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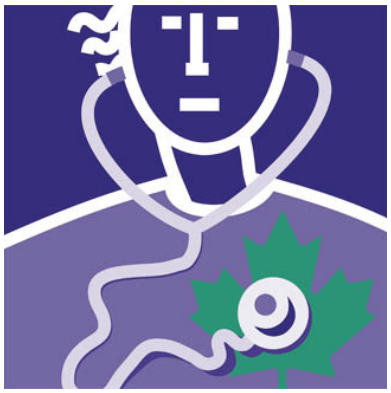

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Canadian Health Measures Survey: Ethical, legal and social issues

Brent Day, Renée Langlois, Mark Tremblay and Bartha-Maria Knoppers

Abstract

This article describes how the Canadian Health Measures Survey (CHMS) of Statistics Canada has addressed the ethical, legal and social issues (ELSI) arising from the survey. The development of appropriate procedures and the rationale behind them are discussed in detail for some specific ELSI. Health Canada's Research Ethics Board, the Office of the Privacy Commissioner of Canada, and the Data Access and Control Services Division at Statistics Canada, provided advice to the CHMS on ELSI. Statistics Canada's legal obligation to protect confidentiality, the oath of office, and security measures at Statistics Canada are explained. Additional information on safeguards specific to the CHMS is presented. The ELSI discussed include communication and consent, privacy and confidentiality, reporting results to survey respondents, inclusiveness, and storage of biospecimens. Common to all ELSI is the need for respondents' awareness and acceptance of their role in the survey process, and the obligation of the CHMS to respect respondents and the data they provide.

Keywords

blood specimen collection, confidentiality, consent forms, disclosure, ethics, ethics committees, health surveys, privacy

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The Canadian Health Measures Survey (CHMS) is the most comprehensive, nationally representative direct health measures survey ever undertaken in Canada. It is a voluntary survey conducted by Statistics Canada in partnership with Health Canada and the Public Health Agency of Canada. In 2007-2009, data will be collected from a nationally representative sample of Canadians aged 6 to 79 years.

The CHMS consists of an in-home health interview and a physical health examination at a mobile clinic where measures of anthropometry, spirometry, blood pressure, fitness, physical activity and oral health are taken. Blood (serum and plasma) and urine samples are collected to be analyzed for chronic disease, infectious disease, and nutritional and environmental biomarkers (for a complete list of analytes see Tremblay et al, 2007[1]), and then stored in a secure biorepository for future research. Details on the background and rationale for the survey,[1] sampling strategy,[2] logistical and operational challenges[3] and results of pre-test research[4] are described elsewhere in this supplement.

Table 1
Key consultative partners: Health Canada Research Ethics Board (REB) and Office of the Privacy Commissioner of Canada (OPC)

	Health Canada Research Ethics Board (REB)	Office of the Privacy Commissioner of Canada (OPC)
Who they are	The Health Canada REB has eight members: two ethicists; three researchers (two from Health Canada and one from outside); two community representatives; and one member with legal expertise. Members will participate for three to six years.	The Office of the Privacy Commissioner of Canada (OPC) consists of the Privacy Commissioner of Canada, two Assistant Privacy Commissioners, and their staff. The Privacy Commissioner is an Officer of Parliament who reports directly to the government (House of Commons and Senate). The Office also seeks guidance from an External Advisory Committee made up of approximately 15 members from a variety of backgrounds.[8]
Role	The REB "helps ensure that research meets the highest ethical standards, and that the greatest protection is provided to participants who serve as research subjects."[5] The Health Canada REB reviews research that is carried out by Health Canada, in collaboration with Health Canada, funded by Health Canada through grants to external researchers, or done on Health Canada premises. Because of the close involvement of Health Canada with the CHMS and because Statistics Canada does not have an REB, Health Canada agreed to provide the services of its REB. The Board has reviewed and will continue to review CHMS survey and research documentation and to monitor the treatment of survey participants.	In the context of the CHMS, the OPC is responsible for ensuring that the federal government collects, uses and discloses personal information in a responsible and transparent manner. The OPC also oversees how private sector organizations handle the personal information of Canadians in the course of commercial activities.
Governing policy/legislation	The REB is guided by the ethical principles set out in the standard for research ethics boards in Canada—the Tri-Council Policy Statement (TCPS).[6] The main guiding ethical principles of the TCPS are: Respect for human dignity Respect for free and informed consent Respect for vulnerable persons Respect for privacy and confidentiality Respect for justice and inclusiveness Balancing harms and benefits Minimizing harm Maximizing benefit In addition, the Canadian Institutes of Health Research (CIHR) has developed 10 privacy best practices that are intended to help research ethics boards in the interpretation of the TCPS by offering "additional detail and practicality."[7] These principles are similar to the 10 privacy principles described under the OPC's Governing Policy/Legislation (at the right).	The Canadian federal government, including Statistics Canada, is subject to the Privacy Act, "an Act to extend the present laws of Canada that protect the privacy of individuals and that provide individuals with a right of access to personal information about themselves."[9] The Act allows individuals to complain in writing to the Privacy Commissioner about how their personal information has been used or disclosed other than in accordance with the Act. Federal government and Statistics Canada's privacy impact assessment policies have been developed in keeping with the Code of Fair Information Practices in the Privacy Act and the 10 privacy principles from the Canadian Standards Association.[10] The 10 privacy principles are: Accountability Identifying purposes Consent Limiting collection Limiting use, disclosure and retention Accuracy Safeguards Openness Individual access Challenging compliance
Information submitted	Detailed information about the survey was presented to the REB so that they could evaluate how the CHMS has followed the TCPS ethical principles and the CIHR privacy best practices described above. This information included: • Background and rationale of the survey including information on the consultative process • Informed consent process and forms • Communications materials and strategy • Physical and lab measure tests • Survey procedures (household, clinic and lab; safety; reporting results to respondents) • Household and clinic questionnaires • Infrastructure and security measures • Quality assurance/quality control strategy • Access to data strategy • Analysis and dissemination plans • Proposal for storage of biospecimens	To meet the requirements of federal government/Statistics Canada policies, a Privacy Impact Assessment (PIA) was sent to the OPC, outlining the potential privacy, confidentiality and security risks posed by the survey, and identifying measures that will be put in place to minimize these risks. The PIA includes a specific assessment of the 10 privacy principles for the CHMS, process flows and threat and risk assessments for the household interview, clinic visit, home visit, laboratories and reporting of results to respondents. In addition, a CHMS proposal for the collection, storage and management of bio-specimens, including information on consent and access to data, was provided. The PIA and other documentation was also used to inform provincial privacy commissioners about the survey.
For more information	Further information is available from Health Canada's REB: Research Ethics Board Office of the Chief Scientist Health Canada Holland Cross, Tower B Postal Locator 3104A Ottawa, Ontario, K1A 0K9 Telephone: 613-941-5199 Fax: 613-948-6781 E-mail: reb-cer@hc-sc.gc.ca Online: http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/index_e.html	Further information is available from the OPC: Office of the Privacy Commissioner of Canada 112 Kent Street Place de Ville Tower B, 3rd Floor Ottawa, Ontario, K1A 1H3 Telephone: 613-995-8210 Fax: 613-947-6850 TTY: 613-992-9190 Toll-free: 1-800-282-1376 Online: http://www.privcom.gc.ca

