following concerns: "... information and consent forms must be broad enough to cover the potential research for which data and specimens are used, yet be specific enough to constitute true informed consent on the part of participants. Failure to carry out the due diligence on these issues at the project outset can result in costly and time-consuming re-consenting procedures,

<sup>34</sup> The intention in the four provinces of Atlantic Canada is that identification of potential participants will be through the Provincial health card number system and initial contact will be made either by telephone or by letter, depending on the outcome of pilot studies. CPAC, "Canadian Cancer Cohort Proposal," p. 11.

<sup>35</sup> BC Biobank V1.3, October 15, 2008.

<sup>36</sup> BC Biobank V1.3, October 15, 2008.

<sup>37</sup> BC Biobank V1.3, October 15, 2008.

<sup>38</sup> BC Biobank V1.3, October 15, 2008.

and perhaps in extreme cases being unable legally or ethically to carry out important research.”<sup>39</sup> The intention in British Columbia is for the Generations Project to get its own house in order from a privacy and data protection perspective in compliance with provincial law, policy, and ethical guidelines.

- At entry into the cohort, potential participants will not be accepted unless they are willing to give informed consent, complete the etiologic questionnaire, donate a blood and urine sample, and give consent to follow them over time through linkage with routinely-collected health and vital statistics data collected by the Ministry of Health Services and the Vital statistics Agency (and held at Population Data BC), and the BC Cancer Registry (within the BC Cancer Agency).
- Generations Project participants will have the right to withdraw from the project at any time.<sup>40</sup>
- A participant may choose between two forms of withdrawal after previously consenting to participate in the Cohort:
  - The first would allow no further contact and no access to further participant health information through linkage to Ministry of Health databases;
  - The second would be complete withdrawal, including destruction of any information and specimens within the Cohort.<sup>41</sup>
- In order to maximize the value of the BC Generations Project over its useful lifetime, **further contact** will be required with subsets of participants within the Cohort, because risk factors for disease will continue to be discovered in studies throughout the world. These lifestyle, occupational, and environmental factors (which were unknown at the time of recruitment) may be critical in determining risk of disease, and failure to incorporate such new information into the cohort will rapidly make the platform unable to answer new questions concerning the etiology of chronic diseases. Participants will have to consent to be re-contacted in this manner. Collection of new information, or updating of older information, will proceed in the same fashion as outlined above in the section on short-term storage of participant information and, at the conclusion of data acquisition, the encrypted files will once more be returned to Population Data BC. At all phases of the study a new copy of the data will be made monthly on a flash drive and will be placed in a secure vault in case of catastrophic event at Population Data BC.<sup>42</sup>
  - All re-contact with participants will be in the form of a written communication asking for either further information on aspects of their lifestyle (for instance, new dietary factors) or their environmental exposures (for instance to sunlight, or new occupational carcinogens). Actual data collection may be done using computer-aided telephone interviews (CATI), on-line or postal instruments. Re-contact might also request donation of a further specimen (for instance, fingernail clippings or a lock of hair for assessing body burden of heavy metals) as scientific knowledge advances. Participants will always be free to refuse such further contact, because, for example, of illness or a major geographic relocation, or for any other reason. Any contact with participants for the

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<sup>39</sup> CPAC, “Canadian Cancer Cohort Proposal,” pp. 30-31.

<sup>40</sup> The proposal for the national cohort made the following statement on this issue: “Total withdrawal from the cohort (i.e. accompanied by a request that baseline information not be used) will be rare. Experience to date in Alberta’s *Tomorrow Project* indicates that this assumption is likely to hold true.” CPAC, “Canadian Cancer Cohort Proposal,” p. 33.

<sup>41</sup> BC Biobank V1.3, October 15, 2008.

<sup>42</sup> BC Biobank V1.3, October 15, 2008.

purposes of obtaining new information or specimens will require full approval by the UBC Research Ethics Board prior to implementation. Such REB approval will not be sought for information exchange (newsletters, responses to queries, etc) with the participants.

- In order to facilitate maintenance of re-contact with cohort members, participants will be asked for the name, address, and phone number of a close personal friend who will always know the whereabouts of the participant should a move take place. This is a standard practice in longitudinal surveys.<sup>43</sup>
- For the Alberta Cohort Study (The Tomorrow Project), 98% of participants to date (30,000) consented to linkages with databases held by the Alberta Cancer Registry and the provincial health ministry (Alberta Health and Wellness).<sup>44</sup>

## 7. Personal Information Collected for the BC Generations Project

- At entry into an assessment centre, potential participants will be asked to go through a number of steps:
  - 1) They will be asked to read the Participant Information and Consent Form (Appendix 2) and to ask any questions about the implications of participation. They will then be asked to sign the electronic information and consent form, which will describe the project and an itemized list of procedures for participants to agree to participate in as follows:
    - a) Completion of the baseline information questionnaire. This questionnaire is based on the instrument successfully used in the Alberta “Tomorrow” cohort. To date some 30,000 Albertans have completed this with no major difficulties.
    - b) Donate a blood sample (40 ml or about 3 tablespoons) to provide the project with DNA, serum, and plasma for the individual.
    - c) Undergo a set of non-intrusive baseline measurements (height, weight, waist and hip circumference, respiratory function, blood pressure, bone density, and grip strength).
    - d) Allow access to past and future health information through linking with routinely collected Ministry of Health databases for research and statistical purposes only. Examples of such information include records of physician visits, hospital admissions, cancer diagnoses, deaths, etc.
    - e) Allow the BC Generations Project to store their specimens and information and utilize them (even after death or disablement) anonymously for bona fide research projects.<sup>45</sup> This consent would mean that anonymized information and specimens of individuals could be used for approved projects (of high scientific merit and with Research Ethics Board approval) by scientists throughout Canada and potentially the world., including commercial research groups, such as drug companies.

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<sup>43</sup> The Tomorrow Project (Alberta Cohort Study) of the Alberta Cancer Board asks for two such contact persons. See [http://www.cancerboard.ab.ca/tomorrow/Study\\_FAQs.htm](http://www.cancerboard.ab.ca/tomorrow/Study_FAQs.htm)

<sup>44</sup> CPAC, “Canadian Cancer Cohort Proposal,” p. 7.

<sup>45</sup> Bona fide means critically reviewed and approved by a Research Ethics Board constituted under the Tri-Council Guidelines and in compliance with applicable law. See Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans (Interagency Secretariat on Research Ethics, Ottawa, 2005), at [http://pre.ethics.gc.ca/english/pdf/TCPS%20October%202005\\_E.pdf](http://pre.ethics.gc.ca/english/pdf/TCPS%20October%202005_E.pdf)

- f) Allow cohort personnel to re-contact them in the future to collect further information or specimens. In the area of new environmental factors, for example, a task force will report back at the end of 2009 or in early 2010 on new ways to assess environmental exposures to potentially carcinogenic chemicals and other physical agents that affect risk of cancer, heart, neurological, and other diseases. This will mean that participants may need to be re-contacted and re-consented for new tests or information on the basis of new insights into research possibilities as noted earlier in this Privacy Impact Assessment.
- o The basic questionnaire of the Canadian Partnership for Tomorrow collects personal information under the following broad areas of interest: personal history of cancer and other diseases (using standardized questions adapted from those used successfully in various health surveys including the Alberta “Tomorrow” cohort); female reproductive health; family history of disease; life habits and behaviour (alcohol consumption, cigarette smoking); physical environment, including residential history and usual occupation;<sup>46</sup> socio-demographics; diet;<sup>47</sup> physical activity; new environmental factors. Physical measurements will also be made including weight, height, waist and hip circumference,<sup>48</sup> bioelectrical impedance (measuring lean body mass versus fat with a small electrical current passing through the body), bone densitometry, blood pressure, hand grip strength, and spirometry (a measurement of respiratory health).<sup>49</sup>
- o As noted above, the BC Cancer Agency will anonymize personal information collected from cohort participants at assessment centres, leaving only the participant’s unique study number as the basis for future re-contact and accurate record linkages.
- o At the assessment centres, blood and urine specimens will be taken into barcode numbered tubes and stored under refrigeration until the end of the day. The barcoded tubes will only be linked to the participant through a reader that scans the barcode number into the participant’s electronic file.
- o A small tube of blood will also be collected and stored to ensure a future supply of constitutional DNA on study participants. Specimens will be barcoded with the participant’s unique study number only; no other identifying information will be maintained on the tubes. The specimen collection data, with participant unique study ID, will be stored on a separate server from the questionnaire data at the BC Cancer Agency. The same electronic key used for questionnaire data will enable linkage with the participant’s identity. The key will be stored under password protection in an encrypted fashion on a third server.<sup>50</sup>

## 8. Location of the Personal Data for the BC Generations Project

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<sup>46</sup> These will include current address, residence at birth, and a residence history. Current address will allow researchers to explore multiple potential environmental risk factors by linking records anonymously with various Canadian national ecological databases (while maintaining the confidentiality of individual information).

<sup>47</sup> The availability of biological samples in the Canadian cohort resource will allow the direct measurement of the levels of many biomarkers of interest. Since biomarkers do not necessarily reflect true intakes and are not available for many dietary items, questionnaire methods must also be employed. The Canadian Cohort approach will seek a 3 day food diary from selected participants, which they can complete and return at their own convenience with the usual measures in place to provide for anonymization upon receipt.

<sup>48</sup> Participants will only be required to remove bulky clothing (for instance winter coats) to facilitate measurement.

<sup>49</sup> BC Biobank V1.3, October 15, 2008.

