Statement of Principles on the Return of Research Results and Incidental Findings

Prepared by:
Karine Sénécal¹, Emmanuelle Lévesque¹, Conrad Fernandez², Anne Marie Tassé¹,
Ma’n Zawati¹, Bartha Maria Knoppers¹, Denise Avard¹

Centre of Genomics and Policy
Université McGill

RMGA

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¹Karine Sénécal, Me Emmanuelle Lévesque, Me Anne Marie Tassé, and Me Ma’n Zawati are Academic Associates at the Centre of Genomics and Policy at McGill University. Denise Avard is Associate Professor and Director of Research at the Centre of Genomics and Policy at McGill University. Bartha Maria Knoppers is Professor and Director of the Centre of Genomics and Policy at McGill University.

²Dr. Conrad Fernandez is a pediatrician, head of the division of Pediatric Hematology/Oncology at the IWK Health Centre of Halifax, and Professor in the Department of Bioethics of the Faculty of Medicine at Dalhousie University.
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1) Does the result meet generally accepted criteria of scientific and clinical validity? 
2) Do the benefits of returning results outweigh the risks? 
3) Has the agreement of the REB been obtained? 
4) Has the participant consented to return? 
   4.1) Participant choice and the right not to know 
   4.2) What happens when the initial consent does not address the return of research results issue? 
5) Has the result been confirmed?

C) THAT HAVE IMPLICATIONS FOR FAMILY MEMBERS

PRINCIPLE 4 – may be returned

PROCEDURES

1) Is the result meeting generally accepted criteria of scientific and clinical validity? 
2) Do the benefits of returning results outweigh the risks? 
3) Has the agreement of the REB been obtained? 
4) Has the research result been confirmed? 
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PRINCIPLE 6 – may be returned

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ACKNOWLEDGMENTS
PREAMBLE

The Network of Applied Genetic Medicine (hereafter RMGA) of the Fonds de la Recherche en Santé du Québec herein puts forward a “Statement of Principles on the Return of Research Results and Incidental Findings.” These principles will guide RMGA researchers, and researchers across Québec, in the planning and execution of genetic and genomic research projects. More precisely, the Statement intends to be a guide for the management and the communication of research results, and addresses research projects in genetics and genomics.

Considering the second version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*¹ (TCPS 2), which requires researchers to develop a plan for managing information for the data issuing from their research, and, under certain circumstances, to return material incidental findings;

Considering that the rules of the TCPS 2 supplement Québec law, and are applied in the province’s hospitals and universities;²

Recognizing that research aims to procure generalizable knowledge and, as a consequence, that the return of individual results and incidental findings should be considered only under certain specified conditions;

Recognizing that researchers may wish to return certain individual results and incidental findings to participants, notably for reasons of reciprocity;

The RMGA believes that complementary principles could benefit the Network’s researchers as well as researchers across Québec, notably for guiding them at the time of creating their plans for managing information revealed through research and determining which research results could/should be returned (or not), as well as when, to whom, how, etc.

This statement conforms to Québec law, notably the *Charter of human rights and freedoms*,³ the *Civil Code of Québec*,⁴ the *Act respecting health services and social services*,⁵ the *Act respecting access to documents held by public bodies and the protection of personal information*,⁶ and the *Code of ethics of physicians*.⁷

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² In Canadian university and hospital settings, all researchers are bound to act in accordance with this normative document to receive ethical approval for the realization of their research project, and to receive research funding (*ibid* at 5-6).
³ *Charter of human rights and freedoms*, RSQ c C-12 [Québec Charter].
⁴ *Civil Code of Québec*, LRQ c C-1991(CCQ).
⁵ *Act respecting health services and social services*, RSQ c S-4.2.
⁶ *Act respecting access to documents held by public bodies and the protection of personal information*, RSQ c A-2.1.
⁷ *Code of ethics of physicians*, RRQ c M-9, r 17.
Conforming to Québec law, this statement considers that certain situations require action. More specifically, the statement recognizes that all human beings whose lives are in peril have the right to assistance. Therefore, a researcher who has discovered a condition showing that the life of the participant is in danger and for which an effective intervention is available could be obligated to offer this information to the affected participant or to have a mechanism in place to do so, if the researcher does not have direct contact with the participant or is not qualified to communicate the finding.