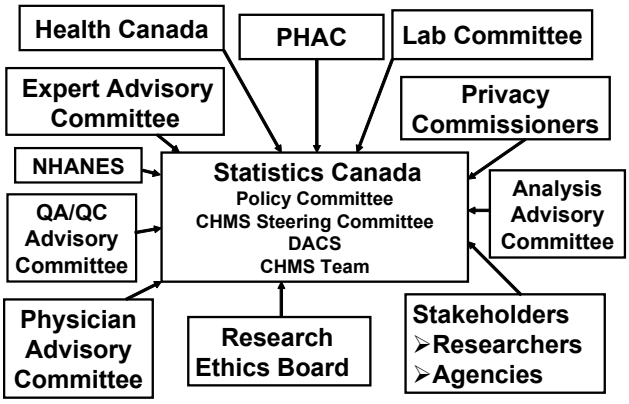
For a variety of reasons—sampling, operational logistics, managing stakeholder expectations, communications, and staffing—the CHMS is complex. However, the ethical, legal and social implications are arguably the most intricate elements of a survey of this nature. Accordingly, considerable time and resources have been dedicated to preparing and implementing protocols and procedures to address ethical, legal and social issues (ELSI). This paper discusses the consultation process and some of these issues: communication/consent, privacy/confidentiality, the return of results, reportable diseases, inclusiveness, and storage of biospecimens.

Consultations

Consulting a wide variety of groups has been instrumental in developing the CHMS. Advice was obtained from several countries with significant experience and distinguished histories in conducting surveys of this nature.[11,12] Notable among them are the National Health and Nutrition Examination Survey (NHANES) in the United States[13] and the Health 2000[14] and Finrisk[15] surveys in Finland. International efforts to address and catalogue ELSI have been widespread.[12, 16-19] The CHMS benefited tremendously from research on, guidance from, and interaction with many of these international studies.

To further assist and advise the CHMS, Statistics Canada established a network of consultation processes and committees (Figure 1). These included expert advisory committees on scientific, medical, laboratory and analytical issues; content and funding partners; other international surveys and experts; stakeholders; privacy commissioners and officials; the Health Canada Research Ethics Board; and focus groups in which Canadian citizens participated. Within Statistics Canada, the CHMS received guidance on ethical, legal and social matters from the Data Access and Control Services Division (the Agency's Access to Information and Privacy Office), departmental legal counsel, a multi-disciplinary Steering Committee, and ultimately, the Policy Committee (committee of the Chief Statistician and Assistant Chief Statisticians).

Figure 1
Canadian Health Measures Survey consultation structure



PHAC – Public Health Agency of Canada
NHANES – National Health and Nutrition Examination Survey
QA/QC - quality assurance/quality control
DACS - Data Access and Control Services Division

Statistics Canada policies and procedures have been developed in accordance with the requirements of the Statistics Act[20] and the Privacy Act.[9] Both Acts have been in the forefront of discussions with Statistics Canada's legal counsel, the various committees, and particularly, in discussions with Health Canada's Research Ethics Board (REB) and the Office of the Privacy Commissioner of Canada (OPC) (Table 1).[5,8-10]

The CHMS is the first survey for which Statistics Canada has sought the expertise of a REB. Physical measures tests and the taking of blood and urine samples demand such review. The possibility of Statistics Canada having its own REB has been explored in the past.[21] In the meantime, plans are in place to create an REB and/or Data/Specimen Access Committee specific to the CHMS, at arms length from Statistics Canada, to provide ongoing oversight for ELSI that arise from the survey.