<sup>50</sup> BC Biobank V1.3, October 15, 2008.

- Personal information of cohort participants will be stored in secure electronic form in a dedicated server at the assessment centre and transferred to the BC Cancer Agency daily in password protected and encrypted files. An electronic key linking participant name, address, and phone number, with the cohort ID number (same as the unique study number), will be stored in an encrypted form in a separate password protected file on a different server. Monthly this key file will be transferred to a separate zip drive, which will be kept in a safe within the BC Cancer Agency with extremely limited access to it.<sup>51</sup> (See appendix 3 below).
- Discussions are underway with Population Data BC to enable all data from Generations Project participants to be stored at its secure long-term storage site at the University of British Columbia in order to facilitate authorized record linkages there, for research and statistical purposes only, for those who have given consent and not revoked it.<sup>52</sup>

## **9. Data Storage/Retention/Destruction for the BC Generations Project**

- With respect to long-term storage of study data, the BC Generations Project is arranging to store participant data, participant identifying information, and participant key file linking ID and study number at the Population Data BC facility at the University of BC, which features exceptional security measures. See below.
- In the event of the cancellation of the BC Generations Project, the BC Cancer Agency would likely maintain the database and specimens as a valuable resource and do annual linkages through Population Data BC using grant funding from the Canadian Institutes of Health Research (CIHR), Canadian Cancer Society Research Institute , etc.

## **10. Access Rights for Individuals to their Personal Information in the BC Generations Project**

- As provided for in section 29 of BC *FIPPA*, individuals have a right to access and correct their personal information held in the BC Generations Project. Since basic personal information is being collected from the individual in the first instance, the need for correction or annotation of a record will likely be minimal.<sup>53</sup>
- In reality, individuals will have only limited access to their basic personal information once it has been entered into the Generations Project, since it will be essentially anonymized, non-identifiable, and coded with a linkage key in order to protect the privacy of individual participants during the research processes. Re-identification for administrative purposes is contrary to the intent of the Generations Project.
- The data on Generations Project members held at Population Data BC are deliberately not identifiable in the normal course of events. Software will likely make it impossible to search for the records of a particular person; it will only facilitate ongoing linkages.
- Another major problem with allowing people to access and potentially modify their data is that at no time will participants' information, as given at recruitment, be considered 'fixed' for the purposes of analysis. For example, it is well known that data collected in retrospective case-control studies are open to 'rumination bias,' as those who develop disease begin to ask themselves 'why did this happen.' If these individuals were to

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<sup>51</sup> BC Biobank V1.3, October 15, 2008.

<sup>52</sup> See [www.popdata.bc.ca](http://www.popdata.bc.ca)

<sup>53</sup> In practice, the right of correction actually means a right to annotate a record that a person believes is inaccurate.

access their cohort data and change them based on such ruminations, a systematic bias would result, since those without disease are substantially less likely to modify their data. This systematic bias would surely compromise the value of the data for investigation of the etiology of disease. One of the major methodological advantages of the prospective cohort study over the retrospective case control study is that information is collected before disease develops, thus reducing the possibility of study results being affected by such bias.

- A further concern might be that if insurance companies knew that individuals were in the Generations Project and had access to their own health information, they might demand a copy of an individual's profile as a condition of insurance. The Generations Project does not collect clinical information for use as such. The data are experimental in character for research and statistical purposes only. Hospitals and physicians have the most valid data about individuals, who will be encouraged to access their personal information through there.

## **11. Uses and Disclosures of Personal Information from the BC Generations Project**

- All uses of data held in the BC Generations Project will be for research and statistical purposes only and in compliance with what BC *FIPPA* authorizes and permits. This will only begin to occur after a number of years of data collection and linkage. The model of the UK Biobank will be adapted to Canadian circumstances under the Tri-Council guidelines, current ethical and legal requirements, and overall best practices. The ELSI group is developing the protocol and access rules for Canada.
- The standard practice will be for particular research projects from Canada and abroad to apply to the BC Generations Project to use anonymized data only on a particular group of persons. An example would be a research project examining how particular exposures affect risk of developing a particular type of cancer, while controlling for other variables known about individuals developing such a cancer. Re-identification will be both almost impossible and prohibited by written agreement. The research team will only be interested in what can be learned from a sample of perhaps 1,000 cases, where only 200 to 300 of them would be from the BC Generations Project.
- The principal investigators of the five provincial cohorts are currently developing a protocol for health researchers to apply for use of data from the BC Health Cohort. The work is being chaired by Dr. Bartha Maria Knoppers of the Université de Montréal.<sup>54</sup>
- Researchers will not be permitted by their research agreement to attempt to re-identify or to contact participants. The access process will include preparation of a full research protocol by all scientists wishing to use the data, including principal investigators of the provincial cohorts. Access will further require that the protocol be approved by the scientist's local bona-fide Research Ethics Board, and it will also be examined by an independent cohort committee for scientific validity and scientific importance. Every effort will be made to make the rules on usage open, transparent, and fair to all researchers.

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<sup>54</sup> Dr. Knoppers is a Law Professor and Senior Researcher at the Centre for Public Law Research, Université de Montréal, and holder of the Canada Research Chair in Law and Medicine. See <http://www.humgen.umontreal.ca/int/team.cfm?id=9>

## Privacy Standards: Concerns and Security Measures

### 12. Privacy Risk Management for the BC Generations Project

- The intent of the Canadian Partnership for Tomorrow Project is to operate “under the highest standards of ethics, privacy and confidentiality.”<sup>55</sup> These will include training on privacy and confidentiality for Generations Project staff, in addition to signed and witnessed confidentiality agreements. In addition, there will be minimization of use of paper files containing either personal identifiers or participant information, use of touch screen technology for questionnaire completion whenever possible with immediate transfer to secure server storage, and use of physical security (locked rooms for computer terminals when data are stored long term at Population Data BC). All stored files will be encrypted and password protected with individual passwords enabling audit trails. Specimens will be barcoded with no personal identifying information appearing on ampoules in storage.
- The proponents of the Canadian Partnership for Tomorrow Project have concluded that the UK Biobank approach to collecting data and specimens is the optimum way of actually collecting data and specimens on a day-to-day basis. Its protocol, information and consent forms, and the reports of their pilot studies will continue to influence BC practices.<sup>56</sup>
- The Canadian Cohort Steering Committee will be responsible for the overall direction of the national cohort study with a National Coordinator already in place (who has already been managing the Alberta Tomorrow project). In the first two years of the Canadian Cancer Cohort, its Task Force on Ethics, Legal, and Social Issues (ELSI) will examine governance issues surrounding the Canadian Cancer Cohort and make recommendations on permanent governance structures.<sup>57</sup>
- A working group at the national level is developing consent, privacy, and confidentiality standards and addressing ethical and legal issues for all aspects of the Canadian Cancer Cohort. The ELSI task force is working currently to develop interoperable recruitment and access documents and to deal with legal issues surrounding data sharing arising from the different laws in place in each province. Dr. Knoppers is also directing this task force.<sup>58</sup>
- A member of the BC Generations Project team will have the title and responsibilities of being its Chief Privacy Officer. The role is primarily one of giving privacy advice to responsible senior management, the cohort team, members of the public, and the media and monitoring for compliance. The BC Generations Project will also have an external Chief Privacy Advisor to give advice upon request and to act as a sounding board. The latter should also conduct periodic privacy audits and site visits to monitor compliance, since critics, including privacy fundamentalists, will be concerned about whether initial good steps are followed over a long time.
- The BC Cancer Agency already has a privacy risk management plan in place for its multiple research activities. Systematic privacy management includes such key

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<sup>55</sup> CPAC, “Canadian Cancer Cohort Proposal,” p. 11.

<sup>56</sup> See [www.ukbiobank.ac.uk](http://www.ukbiobank.ac.uk)

<sup>57</sup> CPAC, “Canadian Cancer Cohort Proposal,” p. 24.

<sup>58</sup> CPAC, “Canadian Cancer Cohort Proposal,” pp. 24, 26, 30. See also pp. 31-32.

components as a Chief Privacy Officer with appropriate human and financial resources to do the job, a Privacy Team, a privacy law, general and specific privacy Policies and related procedures and processes, Privacy Impact Assessments as appropriate, on-line privacy training, robust security practices, and meaningful confidentiality agreements.<sup>59</sup> A BCCA confidentiality policy is in place along with a confidentiality pledge that employees sign. Computer security policies in place include encryption of any identifiable information taken off BCCA premises, individual password for audit trails, etc. [Cite the Privacy Policy?]