This statement also recognizes that professionals have legal obligations to report when, for example, the security or development of a child is compromised, or when a reportable disease is ascertained by a physician or any chief executive officer of a laboratory or a medical biology department. In these situations, there is a legal requirement (for clinician researchers and laboratory director) that the information be reported to the competent authorities, and researchers should be aware of them.

In conformity with the Civil Code of Québec, the Statement also recognizes that decisions concerning children must be made in the child’s best interest. This is why our proposed principles of communication differ in the context of paediatric research (Principles of exception 5 and 6).

This Statement is inspired by other normative texts addressing the return of results in research. Although these texts do not have the force of law, they nonetheless serve as a source of inspiration for Québec.

Some of these normative texts come from professional organizations or subsidized groups, such as the Joint Statement of the Canadian College of Medical Geneticists and the Canadian Association of Genetic Counsellors on the Process of Informed Consent for Genetic Research, the Canadian Institutes of Health and Research’s Best Practices for Protecting Privacy in Health Research (2005) and Best Practices for Health Research Involving Children and Adolescents (2012), and the Position Statement: Ethical issues in health research in children of the Canadian Paediatric Society.

Other normative texts emanate from international and European organizations, and include research ethics rules that are internationally recognized. Notably, this Statement is inspired

8 Québec Charter, supra note 3 at s 2.
9 Youth Protection Act, RSQ c P-34.1, s 39 (1).
10 Public Health Act, RSQ c S-2.2, s 82; Minister’s Regulation under the Public Health Act, RRQ c S-2.2, r 2, ss 1, 2.
11 TCPS 2, supra note 1 at art 5.1.
12 Canadian College of Medical Geneticists and the Canadian Association of Genetic Counsellors, Joint Statement on the Process of Informed Consent for Genetic Research (July 2008), s 7(vii), online: Canadian College of Medical Geneticists http://www.ccmg-ccgm.org/.
13 Canadian Institutes of Health Research (CIHR), Best Practices for Protecting Privacy in Health Research (September 2005), ss 5.3.1, 5.3.2, online: http://www.cihr-irsc.gc.ca/e/29072.html.
by the *International Ethical Guidelines for Biomedical Research Involving Human Subjects*,\textsuperscript{16} the *International Ethical Guidelines for Epidemiological Studies*,\textsuperscript{17} and the *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research*\textsuperscript{18}.

The Statement is founded on the following guiding principles: beneficence (non-maleficence), respect for the individual (individual autonomy), respect for the privacy, and reciprocity.

It recognizes the social value of research and the importance of avoiding the therapeutic misconception; promotes transparency of research, notably in improving the diffusion of research results; and respects reciprocity in the relations between researchers and participants.

**INTRODUCTION**

Genetics and genomics research generates different types of results. Some are generalizable to a given group or to society in general; these are the general results of research. Other results have a more personal component and can have medical, familial (e.g. reproductive), or social (e.g. lifestyle) implications for the participant. In the context of genetic research, these “personal” results can nevertheless include a familial dimension, since they can have significant import for the participant’s biological relatives.

Additionally, using whole genome/exome sequencing in research can complicate the return of research results, as these techniques increase the amount of individual data that is generated. Some of this data can be clinically pertinent and validated, but most will have an uncertain predictive value, at least for the moment. Although this uncertainty is a challenge for managing and communicating the return of research results, the basic principles remain the same as those discussed in this Statement.

It is important to highlight that while it is possible to define in a variety of ways the different types of research results, no definition is perfect or unanimously accepted. For the Statement’s purposes, research results are divided into two large categories:

- General results; and
- Individual results and incidental findings.


Please refer to the Glossary (below) for the definitions of each of these categories as employed in the Statement.

The return of research results raises several ethical questions, notably with regard to beneficence, respect for autonomy, and respect for privacy. Return of research results also raises issues of justice (the right to care), of participants’ trust in biomedical research, the health system and health professionals, as well as reciprocity.

Moreover, researchers should consider their responsibilities with respect to the return of results. This is all the more important since the TCPS 219 stipulates both a duty for all researchers to disclose any material incidental findings discovered in the course of research to participants,20 and a duty for researchers in medical or genetics research specifically to develop a plan for the management of information revealed during their research21.

Against this background, the RMGA has developed a *Statement of Principles on the Return of Research Results and Incidental Findings*. The objective of this Statement is to provide the researchers of the RMGA and Québec with tools for developing their plan for managing information that may be revealed through their research; determining which results should/could be returned (or not); and how, when, to whom, by whom, etc., the results should be returned.