With regard to a privacy impact assessment (PIA), the CHMS has followed federal government and Statistics Canada policies that require:

- a PIA "for all new and significantly redesigned collections, uses or disclosures of personal information that raise privacy, confidentiality or data security risks";[22]
- the PIA to be sent to the OPC for review;

Table 2
Key Canadian Health Measures Survey committees addressing ELSI

Expert Advisory Committee	Physician Advisory Committee	Laboratory Advisory Committee
Provide advice and guidance about all aspects of survey objectives, development, testing, implementation, analysis and dissemination.	Provide advice on appropriate engagement and communication with physicians and wider medical community.	Provide advice on standard collection, processing, storage and shipping procedures for biospecimens collected.
Share specific expertise on technical, scientific, logistical, ethical, legal and social issues to assist in meeting overall survey objectives.	Provide advice on content, format and process of reporting health measures results to participants.	Provide advice on the content, format and process of reporting biospecimen results to respondents.
Provide information about the survey and serve as a conduit for information exchange, particularly within their geographic and scientific constituency.	Identify potential problems and solutions arising from the CHMS as they may affect medical community.	Identify potential problems and solutions related to the collection and analysis of biological measures.
Advise on important and emerging health issues and technologies that may affect need for data, relevancy of measures or survey content, survey parameters and/or sample design.	Provide general advice on the CHMS, particularly as it relates to interactions with physicians (ensuring appropriate communication occurs between respondents and their physician) and on how the CHMS team can exploit the survey in an educational fashion with the medical community.	Provide advice on the purchase of laboratory equipment, staff qualifications, mobile laboratory set-up and licensing and quality control/assurance procedures.
	Provide communications support and liaise with the Canadian Medical Association and medical community.	Provide support for the development of communications material related to biospecimens.

- CHMS team members to meet regularly with Statistics Canada's PIA Review Committee to discuss the PIA;
- the Chief Statistician to approve the PIA before sending it to the OPC.

A summary of the final version of the PIA is available on Statistics Canada's website.[23]

The importance of the REB and the OPC was highlighted by the Policy Committee's request to receive the approval of the REB and the views of the OPC before a final decision was taken on the storage of blood and urine. The Policy Committee also recommended that the CHMS obtain the views of the privacy commissioners or equivalent in each province where collection takes place (New Brunswick, Québec, Ontario, Alberta and British Columbia).

Among the other groups that have been influential in decision-making about ELSI are the Expert Advisory Committee, the Physician Advisory Committee and the Laboratory Advisory Committee (Table 2).

Informed consent process

A well-reasoned consent strategy enables survey respondents to feel knowledgeable about and comfortable with their participation and helps researchers justify and document their goals. Governing policies for both the REB and OPC incorporate the principle of consent. In fact, obtaining informed consent "has been the focal point of research ethics review."[24] A number of Statistics Canada policies incorporate principles related to consent: the Policy on Informing Survey Respondents,[25] the Policy on Record Linkage,[26] and the legal requirements of section 12 of the Statistics Act.[20]

The CHMS follows the Policy on Informing Survey Respondents by telling respondents, before and at the time of collection, that their participation is voluntary. Information about the voluntary nature of the CHMS is included in all materials presented to or available to potential respondents before they agree to participate. Even after agreeing, they can decline to answer specific questions that they consider sensitive or that make them uncomfortable. They can also withdraw from any part of the survey at any time, including having their biospecimen samples withdrawn.

The Statistics Canada Policy on Record Linkage requires that respondents be notified of record linkage plans at the time of data collection. Section 12 of the Statistics Act[20] sets out the legal requirements Statistics Canada must follow for sharing survey information with federal departments. For the CHMS, data-sharing agreements are in place only with Health Canada and the Public Health Agency of Canada.

The CHMS has produced a large amount of documentation to inform respondents about what their participation entails. Before any personal contact is made, an advance letter and brochure are sent to the household. Both documents state that participation in the survey is voluntary and direct potential respondents to Statistics Canada's toll-free number and website for more information. The question-and-answer section of the website also explains the voluntary nature of the survey.

The voluntary nature of the survey is reiterated in the interviewer introduction, when potential respondents are first contacted to arrange for an interview appointment, and also in the introductory video that is played for each respondent before the household interview begins.

Voluntary participation extends throughout the interview. Standard interviewing procedures advise respondents that they may skip questions they do not feel comfortable answering. For the CHMS household interview, consent is implied when the respondent begins answering questions; no consent forms are used for this part of the survey.

The advance letter, brochure and introductory video provide information not only about the household interview, but also about the clinic visit, which takes place a few days to several weeks after the household interview. As well, during the household interview, respondents receive an *Information and Consent Booklet* that explains the clinic portion of the CHMS. Interviewers draw respondents' attention to information about the consent form that they will be asked to sign in the clinic and provide explanations about the informed consent process. The booklet is left with the respondents to read and consider before their clinic visit.