- BCCA also has a Research Ethics Board, which is a branch of the University of BC Research Ethics Board and adheres to all of the standards of that Board. Approval by the University of British Columbia (UBC)/ British Columbia Cancer Agency (BCCA) Research Ethics Board is also a full approval by the UBC REB. The board is chaired by Dr. George Browman and includes physicians, scientists, several lawyers not affiliated with BCCA, and 2 outside community members. The members from outside BCCA have full voting privileges.
- Recruitment for the BC Generations Project will only start in 2009, and with relatively small numbers in the first instance, so there is appropriate time to test the privacy risk management framework and practices that the BC Generations Project is putting in place.
- Since this Generations Project involves physical privacy issues, the BC Cancer Agency has anticipated their management in the project protocol. For example, for urine samples participants will provide the specimen in a locked washroom, place the plastic collection vessel in an opaque plastic bag, and deposit the bag in a collection rack at the door before leaving the assessment centre.<sup>60</sup> Individuals who choose to participate in the Generations Project will enter their own responses to the questionnaire on a screen; the process will take about half of the ninety minutes that they spend at the assessment centre. Responses to the questionnaire will be recorded and transferred electronically in coded and encrypted form. Staff members will not therefore be able to review participant responses to any questions. The data in the on-site server will be downloaded daily to the main servers at BCCA in a secure manner.
- The personal information and data collected from Generations Project participants will not be used for decision-making affecting the particular individual. The fact that the Generations Project only contains research and statistical data is a critical issue for ensuring privacy and data protection for participants. Participants will receive the results of the physical tests administered on site at the assessment Centre, which might include a recommendation to contact their physicians. Even if a health condition was observed at the assessment centre, the staff would only suggest to the person that he or she visit their family doctor and, for example, have their blood pressure tested. The assessment centre is not doing clinical tests as such but research tests. The Generations Project is currently finalizing Standard Operating Procedures for conducting and reporting back to participants on physical tests.
- With advances in science, the concern is what the BC Generations Project would do if serious issues were identified for a specific participant or a group of participants, at the initial point of contact and/or further down the road. BC *FIPPA* imposes a duty to warn

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<sup>59</sup> See Guidelines for Managing Privacy, Data Protection and Security for Ontario Hospitals (A Report prepared by the Ontario Hospital eHealth Council's Privacy and Security Working Group – July 2003). [www.oha.com](http://www.oha.com).

<sup>60</sup> BC Biobank V1.3, October 15, 2008.

- on BCCA as a public body.<sup>61</sup> Such health warnings could be in the aggregate. The Generations Project is working on this issue through the harmonization protocol.
- The Generations Project's Laboratory Information Management System (LIMS) will be able to positively link all specimens to the participant's unique study number and hence to his/her information without use of any additional personal identifying information.
  - During conduct of the recruitment phase of the Generations Project (at least five years), data will be stored on three servers at the BC Cancer Agency's Cancer Control Research Program. See appendix 2 below. The mailing and appointment database will be maintained on a password protected and encrypted server. Only named appointment clerks and programmers will have authorized access. Each log-on to the database will result in an audit trail delineating time of log-on and log-off and the name of the staff member seeking access.<sup>62</sup>
  - As participants move through the assessment centre, their questionnaire responses and measurement results will be collected using their unique study identification number allocated at invitation. This information will be maintained on a second server, with independent passwords, encryption, and user access trails.<sup>63</sup> See appendix 2 below. The goal is to audit constantly with machines watching machines, and security staff being notified when intervention is required to explain suspicious behaviour.
  - Further, the key which allows linkages among the name, address, and phone number of each participant and his/her unique cohort identification number will be resident on a third server, again with independent password protection, encryption, and audit trail capability. At the end of every month the data on the BCCA servers will be transferred to the Population Data BC site using an encrypted secure download.<sup>64</sup>
  - Discussions are currently underway with Population Data BC on the nature of the relationship to be established with the BC Generations Project for purposes of performing authorized record linkages and long-term data storage. The most likely relationship will be to frame Population Data BC as a service provider to the Cohort; however, other closer relationships are also being discussed. Population Data BC will also have information sharing agreements with, for example, the BC Ministry of Health Services. The BC Cancer Agency will be the public body contracting for the services of Population Data BC, which is a component of another public body, the University of British Columbia. Each is bound to comply with BC *FIPPA* and the oversight of the Office of the Information and Privacy Commissioner. More importantly, each has a reputation to protect vigorously as a secure custodian of sensitive personal information for research and statistical purposes only.
  - The BC Cancer Agency, on behalf of the BC Generations Project, will ensure that all service providers are required to comply with an enhanced and customized version of the BC Privacy Protection Schedule. See appendix 3 below. It should be "completed and attached as a schedule to any contract between a public body and a contractor under which the contractor will be collecting, creating, using, disclosing or storing "personal

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<sup>61</sup> According to section 25(1) of BC *FIPPA*, "the head of a public body must, without delay, disclose to the public, to an affected group of people or to an applicant, information (a) about a risk of significant harm to the environment or to the health or safety of the public or a group of people, or (b) the disclosure of which is, for any other reason, clearly in the public interest." The BC Cancer Agency is a public body; its Chief Executive Officer is its head. It is also an agency of the Provincial Health Services Authority, one of the provincial health authorities.

<sup>62</sup> BC Biobank V1.3, October 15, 2008.

<sup>63</sup> BC Biobank V1.3, October 15, 2008.

<sup>64</sup> BC Biobank V1.3, October 15, 2008.

information" (as defined in the *FOIPP Act*) unless it is not intended that the public body will own or control the personal information.”<sup>65</sup> The BC Generations Project should also ensure that contracting service providers understand the implications of what they are signing. The contracts with service providers will include the requisite privacy and security rules, including a revised BC Privacy Protection Schedule as an appendix.

- The BC Generations Project will adopt a privacy breach notification procedure inspired by the guidance offered by the Office of the BC Information and Privacy Commissioner.<sup>66</sup>

### **13. Record Linkages as a Privacy Issue for the BC Generations Project**

- The BC Generations Project will naturally involve an expansive amount of record linkages of identifiable personal information about specific individuals who have agreed to participate in the Generations Project on an ongoing basis. Their personal information will continue to be linked over time for research and statistical purposes only, which will not have a targeted impact on specific individuals in the Generations Project.
- Linkage will occur on the basis of unique identifiers using personal information that is essentially non-identifiable to unauthorized parties, including staff of the Generations Project and researchers.
- As noted above, discussions are underway with Population Data BC to enable information from cohort participants to be stored at their secure long-term storage site at the University of British Columbia. This would facilitate linkage with other health information within Population Data BC, on a proposal-by-proposal basis, and after REB review, to answer specific health research questions. Approved researchers could then use the anonymous linked data files to investigate the relationship between environmental, lifestyle and susceptibility factors and chronic diseases.<sup>67</sup> Population Data BC operates a highly-secure facility for these particular purposes.
- Use of the BC Linked Health Database (LHDB) and the data resources of Population Data BC for the BC Generations Project: “It is the intent of the team to be able to link these resources on a systematic basis with the data of cohort participants to investigate how the interaction between individuals’ social and life trajectory, lifestyle and environmental exposures, and genetic make-up affect risk of developing cancer and other chronic diseases. In order to preserve privacy and confidentiality, data will remain in separate databases with individual records labelled with unique linkage identifiers. This technique has been used successfully by the BC LHDB for more than 10 years, and meets the requirements of the Freedom of Information and Protection of Privacy Act.”<sup>68</sup> Such linkages will take place both systematically and on a project-by-project basis. Routine linkages will keep the data more up to date, will facilitate quicker access, and will allow detection of relationships of public health importance to the people of BC much earlier than on a project-by-project basis. It appears through discussions with Population Data BC that these routine linkages would be permitted.

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<sup>65</sup> [http://www.cio.gov.bc.ca/services/privacy/Public\\_Sector/contracting/privacy\\_protection\\_schedule/default.asp](http://www.cio.gov.bc.ca/services/privacy/Public_Sector/contracting/privacy_protection_schedule/default.asp)

<sup>66</sup> See [http://www.oipc.bc.org/pdfs/Policy/Privacy\\_Breach\\_Checklist\(June2008\).doc](http://www.oipc.bc.org/pdfs/Policy/Privacy_Breach_Checklist(June2008).doc)

<sup>67</sup> BC Biobank V1.3, October 15, 2008.

<sup>68</sup> CPAC, “Canadian Cancer Cohort Proposal,” p. 13.

- After collection of blood and urine samples from individuals, the unique barcode on each one will be scanned into the assessment centre IT system in order to link each vacutainer with the unique participant identifier number. This is critical to link the participant interview and measures data from the assessment centre with the Laboratory Information Management System (LIMS). LIMS keeps track of what specimens have been provided by a participant, how they have been processed, and where they have been stored.<sup>69</sup>

#### 14. Security Safeguards for the BC Generations Project

- The intention is to have robust security in place at the BC Cancer Agency's Research Centre for the protection of personal information collected, used, disclosed, and retained for the Generations Project. Discussions and planning are underway, and consultations have occurred with the UK Biobank. The intention is to purchase new servers only for use for this study and to store them in a secure room. These servers will be housed within the existing secure network of the Research Centre, which already features strong passwords, firewall protections, and audit trail capacity. These will likely be enhanced for the Generations Project because of the sensitivity of the personal information being collected over time. Only project staff with a need to know will have access to the project's own servers. Data stored within the servers will be encrypted. Identifiers will be stored separately and securely from the content data (as noted elsewhere in this PIA). Data transfers from the assessment centres will also be secure and the data encrypted.<sup>70</sup>
- The BC Generations Project intends to give serious consideration to adoption of each of the points in the BC Government Chief Information Officer's Information Security Policy, Version 2.1, March, 2008 (278 pp.).<sup>71</sup> The Generations Project will also review the forthcoming security diagnostic tool from the Office of the BC Information and Privacy Commissioner and generally aspire to meet the standards of the current ISO17799 international security standard.<sup>72</sup>
- The intent of the Generations Project will be to commission a Threat Risk Assessment (TRA), or equivalent, for its security plans and keep it evergreen.
- The Population Data BC facility at the University of British Columbia will be used for authorized record linkages and long-term data storage. It has established strict parameters of data security, including a locked physical plant within which all of the facility's computers are kept, further locked doors within the plant (Red zone) within which all personal identifying information is kept, and access to the 'red zone' restricted to a small number of named computer programmers. Sign-on to any computers in Population Data BC leaves an audit trail linked to an individual programmer or investigator. Furthermore, computers within the personal information or 'red zone' use a different set of servers than those on which health data are stored. The system does not permit any data carrying personal identifying information to be released outside the 'red zone.' Anonymized data abstracts released to bona fide investigators are held in a distinct workspace cut off electronically from the red zone and from the servers carrying health data. Investigators conduct analyses using Virtual Personal Networks. Additional details are available from

<sup>69</sup> BC Biobank V1.3, October 15, 2008.