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19 *Supra* note 1.
20 *Ibid* at art 3.4.
GLOSSARY

**Scientific validity:** Capacity of a test to measure the characteristic it is designed to identify. In particular, this concept includes the capacity that the test will be positive if the genetic characteristic is present (analytical sensitivity), and negative if it is absent (analytical specificity).22 “Scientific validity” is also called “analytical validity”.

**Biobank:** An organized collection of human biological material and associated information, stored for one or more research purposes.23

**Clinical utility:** The value of the results in guiding the participant's choices regarding prevention or therapeutic strategies.24 The assessment of utility requires consideration of the benefits but also of the potential risks associated with the knowledge of the result or intervention.

Generally, the criteria considered for determining the clinical utility of a result may be grouped in two broad categories25:

1) Criteria concerning the result:
   a) the “service rendered” (in particular the value of the result to determine the possible medical measures in terms of prevention or treatment); and
   b) the context in which the result is offered (availability of treatment or prevention strategy);

2) Criteria relating to the participant: the measure of the clinical utility of a result may vary from one participant to another (depending on the participant’s situation). Social and cultural aspects should also be taken into account.26

**Clinical validity:** Measurement of the accuracy with which a test identifies or predicts a clinical condition. It is defined in terms of clinical specificity, sensitivity and predictive value.27

**General research results:** Aggregated results concerning a group or cohort of persons. The expression "general results" will be used hereinafter.

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23 Public Population Project in Genomics and Society (P3G), Lexicon, online: [http://p3g.org/biobank-lexicon#b](http://p3g.org/biobank-lexicon#b).
24 Council of Europe, *supra* note 22 at art 5, s 57.
26 Inspired by *ibid*.
27 Inspired by *supra* note 22.
**Human biological materials:** Tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids (whether or not obtained pre or post mortem). The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials.\(^\text{28}\)

**Incidental findings:** Unanticipated discoveries that are outside of the research objectives but that are relevant to the individual participant.\(^\text{29}\)

**Individual research results:** Results which concern an individual participant discovered during the course of research. The expression "individual results" will be used hereinafter.

In the context of the present Statement, “Individual Results” do not include:

- Existing personal information used during research (e.g. medical records).

**Secondary use:** The use in research of information or human biological materials originally collected for another purpose.\(^\text{30}\)

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\(^{28}\) TCPS 2, *supra* note 1 at glossary.

\(^{29}\) Inspired by *ibid.*

\(^{30}\) Inspired by *ibid.*
SCOPE OF DUTIES

I. Expected range of the research results or findings

In light of the boom in genetics research, and the development of techniques for sequencing the whole genome/exome, researchers should be attentive to new ethical questions, notably those addressing return of research results. This Statement of Principles applies to existing whole genome/exome technologies, but researchers should consider these principles to apply to emerging methodologies such as methylome, transcriptome and microRNA interrogation of expression of the human genome. All of these methodologies may uncover findings that are clinically pertinent and validated, or that have an uncertain or totally unknown predictive value.

In the research context, notably since the publication of the TCPS 2, this new reality has intensified debate on the management of incidental findings and the return of individual results, as well as the procedures concerning informed consent and the right to know (or not to know). Applying to all research conducted in Canada, the TCPS 2 established the researcher’s duty to inform participants of all material incidental findings discovered during the course of the research, as long as the participant consents to be informed.

Therefore, before starting a research project, researchers should evaluate the probability that their research will generate individual results and incidental findings. If necessary, they should determine the types of results that will be obtained, the likely implication of these results, for whom, in order to develop a suitable plan for managing this information.

II. Developing a plan for managing information

Because of the nature and quantity of the information analyzed, genetic or genomic research is especially likely to generate material individual results and material incidental findings compared to other research domains. Consequently, in almost all cases, genetics researchers should develop a plan for managing this type of information. The following section is designed to help the researcher to develop an appropriate plan for managing information.

A plan for managing information may not be justified in all circumstances (e.g. if all the samples to be used are anonymous or anonymized samples). If there is uncertainty as to whether a research project warrants such a plan, the necessity of such a plan should be determined by the researcher, in consultation with their local institutional REB.