When a respondent arrives at the clinic, Statistics Canada staff use the clinic questionnaire (computer application) to guide him or her through the consent process, providing ample opportunity to review the consent material and ask questions. The respondent (or the respondent's parent/guardian if he or she is aged 6 to 13 years) is asked to give written consent for participation in various parts of the clinic portion of the CHMS and to sign the form. If requested, a copy of the signed form is given to the respondent.

At the end of the clinic questionnaire, respondents are asked if they agree to data-sharing and data linkage. Their responses are recorded in the clinic application and apply to all data collected as part of the CHMS—household components, clinic test results, activity monitor data, and the results of tests on stored blood and urine samples. The *Information and Consent Booklet* provides additional information about what data-sharing and data linkage entail (Appendix Figure A).

Consent forms

Using consent forms for direct measures surveys and research projects is standard practice.[6,7] These forms serve as legal reassurance and protection for both respondents and researchers, and highlight the importance to both groups of understanding the possible implications and consequences of participation.

"The primacy of consent necessarily carries with it the right of withdrawal."[24] Signing a consent form does not prevent respondents from later declining to participate in some or all parts of a survey or from later withdrawing their data or samples, provided that the data have not been aggregated. This right to withdraw should be made clear on the consent form itself and/or in supplementary material.

Consent forms can range from broad consent to participate in an entire survey to explicit signed written consent for each topic or measure. Nationally representative direct measures surveys in the United States[13] and Finland[14] have asked for relatively broad consent on a form that summarizes the details of participation. The CHMS has taken a more specific approach by separating the survey into several key areas and offering respondents the option of participating or not in each one (Appendix Figure B).

Feedback from focus groups in November 2005 indicated a preference for consent forms that are short and simple, but offer some choice. As a result, CHMS forms have been kept to one page each, and choice has been limited to no more than

five distinct areas (Appendix Figure B). In addition to minimizing response burden, a short form reduces the development and processing costs related to the consent portion of the survey. The trade-off is some loss of detail on the forms. However, the CHMS treats consent as an ongoing process that starts before data collection and continues until after its completion, with communication materials provided to respondents throughout (as previously discussed). The right to withdraw from any part of the survey is presented explicitly on the form. This reminds respondents that if they are not comfortable with an aspect of the survey to which they previously consented, they can refuse to participate in that specific part.

Based on results of the November 2005 focus groups, the consent form for respondents aged 20 to 79 years has separate clauses for the storage of DNA for use in future health studies and for the storage of blood and urine. To maximize consent for the DNA portion, respondents are assured that their DNA samples will be kept confidential and not made available to law enforcement agencies, insurance companies or employers, and will not be used for maternity or paternity verification. The specific components of "participating in the physical measures tests" (for example, strength test, cardiovascular test) are not presented in separate clauses, since they were viewed in a similar way by the focus groups and are expected to be accepted to the same degree by respondents.

Different consent forms are often required for people of different ages in order to allow for the role of parents and guardians in the consent process and to apply various parts of a survey to particular age groups. The CHMS uses four forms: a consent form for respondents aged 20 to 79 years, for respondents aged 14 to 19 years and for parents/guardians of respondents aged 6 to 13 years, and an assent form for respondents aged 6 to 13 years.

The consent form for respondents aged 20 to 79 years is the most complete, since all parts of the CHMS apply to this age group. The consent form for respondents aged 14 to 19 years is virtually identical, except that it does not include the clause asking for consent to store DNA for use in future studies, since DNA is not stored for this age group.

The consent form for parents/guardians of respondents aged 6 to 13 years does not include the DNA clause or the clause on testing respondents' blood for hepatitis B and C viruses. These measures are not performed on respondents in this age group.

On the assent form for 6- to 13-year-olds, the child is asked if he or she wants to participate in the survey as a whole; no choice as to specific areas is offered. The assumption is that children are too young to comprehend the details of the survey and that the parent/guardian will oversee their participation. If the parent/guardian or the child does not give consent, the child does not participate in the survey. When the child reaches 14 years of age, he or she will be recontacted by the CHMS to provide permission for the CHMS to continue to store his or her blood and urine.

Privacy and confidentiality

Respecting the privacy of respondents and maintaining the confidentiality of their information are important ethical, legal and social considerations for surveys such as the CHMS (see *Key concepts*[27]). Statistics Canada has developed a generic privacy impact assessment (PIA)[28] that works well for most of its surveys. Principle 7 of this PIA, which is similar to the "Safeguards" principle in Table 1 (OPC, Governing policy/legislation), outlines many of the precautions Statistics Canada takes to protect the information collected.

Statistics Canada has a legal obligation to safeguard respondents' personal information and

Key concepts

Privacy	The right to be left alone, to be free from interference, surveillance and intrusions.
Confidentiality	Implies a trust relationship between the person providing information and the individual or organization collecting it. This relationship is built on the assurance that the information will not be disclosed without the provider's permission.
Security	The procedures, infrastructure and oversight mechanisms implemented to ensure that each person's privacy and confidentiality are respected.

has made a commitment to keep in trust the information it obtains from the Canadian public. Statistics Canada has a framework of policies, procedures and practices to protect confidential information against loss, theft, unauthorized access, disclosure, copying or use, which includes physical, organizational and technological measures.