<sup>70</sup> Telephone interview, Dr. Tim Lee, Senior Scientist/Computer Scientist, BC Cancer Agency, July 25, 2008.

<sup>71</sup> <http://www.cio.gov.bc.ca/legislation/policy/isp.pdf>

<sup>72</sup> See <http://www.iso.org/iso/home.htm>

the Privacy Impact Assessment prepared for Population Data BC.<sup>73</sup> See also <http://www.popdata.bc.ca/privacy>

- The freezers and vapour phase liquid nitrogen containers for specimens will be stored at the BC Cancer Research Centre or at the Genome Sciences Centre, also a division of BCCA. This facility has on-site security during working hours. Access to floors above and below the entrance floor is controlled by individually-coded proximity cards. Individually-coded proximity cards further control access to laboratories on each floor. Finally, the specimen storage room within the laboratory will be kept locked. These practices will require ongoing, careful management, since a privacy disaster could be the end of the Generations Project.
- The BC Cancer Agency has a security service available 24-hours a day for the offices of its Cancer Control Research Program. It is a contracted service that includes regular rounds night and day, plus protecting all access to the research centre above the main floor by a card-lock system.

### **15. Disclosure Avoidance Practices for the BC Generations Project**

- Identifying information from assessment centres will be anonymized at the BC Cancer Agency; only the participant's unique study number will be maintained on the file. An electronic key linking participant name, address, and phone number, with the cohort ID number (same as the unique study number), will be stored in an encrypted form in a separate password protected file on a different server. Monthly this key file will be transferred to a separate zip drive, which will be kept at Population Data BC and at an escrow agency with extremely limited access to it.<sup>74</sup>
- Publications of research and statistics from the BC Generations Project Project, the Canadian Cohort Project (Canadian Partnership for Tomorrow), and individual research projects will follow standardized disclosure avoidance techniques, such as the suppression of small cell sizes. Of course, research data are already anonymized.

### **16. The Implications of Future Developments of the BC Generations Project**

- “The Canadian Cancer Cohort (Canadian Partnership for Tomorrow) will have sufficient power five years after cohort accrual only to look at the interaction of high prevalence genes and environmental factors in the most common cancers. However, power will increase rapidly over time. It is likely that most, if not all the provincial cohorts in Canadian Cancer Cohort will join the P3G (Public Population Project in Genomics) consortium ([www.p3g.org](http://www.p3g.org)), and partnering with other cohorts internationally through P3G will raise the scientific value of Canadian Cancer Cohort's specimens and data substantially for the investigation of gene-environment interaction.”<sup>75</sup>
- Future developments of the Canadian Partnership for Tomorrow Project and the BC Generations Project will have to be in compliance with the existing privacy, security, and ethical rules and statutory requirements.
- The Generations Project may need to contact participants if new means of assessing environmental exposure are devised. It will likely want to request more information on

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<sup>73</sup> [Need a current citation to it on-line if and when it is available.]

<sup>74</sup> BC Biobank V1.3, October 15, 2008.

<sup>75</sup> CPAC, “Canadian Cancer Cohort Proposal,” p. 35.

subsets of cohort members as time passes. Enhancements in software and computer technology may make it easier to stay in touch with cohort participants.

## **Conclusions: A Privacy Report Card for the BC Generations Project**

- The UK Biobank is a practical model for all aspects of the BC Generations Project, including privacy risk management. The UK Biobank has a successful working relationship to date with the Office of the UK Information Commissioner, which the Generations Project intends to emulate in BC.

## **Accountability for Personal Information**

- The BC Cancer Agency is an agency of the Provincial Health Services Authority (PHSA), one of six health authorities in BC. The PHSA has privacy policies in place that are consistent with those used by BCCA. It also has a Corporate Director, Information Access and Privacy, and a Corporate Manager, Health Information Access and Privacy, who report to the Corporate Director, Health Information Services within the PHSA.<sup>76</sup> They partner with the Health Information Services manager at BCCA. PHSA employees who are not employed at BCCA do not have access to BCCA password protected computers, nor do they have access to any personal information on BCCA study participants.
- PHSA has a Corporate Director, Information Access and Privacy, and a Corporate Manager, Health Information Access and Privacy, who report to the Corporate Director, Health Information Services within the PHSA. They partner with the Health Information Services manager at BCCA to provide privacy advice and recommend solutions. The PHSA Corporate Manager, Health Information Access and Privacy, is also responsible for conducting privacy impact assessments, doing privacy audits, and conducting privacy training for all PHSA agencies and staff.<sup>77</sup>
- The management of the BC Generations Project will be directly responsible to the BC Cancer Agency and to PHSA for compliance with statutory and ethical obligations for privacy and security.
- The Office of the BC Information and Privacy Commissioner will continue to have independent oversight of the BC Generations Project, which is committed to keeping this Office informed of relevant developments affecting privacy and data protection. The BC Generations Project has already had productive meetings with both the Information and Privacy Commissioner and the Executive Director of his Office.
- Other oversight authorities for the BC Generations Project include senior management of the BC Cancer Agency and the Provincial Health Services Authority, the BC Ministry of Health Services, and, ultimately, the Government of British Columbia.

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<sup>76</sup> See the job postings at <http://www.brainhunter.com/frontoffice/seekerViewJobDetailAction.do?sitecode=pl355&jobId=965973&page=search>

<sup>77</sup> See the job postings at <http://www.brainhunter.com/frontoffice/seekerViewJobDetailAction.do?sitecode=pl355&jobId=965973&page=search>

## **Openness about Personal Information Policies and Practices**

- The BC Generations Project is committed to keeping relevant oversight authorities, the general public, and cohort participants fully aware of what it does with personal information and how it keeps data confidential and secure to the highest available standards in the health industry.
- The BC Generations Project will operate its own web site for purposes of informing the interested public, including the media and interest groups.
- In its start up phases, the BC Generations Project will keep interest groups and the media informed about what it is doing, especially with respect to privacy and security, through scheduled meetings with the major players.

## **Identifying Purposes for Personal Information**

- The Participant Information and Consent Form fully informs prospective participants in the BC Generations Project of the purposes for which their personal information, including various kinds of specimens, will be collected, used, disclosed, and retained. See appendix 2 below.
- Participants will also be informed that their personal information will only be used for purposes authorized by BC *FIPPA* and approved by the University of British Columbia (UBC) / British Columbia Cancer Agency (BCCA) Research Ethics Board .
- Since any unanticipated uses would require a costly process of re-consent from participants, the intention is to state the purposes before broadly and accurately from the outset.

## **Consent for Personal Information**

- Participation in the BC Generations Project will require the free and informed consent of male and female adults, who are age forty or over and who should be fully capable of understanding what they are doing.
- Participants will have to be capable of giving their own consent to join the Generations Project.
- Possible re-contact with participants will be another opportunity to give implied consent for further participation in the Generations Project.
- English is not the first language of a significant proportion of BC residents. The participant Information and Consent form is being translated into Chinese, Punjabi and Tagalog to accommodate the 3 principal groups of non-English speakers. In addition, a short paragraph is being added to the Invitation letter in these 3 languages to help potential participants understand the document when it arrives in the mail. Because of funding constraints, we will not be able to guarantee that translators will be available at the assessment centre and those who are uncomfortable with English will be advised to bring a relative or friend to translate for them.

## **Limiting Collection of Personal Information**

- The BC Generations Project will limit its collection of personal information, including specimens, to data deemed relevant to the broad study of the causes of cancer and chronic diseases.
- When pursuing record linkages for a particular individual, the Generations Project will only collect personal health information necessary for that research linkage; it will not be collecting the any personal health record of a participant from either a hospital or a physician's office.
- However, given the broad scope of the Canadian Partnership for Tomorrow Project and its BC component, there are no real limits on what personal information might be collected if scientific advisors deemed it to be of appropriate relevance.

### **Limiting Use, Disclosure, and Retention of Personal Information**

- The BC Generations Project will limit its use, disclosure, and retention of personal information to appropriate purposes agreed with study participants, approved by the UBC/BCCA Research Ethics Board, and authorized under the BC *Freedom of Information and Protection of Privacy Act*.
- Information Sharing Agreements with the BC Ministry of Health Services will also govern the Generations Project's use, disclosure, and retention of personal information.
- BC Generations Project information will only be used, in anonymized form, for legitimate research projects as approved by various levels of authorities noted above, including the management and other responsible officials of the BC Cancer Agency.

### **Ensuring Accuracy of Personal Information**

- The primary way in which the BC Generations Project seeks to ensure the accuracy of personal information in its custody and control is to collect such information directly from individuals who have chosen to participate. In terms of evaluating specimens in an accurate manner, the study also relies on established technologies and systems of measurement.
- In terms of accuracy for records used for linkages, such as the BC Ministry of Health data, the various health authorities have data quality measures in place. Further, studies have shown that such databases are of overall high quality.
- It is also important that the personal information in the BC Generations Project is not being used for administrative purposes affecting the health care of an individual participant, so the consequences of having some inaccurate data are less serious than in the direct health care scenario. In addition, personal information about significant numbers of participants will be aggregated for research and statistical purposes, again lessening the impact of any use of inaccurate information about a particular person.