31 Ibid at 181.
32 Ibid at art 3.4.
33 Ibid at arts 13.2, 13.3.
34 Ibid at art 3.4.
A) Components to consider before the development of a plan for managing information

To respect the autonomy of participants in their choice of whether or not to participate in research, the researcher should develop a plan for managing information explaining the nature of the data that may emerge from the research. The researcher should anticipate the various categories of results likely to emerge from the research and provide appropriate policy for addressing them.

For example, the types of results that may emerge from a research could be: 1) general results; 2) results of the initial evaluation of participants; and 3) individual results and incidental findings. In the case of individual results and incidental findings, a distinction could be made among:

- a) Result that has scientific and clinical validity as well as clinical utility:
  - for the participant;
  - for the members of the participant's biological family;
- b) Results whose consequences are validated and known, with no treatments or preventive measures, but which may affect substantive lifestyle choices;
- c) Results whose consequences are validated and known, with no treatments or preventive measures, but which may affect reproductive choices;
- d) Result for which the clinical repercussions are uncertain or unknown;
- e) Result concerning familial relationships (adoption, non-paternity).

1. Factors to consider when determining the policy for each information category

The researcher should consider the following factors in determining the appropriate policy for each category of result that could be revealed through their genetic research:

- The scientific and clinical validities of the information obtained;
- The clinical utility, i.e. the potential benefits and risks of communicating this information and the availability of treatment or preventive strategies; and
- The validation of the research result before any potential communication to the participant.

2. Modalities of communication

Researchers who anticipate returning results to participants should develop a plan for managing information with an appropriate procedure that clearly presents the modalities of

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36 According to article 13.2 of the TPSC 2, “[r]esearchers conducting genetic research shall [...] c) advise prospective participants of the plan for managing information revealed through the research” [emphasis added]. Elsewhere, article 3.2 stipulates that “[r]esearchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project.” Although the plan for managing information revealed through the research is not part of the list of information generally considered necessary to establishing informed consent (application paragraph of article 3.2), the same article states that the REB must verify whether other supplementary elements are necessary to the consent process. Yet, article 13.2 seems to require that the plan for managing information be one of these supplemental elements (ibid at arts 3.2, 13.2).

37 Ibid at art 13.3.
communication of results. When required, the plan for managing information could, among others, specify who will return the results, to whom, when, with which resources (e.g. genetic counsellors), etc. The plan for managing information, including the modalities of communication, should be submitted to the REB for approval and then presented to prospective participants during the consent process.

3. Information to transmit to participants

3.1) Possible consequences of return of results
Researchers planning to return research results to participants should allow them to make an informed choice of whether to receive the results or not. To make this choice in an enlightened manner, participants should be informed of possible consequences for themselves as well as their families, should they choose to know or not know about certain kinds of results. For example, participants should be aware that knowledge of some results may have a psychological impact (e.g. anxiety), have an impact on insurability or employment, require preventive measures, require the completion of other tests in a clinical setting, or may create a need to consult for a genetic counselling.

3.2) The researcher’s duty to divulge
In light of current professional norms and clauses contained in information and consent forms, researchers have a duty of confidentiality with regards to information gathered in the course of research. However, some situations create legal obligations to divulge information to third parties (e.g. reportable disease that must be declared to public health authorities by a physician or any chief executive officer of a laboratory or a medical biology department or, in cases where the security or development of a minor is compromised and the parent/guardian is unable or unwilling to act in the child’s best interest, notification of the Director of Youth Protection by a professional). It is important to note that participants should be informed of reasonably foreseeable situations in which the researcher could have such duties to divulge.

4. Participant preferences

4.1) Participant choice among established policies
The plan for managing information can present different options to participants. Participants’ preferences should be recorded, according to pre-established policies, for each category of information likely to emerge from the research.

Participant preferences should be respected when such a choice is given. However, beyond what is required by the TCPS 2 (i.e. return of results that have significant implications for the participant), researchers are not required to provide all results or incidental findings to participants (even if some participants want to receive such results). Researchers should

38 Ibid at art 13.2, 13.3.
39 Ibid at art 13.3(a).
40 Ibid at art 13.2.
41 Ibid at art 13.2, 13.4.
42 Ibid at art 5.2.
choose to establish a policy of non-return when the risks outweigh the potential benefits of communication. Examples of findings that can be withheld are raw genomic or other similar data, findings of uncertain significance or scientifically valid information with no clinical utility.