The Statistics Act[20] provides the legal basis for maintaining the confidentiality of information that Statistics Canada collects. No unauthorized person may examine any information collected under the Act or disclose or knowingly cause to be disclosed any information collected under the Act in such a manner that it is possible to relate the particulars to an identifiable individual person, business or organization.

Before assuming their duties under the Statistics Act, all Statistics Canada employees take an oath or solemn affirmation that they will conform to the requirements of the Act and will not, without due authority, disclose or make known confidential information. Employees who contravene the confidentiality provisions of the Act are subject to prosecution and are liable on summary conviction to a fine and/or imprisonment. Actions that contravene the security policies of the Government of Canada or Statistics Canada could lead to administrative, disciplinary or statutory penalties when misconduct or negligence is involved. The nature of the penalty depends on the nature of the offence.

Statistics Canada has taken extensive measures to maintain a secure environment and to make the principle of security a priority (see *Security measures at Statistics Canada*).

Privacy safeguards

One of the ways in which the CHMS is an atypical survey for Statistics Canada is that collection and processing sites include not only the respondent's dwelling, but also a mobile clinic, laboratories and a biorepository (storage facility for blood and urine). Although the previously outlined policies and procedures apply to the CHMS, some modifications were needed because of these different sites.

Physical security measures at the clinic include break-proof windows, bolted panels and steel doors, and security alarms and lights. Paper documents such as consent forms are stored in locked cabinets. Computers in the clinic and the clinic laboratory are locked to desks, and the server is in a locked cabinet in a locked room. All computer data are password-protected and encrypted, and data transmissions from the clinic to head office are encrypted or double-encrypted. An overview of the Information Technology infrastructure and data flows for the clinic is presented elsewhere in this supplement.[3]

Only the complete blood count (CBC) is done in the laboratory at the clinic. Other tests on the blood and urine samples are conducted in three other laboratories: the Public Health Agency of Canada's National Microbiology Lab (NML) in Winnipeg, l'Institut national de santé publique du Québec in Ste-Foy, and the Bureau of National Sciences Laboratory in Ottawa. Each laboratory specializes in a different group of tests.

These laboratories meet the physical and data security requirements of Statistics Canada. Blood and urine samples are sent from the clinic to the laboratories in de-identified tubes (identity of respondents cannot be determined by researchers or laboratory staff). Access to the personal information associated with the identification number on the tube is restricted; it is granted on a need-to-know basis to selected Statistics Canada employees only at head office when it is essential to their work. This occurs when, for example, respondents' blood and urine test results are combined with their household and physical measures data or when respondents request that their samples be withdrawn from the survey. The electronic data based on the results of the blood and urine tests, like other data collected by Statistics Canada under the authority of the Statistics Act,[20] are kept confidential and secure, and are transmitted to head office only after encryption.

Some blood and urine samples are stored indefinitely at the NML biorepository, a facility that meets the physical and data security requirements

Security measures at Statistics Canada

The following security measures are in place at Statistics Canada:

- Access to Statistics Canada buildings is controlled by a combination of physical measures and access procedures.
- All visitors are escorted to the work area and escorted back to the building entrance at the end of the visit.
- Employees' and visitors' identification cards must be visible at all times.
- All staff undergo a reliability (security) check.
- Only Statistics Canada employees with a "need to know" have access to sensitive statistical information and then only to the information required to do their job.
- Within Statistics Canada, interdivisional access to sensitive statistical information must be approved by the director of the division holding the information.
- Disposal of sensitive statistical information is carried out under secure conditions according to government-approved procedures.
- Non-computerized confidential data are stored in security-approved containers.
- Statistics Canada's EDP (electronic data processing) Security Policy outlines the safeguards the Agency has put in place to ensure that its information systems are secure, including:
  - Two separate data processing and communications networks are maintained, one of which is a closed internal computer network preventing physical and electronic access from outside Statistics Canada's facilities and to which public access is not permitted.
  - Access to files is protected through access controls, passwords and servers located in access-controlled areas.
  - Communications within the closed internal computer network between Statistics Canada locations are facilitated through the use of secure data transmission lines and services specifically approved for that purpose.
  - Computing devices with external wireless connections may not be connected to any Statistics Canada network.
  - Electronic transmission of sensitive statistical information under specific special circumstances must adhere to approved security procedures.
  - Transmission of microdata files containing sensitive statistical information to Statistics Canada Regional Offices, Research Data Centres or to data-sharing partners must follow approved security procedures. Such information must be encrypted.
  - Sensitive statistical information is not transmitted from Statistics Canada by fax, except under certain specific conditions.
  - Storage of sensitive statistical information on removable storage media must follow approved security procedures. Such information must be encrypted.
  - Sensitive statistical information may not be taken out of Statistics Canada's secure premises.
  - Personal identifiers are removed from statistical master files after they are no longer required for data processing.
  - Breaches of security are formally reported to the Departmental Security Officer and to the Chief, Departmental Security.

Documents on security are available to all employees on Statistics Canada's Internal Communications Network. These documents include the Statistics Act,[20] the Privacy Act,[9] Statistics Canada's "Security Practices Manual," Statistics Canada's "Policy Manual," "An Employees' Guide to Security at Statistics Canada," "Data Security and You" (a summary of the most important security rules at Statistics Canada), a list of departmental contacts for security-related matters, and the "Companion Guide to the Statistics Act."