### **Safeguards for Personal Information**

- As a cutting edge effort in scientific research that is scheduled to run for more than a generation of data gathering, the BC and Canadian Cohort studies are committed to the highest standards of physical and electronic security available now and over time in the health industry, including encryption standards for data transmission and storage and

the use of Virtual Private Networks. Its partners, such as Population Data BC, are similarly committed.

- The Generations Project intends to follow the advice of its own IT and security people at BCCA and to maintain an evergreen Threat Risk Assessment.

### **Individual Access to Personal Information**

- The Generations Project is a research and statistical database that, under normal circumstances, does not grant individuals access to their own personal information, because the data are held in coded form at Population Data BC. The Generations Project cannot reasonably re-identify anonymized data about cohort members. The re-contact data are held securely only for purposes of re-contact and updating.
- Individuals who request their own data from Population Data BC will be directed to the original Data Provider in order to fulfill the request because a) it will be the best /most direct source of the data, and b) Population Data BC will not store information identifying individuals in conjunction with the Content Data about that person.<sup>78</sup>
- Certain results given to participants at the Assessment Centre can be given out again while the data are still at the Assessment Centre, subject to receipt of standard identification from the participant.

### **Challenging Compliance with the Privacy Policy**

- Individuals will be informed of their right to complain about any aspect of privacy risk management in the BC Generations Project to the BC Cancer Agency and/or to the Office of the BC Information and Privacy Commissioner (which will likely insist that the complainant began with the BC Cancer Agency).
- The UBC/BCCA Research Ethics Board will also receive and process any complaints about the BC Generations Project.

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<sup>78</sup> Population Data BC, "Privacy Impact Assessment," December 2007, v12 final (44 pp.).

## **Summary of Recommendations for the BC Generations Project**

1. In any collaborate efforts at recruitment for the BC Generations Project, the BC Cancer Agency should retain control of the personal information of all data subjects.
2. Any volunteers participating in the recruitment process should receive privacy training comparable to that delivered to BC Generations Project staff.
3. Privacy risk management for the BC Generations Project should include regular privacy audits and site visits to ensure ongoing compliance.
4. The BC Generations Project should ensure that all of its service providers, contractors, and consultants have agreed to comply with an enhanced version of the BC Privacy Protection Schedule and understood its implications.
5. The BC Generations Project should commission a Threat Risk Assessment (TRA), or equivalent, for its security plans and keep it evergreen.
6. The BC Generations Project should keep an updated copy of this Privacy Impact Assessment on its web site.

## Appendix 1: Invitation to Join a Medical Research Project:

### On BC Generations Project Stationery

Ms. [given\_name] [family\_name]  
[address]  
[city], [province] [postal code]

[today's date]

Dear Ms. [family\_name]:

#### Invitation to join a medical research project

The BC Cancer Agency is initiating a new project, called the **BC Generations Project**, aimed at assembling a large group of British Columbians to find out more about how people develop cancer and other diseases over time. These invitation letters are going to thousands of people in BC and sometimes, unfortunately, may arrive at a difficult time. If this is the case for you, please accept our sincere apologies.

Your name and address or phone number has been selected at random. Your contact information will be kept confidential and will only be used to contact you for this study. Your participation in the study is **voluntary**, and you may withdraw at any time. Deciding not to participate will not influence your future medical care. Any information you provide to us will be kept strictly confidential in compliance with the *BC Freedom of Information and Protection of Privacy Act*.

This study is part of the national Canadian Partnership for Tomorrow Project. This research program is open to British Columbia residents aged 40-69. It is important that people from all walks of life join, and your involvement would be very valuable, so we encourage you to consider participating.

If you choose to participate, your part will require about 90 minutes and you will be asked to visit our Assessment Centre at [location] and:

- Give signed consent,
- Complete a questionnaire about your environmental exposures and lifestyle,
- Have basic physical measurements taken (height, weight, waist and hip circumference, body fat, blood pressure, grip strength, bone density and lung function),
- Donate a blood sample (less than 3 tablespoons) and a urine sample,
- Allow us to obtain your health services usage information over time from routinely collected Ministry of Health Services databases.

**Here is what we would like you to do:**

1. Please read the enclosed Information Pamphlet and Consent Form. It provides complete information about the study. It is for your information only, so you don't need to mail this one in.
2. If you are interested in participating or if you have any questions, please contact us
  - a. by phone: **604-675-8221 or toll-free at 1-877-675-8221.**
  - b. by email: [ID@bcgenerationsproject.ca](mailto:ID@bcgenerationsproject.ca).
3. Even if you do not wish to participate, we would appreciate a response by either phone or email, because your reason for declining is important to us.

More information on the study is also available on our website at [www.bcgenerationsproject.ca](http://www.bcgenerationsproject.ca).

**If English is not your first language, this letter is an invitation to participate in a health study, and a translation is available on our website in Chinese, Punjabi and Tagalog at [www.bcgenerationsproject.ca](http://www.bcgenerationsproject.ca).**

如果英语不是您的母语，这封信就是邀您参加健康研讨的邀请函，登录网站 [www.bcgenerationsproject.ca](http://www.bcgenerationsproject.ca) 可参阅中文译本。

如果您的母语并非英语，我们谨此邀请您参加一项健康研究计划。邀请函中译本见我们的网址 [www.bcgenerationsproject.ca](http://www.bcgenerationsproject.ca)。

Kung hindi Ingles ang inyong pangunahing wika, ang sulat na ito ay isang imbitasyon upang lumahok sa isang health study, at may **isinaling sulat** na makukuha sa aming website sa [www.bcgenerationsproject.ca](http://www.bcgenerationsproject.ca).

iykr AMgRyzI quhwfI pihlI BwSw nhIN hY, qW  
ieh p`qr quhwnMU ie`k ishq AiDAYn iv`c ih`sw  
lYx leI s`dw idMdw hY, Aqy Anuvwd kIqw p`qr  
swfI vY~b-sweIt [www.bcgenerationsproject.ca](http://www.bcgenerationsproject.ca). 'qy auplbD  
hY[

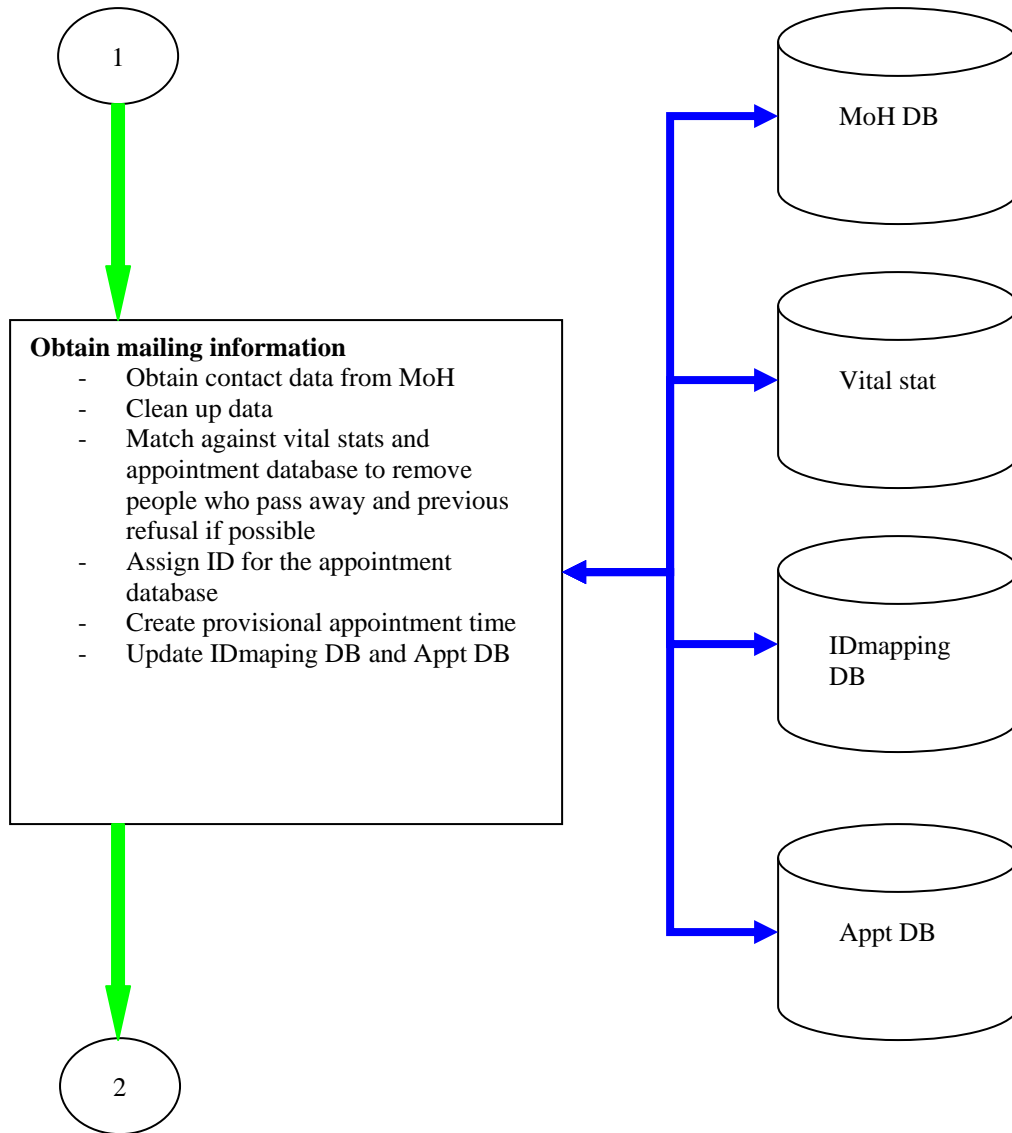
Thank you in advance for helping us in our continuing effort to understand the causes of cancer and other diseases.

