



Small Business and Special Surveys Division

The Human Genetic Material Survey

CONFIDENTIAL when completed

Collected under authority of Statistics Act,
Revised Statutes of Canada, 1985, Chapter S19.
Français au verso.



The purpose of the survey

Statistics Canada is conducting this survey on behalf of the Genetic Privacy Working Group of the Canadian Biotechnology Strategy. The objective of the survey is to produce new statistical information on the collection, use and disclosure of human genetic material in Canada.

Your participation is important

Participation in this survey is voluntary. However, your co-operation is essential to ensure the accuracy of the information collected.

The data you report are confidential

Statistics Canada is prohibited by law from publishing or releasing statistics that could reveal information obtained from this survey relating to an identifiable department, individual business or person. The data reported on the questionnaire will be treated in strict confidence, used for statistical purposes and released in aggregated form only. The confidentiality provisions of the *Statistics Act* are not affected by either the Access to Information Act or any other legislation.

Who should complete this questionnaire?

A senior manager, scientist/researcher should complete this questionnaire. If you are part of a commercial operation, please complete the questionnaire on behalf of all scientific activities at your physical location. If you are a federal government department or agency, please complete this questionnaire on behalf of your division.

If you have any questions regarding this survey or the questionnaire, please contact the Survey Manager, David Ogden (English) or Joanne Linekar (French), toll-free at 1-877-679-2746 or by e-mail at dave.ogden@statcan.ca or joanne.linekar@statcan.ca.

Please complete the following information

Name of Respondent:

Title of Respondent:

Organization:

Address:

Telephone Number: -- ext.:

5-5200-30.1: 2002-09-01 STC/SBS-524-75337

Confirmation of Holdings

S1: Does your organization currently hold, store or have in its possession, any sources of human genetic information such as blood, hair, bone, tissue, embryos, etc. or extracted genetic information such as DNA stored electronically?

- 1 - Yes
 2 - No → Thank you. Please return the questionnaire in the envelope provided.

Section A: Current Genetic Material Holdings

Primary sources of genetic information represents any and all organic human samples such as; blood, hair, bone, teeth, etc. and can be in many different forms such as slides, paraffin tissue blocks, tissue cultures, blood stained cards, swabs, frozen, etc.

Secondary sources of genetic information represents any and all copies of primary samples such as; cDNA, expressed sequence tags, vector libraries, PCR and RAPD products, cellular protein.

Tertiary sources of genetic information represents any and all derived or extracted information that is stored electronically such as; DNA sequences, DNA fingerprints or Gene-array hybridization data.

A1: Which of the following sources of genetic information does your organization currently hold?

Please mark all that apply.

- 1 - Primary sources of genetic information
 2 - Secondary sources of genetic information
 3 - Tertiary sources of genetic information

A2: For each source you identified in Question A1, please approximate the total number of samples, and if possible, the number of individuals represented by that source.

Please mark all that apply.

	Number of Samples	Number of Individuals
Primary Sources (i.e. blood, hair, bone, etc.)	a Number _____ <input type="radio"/> b - Don't Know	g Number _____ <input type="radio"/> h - Don't Know
Secondary Sources (i.e. copies of primary samples)	e Number _____ <input type="radio"/> d - Don't Know	i Number _____ <input type="radio"/> j - Don't Know
Tertiary Sources (extracted or derived electronic information)	c Number _____ <input type="radio"/> f - Don't Know	k Number _____ <input type="radio"/> l - Don't Know

A3: For what purpose(s) were your primary sources of genetic information originally collected?

Please mark all that apply.

- 1 - Diagnostic purposes
 2 - Research
 3 - Do not hold primary sources → go to Section B
 4 - Other, please specify _____

A3a: For what purpose(s) have most of your primary sources of genetic information actually been used?

Please mark all that apply.

- 1 - Diagnostic purposes
- 2 - Research, similar to the intent of the collection
- 3 - Research, secondary to the intent of the collection
- 4 - Other, please specify _____

A3b: How were your primary sources of genetic information obtained?

Please mark all that apply.

- 1 - Collected directly from donors
- 2 - Purchased
- 3 - Shared from another party (i.e. another researcher, corporation, etc.)
- 4 - Other, please specify _____

A3c: When your primary sources of genetic information were collected, were donors informed of the purpose of the collection?

- 1 - Yes
- 2 - Sometimes
- 3 - No → go to Section B
- 4 - Don't know → go to Section B

A3d: When your primary sources of genetic information were collected, were donors informed of any potential secondary usages of the collection?

- 1 - Yes
- 2 - Sometimes
- 3 - No → go to Section B
- 4 - Don't know → go to Section B

A3e: How were donors normally informed of the potential usages of the collection?

Please mark all that apply.

- 1 - Written documentation other than a consent form
- 2 - Verbally
- 3 - Consent form
- 4 - Ethics review board
- 5 - Don't know
- 6 - Other, please specify _____

Section B: Geographic Location of Holdings

The term “genetic material holdings” includes primary, secondary and tertiary sources of information.

B1: What is the origin of your genetic material holdings?

- 1 - All sources originate from Canadian residents
- 2 - Most sources originate from Canadian residents
- 3 - Equal sources of Canadian residents and non-Canadian residents
- 4 - Few sources originate from Canadian residents
- 5 - No sources originate from Canadian residents
- 6 - Don't know

B2: Geographically, where are your genetic material holdings stored?

- 1 - Entirely within Canada
- 2 - Mostly within Canada
- 3 - Half within Canada
- 4 - Mostly outside of Canada
- 5 - Entirely outside of Canada
- 6 - Don't know

Section C: Identification and Retention of Holdings

C1: How long do you retain most of your sources of genetic information?