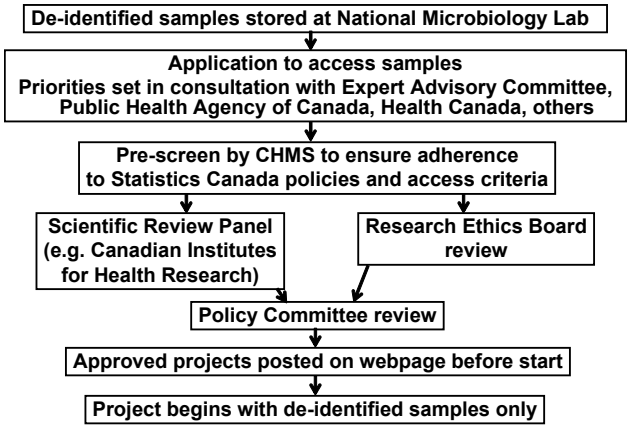
of Statistics Canada. Again, these samples are in de-identified tubes. The process for accessing these blood and urine samples is illustrated in Figure 2.

Reporting results to respondents

The November 2005 focus groups and the CHMS pre-test experience[4] showed that one of the reasons motivating people to participate in the survey is the opportunity to receive the results of their health measures and laboratory tests. To develop a process to inform respondents about their results, the CHMS had to identify, analyze and resolve a number of ELSI.

Typically, respondents to Statistics Canada surveys know the information that they provide about themselves. However, for the CHMS, the data collected from the physical measures and the laboratory tests are often unknown to respondents (for example, blood pressure). Although most people want to receive information about their health, some do not.

Figure 2
Canadian Health Measures Survey biospecimen access and use procedures



De-identified samples - Researchers are not given information about the person who provided the sample; they are given an anonymous number. Only a select few Statistics Canada employees at head office, on a need-to-know basis, have access to the key that makes it possible to combine results from a specific sample with the rest of that respondent's survey data. This key is needed to add new data to each respondent's file. The key is also used to identify samples destined for destruction if a respondent requests that his or her sample be withdrawn.

In accordance with ethical, legal and social principles, any information collected about a person should be provided to that person if requested.[6,7,10] To respect the preferences of respondents, the CHMS consent form (Appendix Figure B) seeks permission to provide them with their results. In addition, respondents are asked, as part of the computer application at the clinic, if they want to receive their clinic and laboratory results via regular mail or via a method such as courier where the delivery can be tracked. More details about the reporting process can be found elsewhere in this supplement.[3]

Parents or guardians of 14- to 17-year-olds are advised that if their adolescent agrees to participate in the survey and to receive his or her results, the results will be sent to the adolescent, not to the parent. This ensures that the privacy of these youths is respected. Results for children aged 6 to 13 years are sent to the child's parent/guardian if the parent/guardian consents to receive these results.

By law, when some infectious diseases are detected, they must be reported to public health officials. The CHMS lab analyses can yield two such reportable results: hepatitis B and hepatitis C. Under provincial public health legislation,[29-33] positive results to the hepatitis B core antigen and to the hepatitis C virus must be reported to provincial health authorities. This requirement creates a potential conflict for Statistics Canada since the CHMS data are collected under the Statistics Act,[20] which guarantees that individual results are confidential and are not shared without the respondent's consent.

Although from a legal point of view it would seem that the Statistics Act would take precedence, Statistics Canada's Policy Committee recognized the importance of contributing to the improvement of public health. The solution for the CHMS is to inform respondents about the requirement to share positive hepatitis B and hepatitis C results with provincial health authorities. If respondents are unwilling to share such results, they do not consent to having the hepatitis tests.

Because of the sensitive nature of such results, a personal contact process was developed to advise respondents who test positive. A CHMS Medical Advisor telephones to inform them and to provide counselling. Respondents are then sent the results and a letter to take to a regulated health care professional for follow-up.

The CHMS devoted considerable effort to the design of the results package that is sent to respondents. The objective is to provide useful information in an intelligible format for both respondents and health care providers.

Expert advice on the design of the results package was obtained from the Health Canada Research Ethics Board (Table 1) and other key CHMS committees (Table 2). Debriefings with participants in the CHMS pre-test that took place in the fall of 2004[4] were held to obtain their feedback on the usefulness of the report. Based on these consultations, the report provides the results of each physical measure taken at the clinic, the results from the laboratory analyses of the blood and urine samples, definitions of the laboratory

tests, and interpretations of the findings where reference ranges have been established. These interpretations are presented in a simple message that gives details about the respondent's specific results and/or advises the respondent to take some action (in most cases, follow-up with a health care professional).

For results that require immediate attention, a process was developed to advise respondents at the clinic. For blood pressure and oral health results that are potentially dangerous, a letter is generated and given to respondents before they leave the clinic, which they can take to a health care professional. This follow-up is required because the CHMS does not provide diagnoses.

Results of the blood and urine tests are normally provided to respondents 8 to 12 weeks after their visit to the clinic. If a laboratory result is not within established reference ranges, respondents receive an early report containing all results that have been analysed up to that point. This early report includes information about the abnormal results and contact information for the CHMS Medical Advisor, who is available to discuss the results, provide more in-depth information and offer counselling. Again, no diagnosis is given—respondents are advised to follow up with a health care professional as soon as possible.