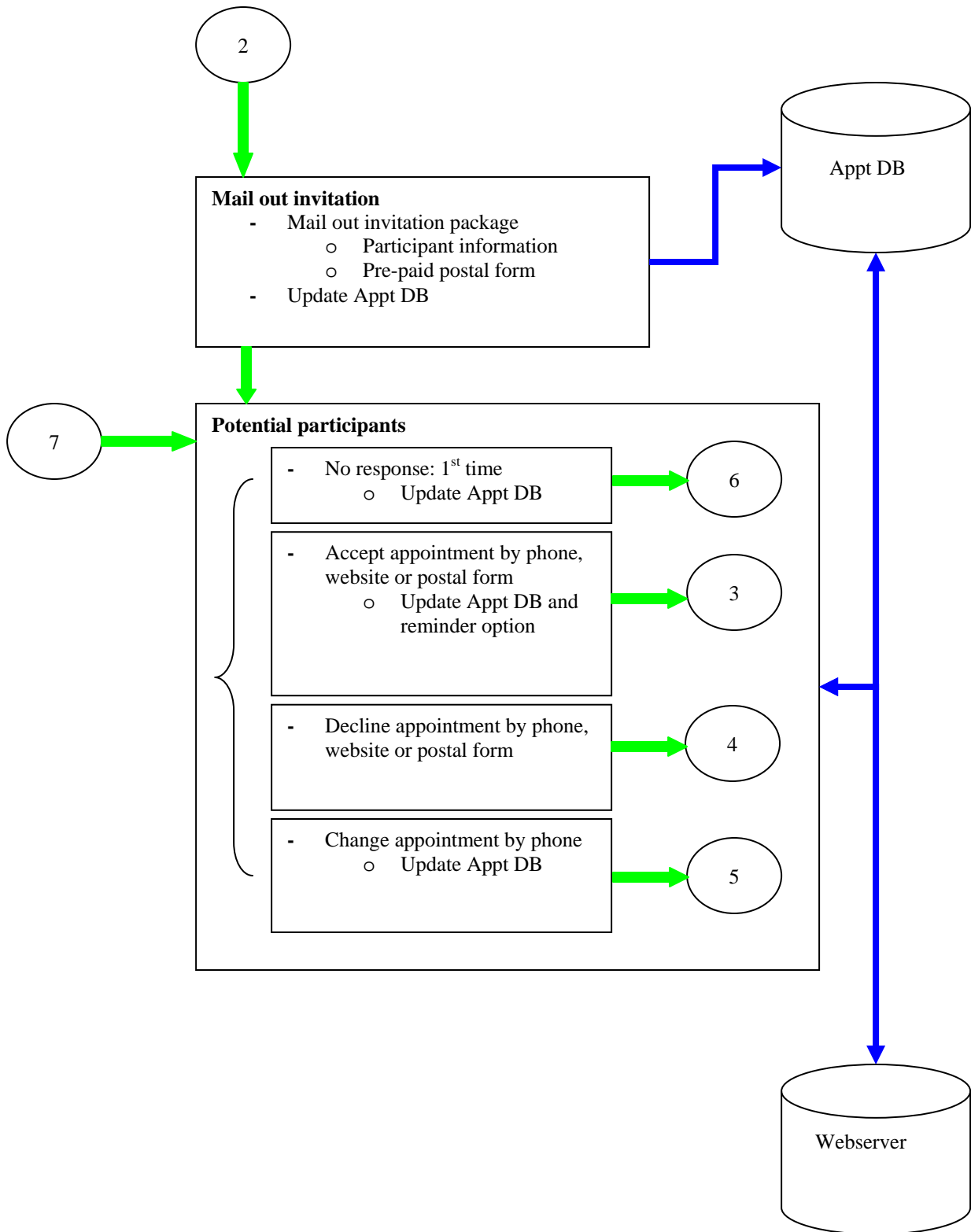
Kind regards,  
Marilyn Borugian, PhD  
Senior Scientist, Cancer Control Research Program and  
Director, BC Generations Project

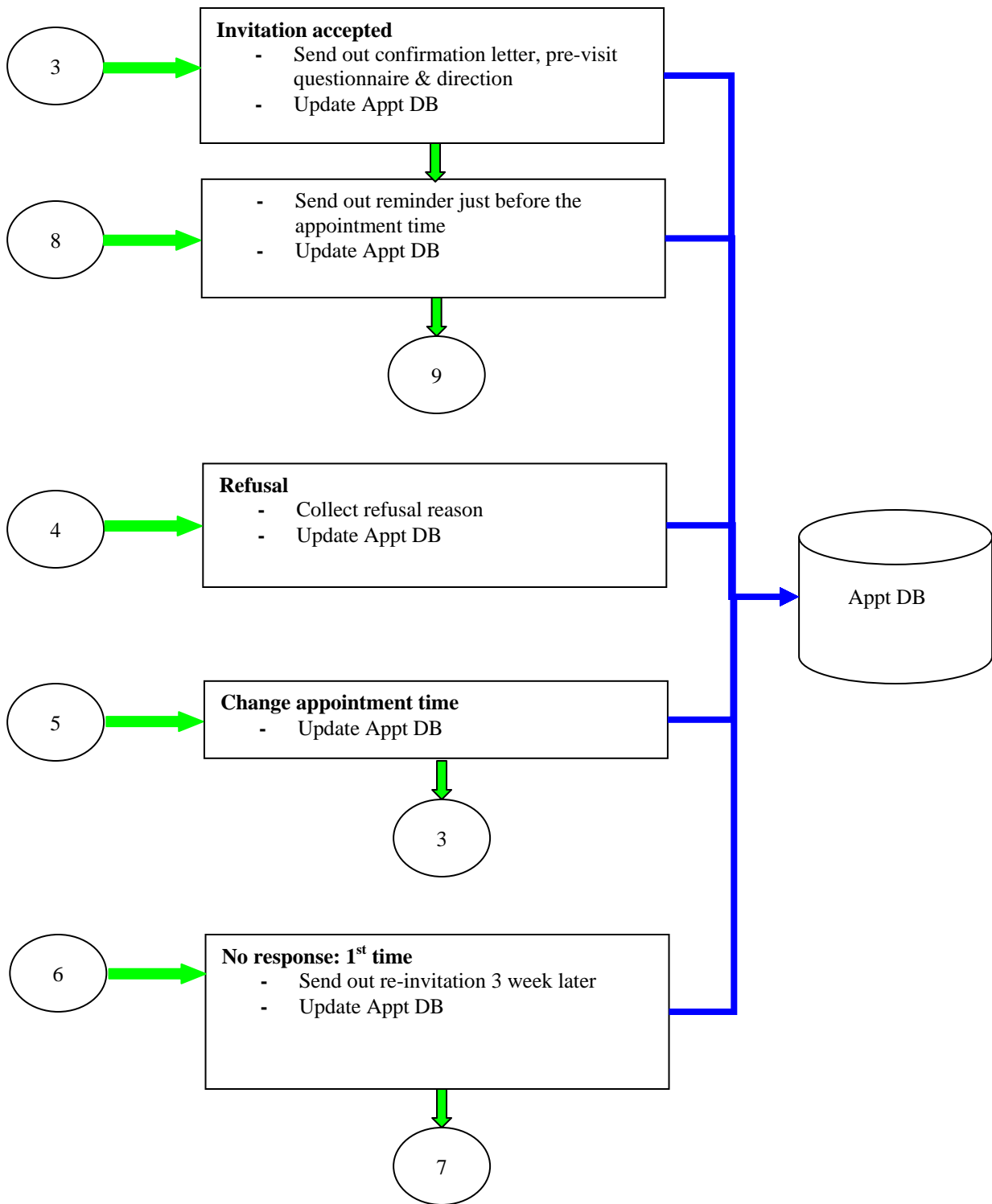
## **Appendix 2: Participant Information and Consent Form**