Please mark one for each source.

Primary Sources	Secondary Sources	Tertiary Sources
<input type="radio"/> a1: Months, number _____	<input type="radio"/> b1: Months, number _____	<input type="radio"/> c1: Months, number _____
<input type="radio"/> a2: 1 year	<input type="radio"/> b2: 1 year	<input type="radio"/> c2: 1 year
<input type="radio"/> a3: 2 – 5 years	<input type="radio"/> b3: 2 – 5 years	<input type="radio"/> c3: 2 – 5 years
<input type="radio"/> a4: 6 – 10 years	<input type="radio"/> b4: 6 – 10 years	<input type="radio"/> c4: 6 – 10 years
<input type="radio"/> a5: 11 – 20 years	<input type="radio"/> b5: 11 – 20 years	<input type="radio"/> c5: 11 – 20 years
<input type="radio"/> a6: Indefinitely	<input type="radio"/> b6: Indefinitely	<input type="radio"/> c6: Indefinitely

C2: Who are the donors of your genetic material?

Please mark all that apply.

- 1 - Patients
- 2 - Employees
- 3 - Unpaid Volunteers
- 4 - Paid Volunteers
- 5 - Unknown – holdings are anonymized
- 6 - Don't know
- 7 - Other, please specify _____

C3: What identifying information is normally kept with your sources of genetic information?

Please mark all that apply.

- 1 - Donor name
- 2 - Donor medical records
- 3 - Employee records
- 4 - Indirect identification (i.e. such as a coding key that can be traced back to an individual)
- 5 - None
- 6 - Other, please specify _____

C3a: Beyond that which is normally kept, what identifying information is sometimes kept with your sources of genetic information?

Please mark all that apply.

- 1 - Donor name
- 2 - Donor medical records
- 3 - Employee records
- 4 - Indirect identification (i.e. such as a coding key that can be traced back to an individual)
- 5 - None
- 6 - Not Applicable
- 7 - Other, please specify _____

Section D: Research Practices

The term "genetic material holdings" includes primary, secondary and tertiary sources of information.

D1: Does your organization share genetic material holdings across different projects or studies either internally or externally?

- 1 - Yes, always
- 2 - Yes, sometimes
- 3 - Yes, rarely
- 4 - No, never → go to Question D1c
- 5 - Don't know → go to Question D1c

D1a: With whom do you share your genetic material holdings?

Please mark all that apply.

- 1 - Researchers within the company/division
- 2 - Researchers outside the company/division
- 3 - Donors
- 4 - Insurers
- 5 - Affiliated organizations
- 6 - Other, please specify _____

D1b: When you share sources of genetic information with other parties, do you utilise:

Please mark all that apply.

- 1 - A Memorandum of Understanding
- 2 - Contracts
- 3 - Some form of ethics review board
- 4 - None of the above
- 5 - Other, please specify _____

D1c: In your area of study (i.e. genomics, bioinformatics, etc.), is there sharing of genetic material holdings across different organizations?

- 1 - Yes, always
- 2 - Yes, sometimes
- 3 - Yes, rarely
- 4 - No, never
- 5 - Don't know

D2: Are any of your holdings linked to any other holdings either internal or external to your organization? For example, via a registry (i.e. a central blood bank, etc.)

- 1 - Yes
- 2 - No → go to Question D2c

D2a: What are these holdings linked to?

Please mark all that apply.

- 1 - A registry that is internal to your organization
- 2 - A registry that is external to your organization
- 3 - Medical information
- 4 - Personal information
- 5 - Other, please specify _____

D2b: How are these holdings linked?

Please mark all that apply.

- 1 - Internet
- 2 - Internal network
- 3 - Coding system
- 4 - Other, please specify _____

D2c: Is it possible to link any of your holdings to an individual?

- 1 - Yes
- 2 - No

D3: Do you utilise any procedures to safeguard the disclosure of your holdings?

- 1 - Yes
- 2 - No → go to Question D4

D3a: What disclosure safeguards do you utilise?

Please mark all that apply.

- 1 - Limited personnel access
- 2 - Secure physical premises
- 3 - Secure electronic system
- 4 - Password protected files
- 5 - Anonymization of samples
- 6 - Other, please specify _____

D4: Are you familiar with any of the following?

Please mark all that apply.

- 1 - The International Conference on Harmonization: *Good Clinical Practice* (1997)
- 2 - The Tri-Council Policy Statement: *Ethical Conduct for Research Involving Humans* (1998)
- 3 - Medical Research Council, *Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines* (2001)
- 4 - National Bioethics Advisory Commission, *Research Involving Human Biological Materials: Ethical Issues and Policy Guidelines* (1999)
- 5 - The U.S. Federal *Common Rule* (2001)
- 6 - Not familiar with these documents → go to Question D4b

D4a: Which of the following most closely resembles your organization's research practices?

Please mark all that apply.

- 1 - The International Conference on Harmonization: *Good Clinical Practice* (1997)
- 2 - The Tri-Council Policy Statement: *Ethical Conduct for Research Involving Humans* (1998)
- 3 - Medical Research Council, *Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines* (2001)
- 4 - National Bioethics Advisory Commission, *Research Involving Human Biological Materials: Ethical Issues and Policy Guidelines* (1999)
- 5 - The U.S. Federal *Common Rule* (2001)
- 6 - None of the above

D4b: Does your organization have its own policies and procedures with respect to research practises?

- 1 - Yes → Thank you. Please return the questionnaire in the envelope provided.
- 2 - No → Thank you. Please return the questionnaire in the envelope provided.

Comments?

Thank you for your assistance.
Please return the questionnaire in the accompanying self addressed prepaid envelope.