The CHMS intends to conduct an extensive array of analyses of blood and urine samples.[1] Some results will be difficult, if not impossible, to interpret. For instance, this is the first time in Canada that a national population survey has included many of the environmental measures. The results will be used to establish baseline levels and reference ranges, to support population health risk assessments, and to guide potential interventions and control measures. Because baseline data for such measures currently do not exist, it is not possible to tell respondents how they compare to "normal" or "acceptable" levels. The CHMS team sought advice on this issue from its expert committees and the Health Canada REB, and investigated practices used elsewhere.[13] Consequently, respondents are informed about the exploratory nature of some variables and advised that these results are not routinely included in their results report. However, respondents are given a telephone number to call if they wish to obtain this information.

Inclusiveness

One of the guiding principles set out in the standard for research ethics boards in Canada—the Tri-Council Policy Statement (TCPS)[6]—is respect for justice and inclusiveness (Table 1)[6]: While "no segment of the population should be unfairly burdened with the harms of research,"[6] the statement also "imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances to research."[6]

The CHMS includes children, physically or mentally impaired/disabled individuals, and people who have difficulties reading, speaking and understanding English or French. Some consent procedures were modified for these groups, and CHMS staff have some procedural flexibility, as long as respondents' safety and dignity are not compromised. All CHMS physical measures clinic staff participated in a special workshop[34] to help them determine when and how to adapt procedures to accommodate physical and mental impairments.

Children aged 6 to 17 years participate in both the household and clinic portions of the CHMS. For those aged 6 to 11 years, the parent/guardian answers the questions on the child's behalf, with aid from the child as necessary. Statistics Canada experience has shown that for children younger than 12 years, proxy interviews (information provided by a parent/guardian) often yield more accurate data than do interviews with the child alone.

For almost all parts of the CHMS household interview, respondents 12 years of age or older reply on their own behalf. Unless adolescents grant permission, their responses are not made available to anyone else, including parents. Proxy interviews are conducted for respondents 12 years of age or older only if their mental or physical health makes it impossible for them to complete the interview without assistance.

The age at which children are capable of making their own decisions has been debated extensively.[35,36]

Consent for health care is probably the most closely related area of consent for a survey such as the CHMS, since respondents will receive results on which they may base decisions about their health care and health habits. The age of consent in Canada varies by province and by the topic for which consent is sought. In Ontario, the age of consent for health care is based on competency not age,[37] consistent with the mature minor concept.[38] In Quebec, the age of consent is legislated as 14.[30]

For the clinic portion of the CHMS, respondents aged 14 or older provide their own consent. This age was chosen for both the pre-test[4] and the main survey based on consultations with the Expert Advisory Committee, the Physician Advisory Committee, federal and provincial privacy commissioners, and others.

Physically impaired individuals are included in the CHMS, although some may be excluded from specific measures. Protocols are adapted where possible, depending on the type and degree of impairment.

For visually impaired respondents, at the household, interviewers verbally review the *Information and Consent Booklet*, including the consent forms. At the clinic, staff provide large-print consent forms to respondents whose visual impairment is moderate. For those whose visual impairment is more severe, clinic staff read the written consent form out loud and mark off each box as the respondent replies. If a family member or friend accompanies the respondent, they can observe clinic staff as they complete the form.

For hearing impaired respondents, the laptops used for collection at both the household and clinic interviews are turned to face them so that they are fully informed. The interviewers/clinic staff point to the appropriate text. Physical tests are demonstrated. For the household portion of the survey, respondents have the option of replying through a TTY/TDD service (a telecommunications device that enables conversation in written text by printout or electronic screen). The TTY/TDD number is included in the CHMS introductory brochure. The services of a sign language interpreter are made available if requested.

Interviewers and clinic staff use their judgment to determine if mentally impaired individuals aged 14 or older are able to understand the survey and the consent process well enough to give informed consent. If they cannot, their parent/guardian is asked to provide consent on their behalf. Mentally impaired individuals may be excluded from some physical tests if it is determined that they cannot understand the instructions.

All CHMS information is available in English and French. In addition, various documents relating to consent (brochure and consent form) and to the safety of tests are translated into some of the more common non-official languages. When available, interviewers/clinic staff fluent in the non-official language conduct the interviews and administer the tests. If this is not possible, the assistance of a family member fluent in one of the official languages and the non-official language or an outside interpreter may be used.

Storage

The CHMS plans to store biospecimens indefinitely so that researchers can take advantage of new tests and technologies as they emerge. Further information on the rationale of storage can be found in the CHMS background paper.[1]

National and international legislation and guidelines for the storage of blood and urine generally do not specify how long samples should be stored,[6] and the length of storage varies considerably across research projects. At both the household and the clinic, CHMS respondents are told that storage will be indefinite, and the benefits of indefinite storage are explained. Most participants in the November 2005 focus groups did not consider duration of storage to be an issue, nor could they suggest an ideal length of time for storage.