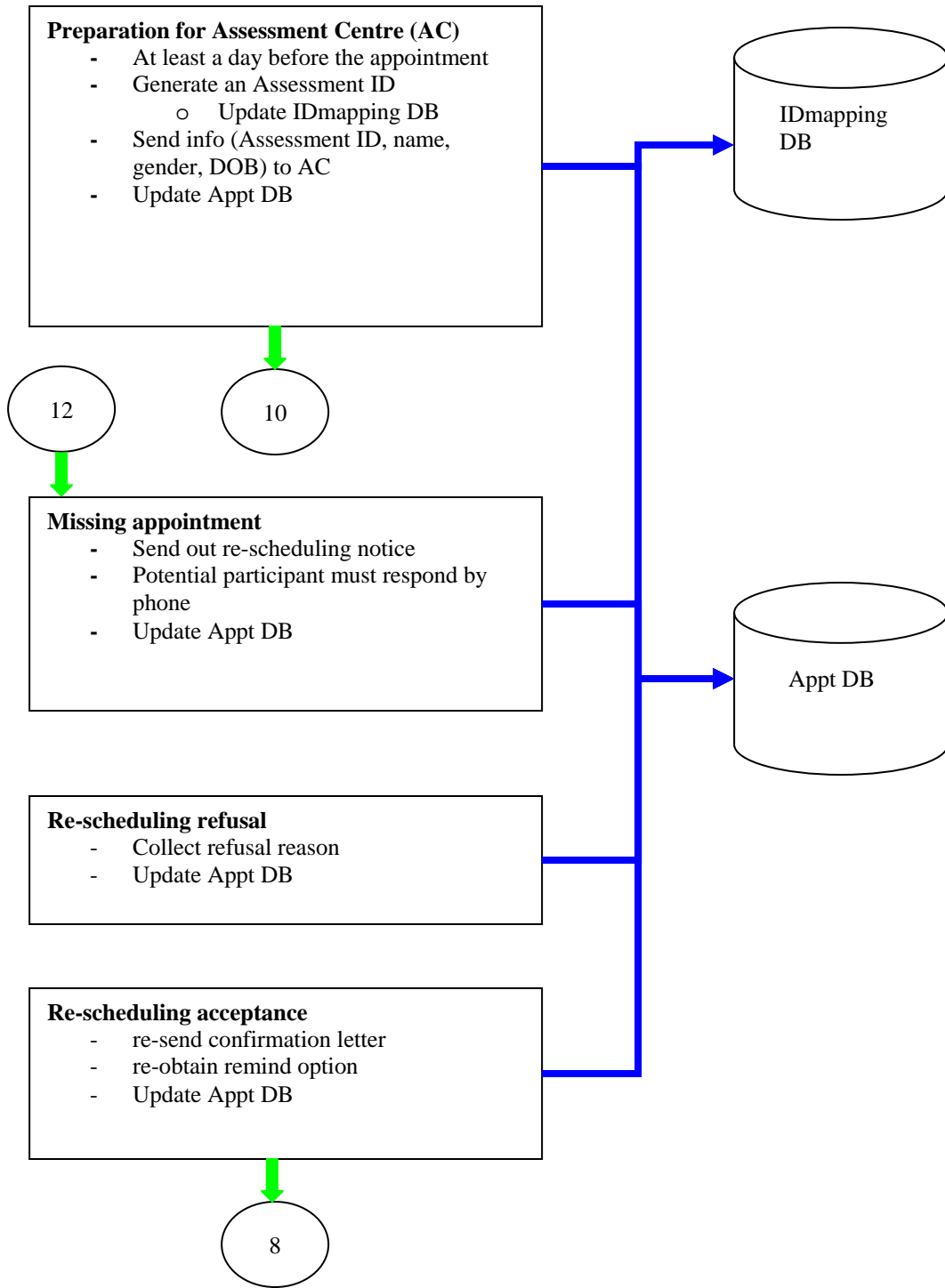
The participant information and consent form current version is attached as a separate document due to difficulties with maintaining changes within the appendix format, May 19, 2009.

**Appendix 3: Data Flow diagram for the British Columbia Generations Project, version 1**  
**Date: June 9, 2008**  
**Based on UK BioBank Model**









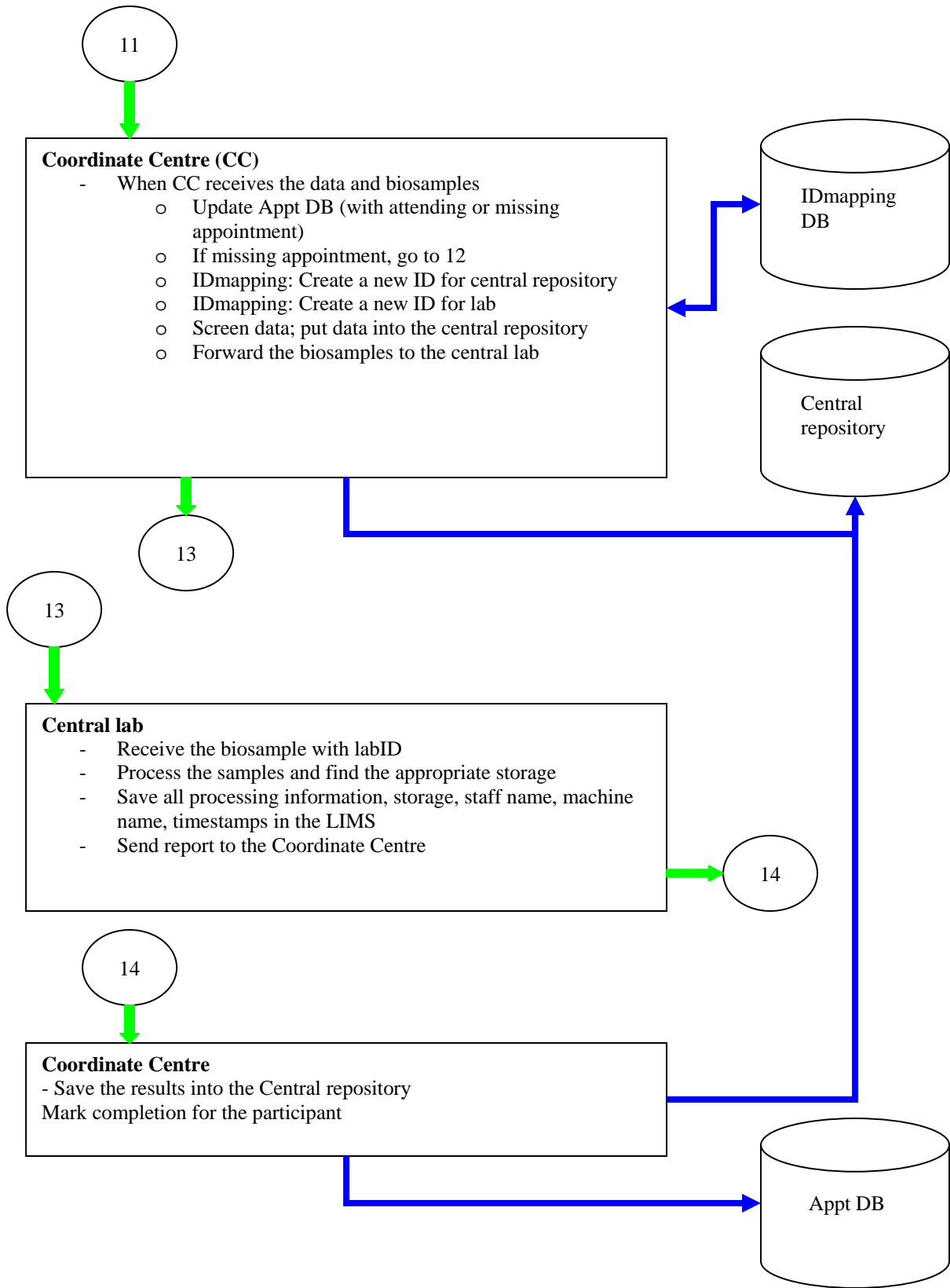
10

### Assessment Centre (AC)

- Every day the Coordinate Centre (CC) updates the Assessment Centre DB for new participant information
- When a participant arrives, his/her name is checked using a barcode reader or is entered into the Assessment Centre DB if the participant does not bring the invitation letter
- Record the arrival time
- Give out an encrypted USB key or print out a barcode as an identifying sheet
- The participant goes through all other stations:
  - o Consent
    - If the participant completes the consent, he/she visits all other workstations
  - o Touch screen questionnaire
  - o Interview – used pre-visit questionnaire as an aid
  - o Blood pressure
  - o Physical measurement
  - o Biosamples (blood and urine)
    - Scan the barcodes on the collection tube – activate the timer for the sample
  - o Give out travel expense form
  - o Print out the signed consent form & measurement report
  - o Collect the USB key or the barcode identifying sheet
- The lab tech processes the biosamples.
- During the data and biosample collection, the staff name, machine name and timestamps are recorded
- All data are encrypted and saved in the workstation's computer and the Assessment Centre DB
- A "fast lane workstation" should be considered
- Data and biosamples are sent to CC periodically and then the data are removed from the Assessment Centre computers.

Assessment  
Centre DB  
DB

11



## Appendix 4: BC Privacy Protection Schedule

Source:

[http://www.cio.gov.bc.ca/services/privacy/Public\\_Sector/contracting/privacy\\_protection\\_schedule/pbpps.doc](http://www.cio.gov.bc.ca/services/privacy/Public_Sector/contracting/privacy_protection_schedule/pbpps.doc)

### PRIVACY PROTECTION SCHEDULE

This Schedule forms part of the agreement between

\_\_\_\_\_ (the "Public Body") and

\_\_\_\_\_ (the "Contractor") respecting

\_\_\_\_\_ (the "Agreement").

#### Definitions

1. In this Schedule,
  - (a) "**access**" means disclosure by the provision of access;
  - (b) "**Act**" means the *Freedom of Information and Protection of Privacy Act* (British Columbia), as amended from time to time;
  - (c) "**contact information**" means information to enable an individual at a place of business to be contacted and includes the name, position name or title, business telephone number, business address, business email or business fax number of the individual;
  - (d) "**personal information**" means recorded information about an identifiable individual, other than contact information, collected or created by the Contractor as a result of the Agreement or any previous agreement between the Public Body and the Contractor dealing with the same subject matter as the Agreement but excluding any such information that, if this Schedule did not apply to it, would not be under the "control of a public body" within the meaning of the Act.

#### Purpose

2. The purpose of this Schedule is to:
  - (a) enable the Public Body to comply with its statutory obligations under the Act with respect to personal information; and
  - (b) ensure that, as a service provider, the Contractor is aware of and complies with its statutory obligations under the Act with respect to personal information.

#### Collection of personal information

3. Unless the Agreement otherwise specifies or the Public Body otherwise directs in writing, the Contractor may only collect or create personal information that is necessary for the performance of the Contractor's obligations, or the exercise of the Contractor's rights, under the Agreement.
4. Unless the Agreement otherwise specifies or the Public Body otherwise directs in writing, the Contractor must collect personal information directly from the individual the information is about.

5. Unless the Agreement otherwise specifies or the Public Body otherwise directs in writing, the Contractor must tell an individual from whom the Contractor collects personal information:
  - (a) the purpose for collecting it;
  - (b) the legal authority for collecting it; and
  - (c) the title, business address and business telephone number of the person designated by the Public Body to answer questions about the Contractor's collection of personal information.

#### **Accuracy of personal information**

6. The Contractor must make every reasonable effort to ensure the accuracy and completeness of any personal information to be used by the Contractor or the Public Body to make a decision that directly affects the individual the information is about.

#### **Requests for access to personal information**

7. If the Contractor receives a request for access to personal information from a person other than the Public Body, the Contractor must promptly advise the person to make the request to the Public Body unless the Agreement expressly requires the Contractor to provide such access and, if the Public Body has advised the Contractor of the name or title and contact information of an official of the Public Body to whom such requests are to be made, the Contractor must also promptly provide that official's name or title and contact information to the person making the request.

#### **Correction of personal information**

8. Within 5 business days of receiving a written direction from the Public Body to correct or annotate any personal information, the Contractor must annotate or correct the information in accordance with the direction.
9. When issuing a written direction under section 8, the Public Body must advise the Contractor of the date the correction request to which the direction relates was received by the Public Body in order that the Contractor may comply with section 10.
10. Within 5 business days of correcting or annotating any personal information under section 8, the Contractor must provide the corrected or annotated information to any party to whom, within one year prior to the date the correction request was made to the Public Body, the Contractor disclosed the information being corrected or annotated.
11. If the Contractor receives a request for correction of personal information from a person other than the Public Body, the Contractor must promptly advise the person to make the request to the Public Body and, if the Public Body has advised the Contractor of the name or title and contact information of an official of the Public Body to whom such requests are to be made, the Contractor must also promptly provide that official's name or title and contact information to the person making the request.

#### **Protection of personal information**

12. The Contractor must protect personal information by making reasonable security arrangements against such risks as unauthorized access, collection, use, disclosure or disposal, including any expressly set out in the Agreement.

### **Storage and access to personal information**

13. Unless the Public Body otherwise directs in writing, the Contractor must not store personal information outside Canada or permit access to personal information from outside Canada.

### **Retention of personal information**

14. Unless the Agreement otherwise specifies, the Contractor must retain personal information until directed by the Public Body in writing to dispose of it or deliver it as specified in the direction.

### **Use of personal information**

15. Unless the Public Body otherwise directs in writing, the Contractor may only use personal information if that use is for the performance of the Contractor's obligations, or the exercise of the Contractor's rights, under the Agreement.

### **Disclosure of personal information**

16. Unless the Public Body otherwise directs in writing, the Contractor may only disclose personal information inside Canada to any person other than the Public Body if the disclosure is for the performance of the Contractor's obligations, or the exercise of the Contractor's rights, under the Agreement.
17. Unless the Agreement otherwise specifies or the Public Body otherwise directs in writing, the Contractor must not disclose personal information outside Canada.

### **Notice of foreign demands for disclosure**

18. In addition to any obligation the Contractor may have to provide the notification contemplated by section 30.2 of the Act, if in relation to personal information in its custody or under its control the Contractor:
  - (a) receives a foreign demand for disclosure;
  - (b) receives a request to disclose, produce or provide access that the Contractor knows or has reason to suspect is for the purpose of responding to a foreign demand for disclosure; or
  - (c) has reason to suspect that an unauthorized disclosure of personal information has occurred in response to a foreign demand for disclosurethe Contractor must immediately notify the Public Body and, in so doing, provide the information described in section 30.2(3) of the Act. In this section, the phrases "foreign demand for disclosure" and "unauthorized disclosure of personal information" will bear the same meanings as in section 30.2 of the Act.

### **Notice of unauthorized disclosure**

19. In addition to any obligation the Contractor may have to provide the notification contemplated by section 30.5 of the Act, if the Contractor knows that there has been an unauthorized disclosure of personal information in its custody or under its control, the Contractor must immediately notify the Public Body. In this section, the phrase "unauthorized disclosure of personal information" will bear the same meaning as in section 30.5 of the Act.

### **Inspection of personal information**

20. In addition to any other rights of inspection the Public Body may have under the Agreement or under statute, the Public Body may, at any reasonable time and on reasonable notice to the Contractor, enter on the Contractor's premises to inspect any personal information in the possession of the Contractor or any of the Contractor's information management policies or practices relevant to its management of personal information or its compliance with this Schedule and the Contractor must permit, and provide reasonable assistance to, any such inspection.

### **Compliance with the Act and directions**

21. The Contractor must in relation to personal information comply with:
- (a) the requirements of the Act applicable to the Contractor as a service provider, including any applicable order of the commissioner under the Act; and
  - (b) any direction given by the Public Body under this Schedule.
22. The Contractor acknowledges that it is familiar with the requirements of the Act governing personal information that are applicable to it as a service provider.

### **Notice of non-compliance**

23. If for any reason the Contractor does not comply, or anticipates that it will be unable to comply, with a provision in this Schedule in any respect, the Contractor must promptly notify the Public Body of the particulars of the non-compliance or anticipated non-compliance and what steps it proposes to take to address, or prevent recurrence of, the non-compliance or anticipated non-compliance.

### **Termination of Agreement**

24. In addition to any other rights of termination which the Public Body may have under the Agreement or otherwise at law, the Public Body may, subject to any provisions in the Agreement establishing mandatory cure periods for defaults by the Contractor, terminate the Agreement by giving written notice of such termination to the Contractor, upon any failure of the Contractor to comply with this Schedule in a material respect.

### **Interpretation**

25. In this Schedule, references to sections by number are to sections of this Schedule unless otherwise specified in this Schedule.
26. Any reference to the "Contractor" in this Schedule includes any subcontractor or agent retained by the Contractor to perform obligations under the Agreement and the Contractor must ensure that any such subcontractors and agents comply with this Schedule.
27. The obligations of the Contractor in this Schedule will survive the termination of the Agreement.
28. If a provision of the Agreement (including any direction given by the Public Body under this Schedule) conflicts with a requirement of the Act or an applicable order of the commissioner under the Act, the conflicting provision of the Agreement (or direction) will be inoperative to the extent of the conflict.

29. The Contractor must comply with the provisions of this Schedule despite any conflicting provision of this Agreement or, subject to section 30, the law of any jurisdiction outside Canada.
30. Nothing in this Schedule requires the Contractor to contravene the law of any jurisdiction outside Canada unless such contravention is required to comply with the Act.

## Appendix 5: The Consultant (David H. Flaherty)

David Flaherty is a specialist in the management of privacy and information policy issues. He served a six-year, non-renewable term as the first *Information and Privacy Commissioner for the Province of British Columbia* (1993-99). He wrote 320 Orders under the *Freedom of Information and Protection of Privacy Act* and also pioneered the development of site visits to public bodies (hospitals in particular) as a form of privacy auditing.

Flaherty began his involvement with privacy issues as an assistant to Alan F. Westin at Columbia University in 1964. Flaherty's first book was *Privacy in Colonial New England* (1972). In 1974 he started comparative public policy work in Europe and North America that led to a series of books, including *Protecting Privacy in Surveillance Societies: The Federal Republic of Germany, Sweden, France, Canada, and the United States* (1989). Flaherty has written or edited fourteen books.

Flaherty is an Honours graduate of McGill University (1962) and has an MA and Ph.D. from Columbia University. His teaching career from 1965 to 1993 included Princeton University, the University of Virginia, and the University of Western Ontario, where he was professor of history and law from 1972 to 1999 and is now professor emeritus. He was the first director (1984-89) of its Centre for American Studies. He has held fellowships and scholarships at Harvard, Oxford, Stanford, and Georgetown Universities. In 1992-93 Flaherty was a Fellow of the Woodrow Wilson International Center for Scholars in Washington, DC and a Canada-US Fulbright Scholar in Law. Flaherty was an adjunct professor in political science at the University of Victoria from 1999 to 2006.

As a consultant, Flaherty's services for clients include strategic advice on the management of privacy issues and of relationships with privacy authorities, privacy advocates, and the general public; conducting overall assessments of privacy compliance (privacy reviews, audits, site visits, knowledge transfer); preparing Privacy Impact Assessments; helping to manage privacy breaches; and developing privacy risk management plans.

With Stephanie Perrin, Heather Black, and Murray Rankin, Flaherty is a co-author of the [Personal Information Protection and Electronic Documents Act: An Annotated Guide](#) (Irwin Law, Toronto, January, 2001). He also co-authored the [Guidelines for Managing Privacy, Data Protection and Security for Ontario Hospitals](#) (A Report prepared by the Ontario Hospital eHealth Council's Privacy and Security Working Group – July 2003). [www.oha.com](http://www.oha.com)

Flaherty is a member of the External Advisory Committee to the Privacy Commissioner of Canada since its inception in 2004. for whose office he wrote "Reflections on Reform of the *Privacy Act*." (38pp., 2008) Since 2000, he has been the Chief Privacy Advisor to the Canadian Institute for Health Information (CIHI).