The ELSI related to access to stored samples received considerable attention during development of the CHMS. Once respondents have provided consent to collect their samples, Statistics Canada becomes the custodian of these samples. However,

respondents can request that their samples be withdrawn at any time, no matter how long they have been at the NML biorepository. Although information about specific projects that will use their samples is not known when respondents consent to storage, as soon as a project is approved the information will be posted on Statistics Canada's website.[39] This gives respondents an opportunity to withdraw their samples if they are uncomfortable with a particular study. Individual respondents will not be contacted for studies using stored biospecimens.

Over time, some respondents may lose the capacity to provide informed consent. They may no longer be able to understand details posted on the Statistics Canada website about projects that have received approval, or at least not in the same way that they understood when they originally consented to the use of their samples. Their ability to make an informed decision about whether they want their samples to be used in a particular study or whether they want them withdrawn may be compromised. The longer the period of storage, the more this becomes an issue.

A biorepository oversight committee has been established to address issues such as this and to ensure the confidentiality and privacy of the information obtained from the specimens. This committee provides oversight, advice and direction to Statistics Canada on established protocols for accessing the specimens and conducting research with them, and makes recommendations for changes to the protocols.

To obtain access to the samples and data files, researchers must follow a prescribed process (Figure 2). Those whose proposals are approved must become deemed employees of Statistics Canada, which entails taking an oath to uphold the confidentiality provisions of the Statistics Act.[20,40]

Summary

Development of the Canadian Health Measures Survey has necessitated addressing ELSI related to consent, privacy, confidentiality of data, reporting of results, inclusiveness, and storage of blood and urine samples. A variety of groups and individuals have been instrumental in establishing procedures to deal with these issues. Based on the specialized knowledge gleaned from the many groups consulted, the CHMS has been able to establish transparent protocols appropriate to the survey. Involvement by the Health Canada Research Ethics Board and the Office of the Privacy Commissioner of Canada has been especially useful. Ongoing oversight of not only the issues presented in this paper, but of all ELSI that arise is critical, especially given the indefinite storage aspect of the survey. This oversight will help ensure that the scope and understanding of the original consent provided by respondents, as well as their trust, are respected. ●

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Appendix

Figure A

Linking and sharing your data

Linking

The data we collect from you will contribute to a greater understanding of the general health of Canadians. It is even more valuable, however, to combine this data with provincial sources of health information, to provide as complete a picture of the health status of Canadians as possible. This is known as data or record linkage, and is only done for statistical purposes.

If you don't agree to have your data linked, it will not happen. However, findings from projects based on linkage could be used by governments to monitor, evaluate and change policies related to health care, health promotion and the use of health services. Further information can be found at www.statcan.ca/english/recrdlink.

At the end of your clinic visit, you will be asked whether you consent to the linkage of all your information. This information includes the responses to your household interview, results from your tests done at the clinic, information from your activity monitor, and results from laboratory tests done on your blood and urine samples. If you agree to linkage, we will

- ask you for your health card number to help with the linkage process
- combine the information that we collected during this survey with some of the information that your provincial health department, health registries or other recognized health organizations already have on file about you
- remove your name, address, date of birth and health card number from the linked file as soon as the linkage is complete
- destroy all linkage files after the project for which linkage was done is finished.

The linkage will take place at Statistics Canada and will be done only by Statistics Canada employees; all linked data will remain confidential under the Statistics Act. We will not provide any information about you to your provincial health department or registries-the flow of information is one-way only, to Statistics Canada.

Sharing

You will also be asked whether you consent to share the same data with Health Canada and the Public Health Agency of Canada (PHAC). This is done to reduce the number of times we have to survey Canadians. If you agree to share your data, this will mean that

- We will share your information with Health Canada and PHAC; however, your name, address, date of birth and health card number will be removed from any files before they are sent.
- Your information will not be shared with anyone else without your consent.
- Health Canada and PHAC will only use the information for statistical and research purposes and must keep the information confidential.
- No information from your provincial health department or registries will be shared.

If you don't agree to share your data, it will not be shared. This would be a missed opportunity, however, since researchers and experts at Health Canada and PHAC could help put the information we collect to its full use, potentially improving health policies and, as a result, the health of Canadians.

Figure B

CONFIDENTIAL WHEN COMPLETED

Date (yyyy/mm/dd):	2007/04/02
Identification Number:	10100015
Name:	JOHN DOE
Age at clinic exam:	45
Gender:	Male

I have read and understood the information provided to me in the Information and Consent Booklet for the Canadian Health Measures Survey. By marking the boxes below and signing this form, I am choosing to consent ("Yes") or not consent ("No") to the following:

participating in the physical measure tests, including providing samples of my blood and urine	Yes ☐	No ☐
receiving a copy of my Report of Laboratory Tests	Yes ☐	No ☐
allowing Statistics Canada to test my blood for the hepatitis B and C viruses and to contact me, as well as the appropriate provincial authorities, if the results are positive	Yes ☐	No ☐
storage of my blood and urine for use in future health studies	Yes ☐	No ☐
storage of my DNA for use in future health studies	Yes ☐	No ☐

I have had time to decide on participating in the clinic portion of the survey. I understand that even though I have consented to some or all of the items on this form, I can still withdraw from any part of this survey or subsequent studies at any time.

JOHN DOE

_____ _____
Signature of participant Date

_____
Name of witness (please print)

_____ _____
Signature of witness Date

Statistics Canada Statistique Canada Canada