4.2) Participant preferences concerning the return of research results
Where individual results or findings will be offered to participants, researchers should develop appropriate procedures for communicating these results, taking into account the participant’s preferences or instructions. Therefore, the plan for managing information should outline the choices available to the participant, e.g. direct communication of the result to the physician or participant or to a third parties authorized to receive the information.43

However, in exceptional circumstances, the preferences expressed by a participant may be overridden, with the REB approval, if there are compelling reasons to do. The reasonably foreseeable disclosure requirements should be explained to prospective participants during the consent process. They should be part of the information explained in the plan for managing information.44

4.3) Transmitting information to third parties
Among the third parties authorized to receive research results, the plan for managing information could include transmitting information to a health professional45 identified by the participant. Moreover, researchers should give participants the opportunity to express preferences or instruction with regards to the return of certain individual results or incidental findings to biological relatives, or others persons with whom the participants have personal ties (non biological family – e.g. wife/husband, community or specific group).46

B) The process of planning and approving a plan for managing information

When a plan for managing information is required, the researcher should anticipate different possible situations (i.e. the diverse categories of results likely to emerge from the research) and anticipate appropriate policies and interventions strategies. As needed, the researcher should not hesitate to consult other resources, such as the research ethics committee (hereinafter, REB) of her organization, or his colleagues.47

43 Ibid at art 13.3
44 Ibid at art 5.2 (b)
46 Ibid at art 13.3.
47 Québec, Ministère de la santé et des services sociaux, unité de l’éthique, Actes de la 5e édition des Journées d’études des comités d’éthique de la recherche et de leurs partenaires – Peut-on se faire confiance? (Québec : Publications de Québec, 2010) at 2, 101, online: http://ethique.mssss.gouv.qc.ca/site/130.0.0.1.0.0.phtml; TCPS 2 supra note 1 at art 3.4.
The plan for managing information should be submitted to the REB for approval and subsequently, the fundamental aspects of it that could influence the decision of potential participants to take part should be presented during the consent process.48

C) Contents of the plan for managing information

The researcher should develop a plan for managing information explaining the nature of the observations likely to emerge from the research.49 Specifically, the researcher should explain for each of the informational categories likely to emerge:

- The policy anticipated in the circumstances (i.e. whether return of results is possible in this category or not);
- If applicable, the participants choices; and
- The modalities of communication.

Consequently, the plan for managing information should not only address results that are likely to be returned, but also identify results likely to be obtained that will not be returned (e.g. results whose significance is uncertain, results that are not clinically validated, etc.).

The plan for managing information could distinguish between 1) general results; 2) results of the initial evaluation of participants; and 3) the different types of individual results and incidental findings that are likely to emerge:

1. General results

Researchers should present to participants the methods that will be employed to share the project’s general results with participants (e.g. information bulletins, web sites, or other methods).50 The anticipated timing and nature of this sharing should be described.

2. Results of participants’ initial evaluations

Researchers may wish to return participant information obtained in the context of an initial evaluation.

When the initial evaluation of a participant reveals a life-threatening condition, the researcher should act. For example, a clinician-researcher should administer the required treatment. In the case of a non-clinician researcher or if the situation exceeds the capacity of the researcher-clinician, the participant should be referred to a professional able to intervene in circumstances.

When the research protocol provides initial evaluation of participants, the plan for managing information should address this issue and inform the participants of the plan in the event a life-threatening condition is found (e.g. necessary care will be administered by a member of the research team if the person is able to do so in the circumstances or the participant will be transferred or referred to a professional able to act in the circumstances).

48 In effect, article 13.2 (c) of the TCPS 2 stipulated that the prospective participant should be informed of the plan for managing information, which leads us to believe that the plan should be presented to participants before they decide whether to participate (TCPS 2, supra note 1 at art 13.2 (c)).
49 Ibid at art 13.2.
50 Ibid.
Others results obtained during the initial evaluation (i.e. those that do not immediately threaten the participant) could be communicated to the participants at the discretion of the researcher on the condition that the plan for managing information addresses this possibility and the participant consents to receive these results. If this is the case, returning this kind of result should be done as soon as possible after the initial evaluation. The researcher should nonetheless exercise caution in this regard: he should not provoke the therapeutic misconception, which is likely to lead participants to believe they are participating in a medical evaluation rather than a research project.

Where applicable, the feedback regarding the initial evaluation for the recruitment should be communicated as soon as possible. If the initial evaluation reveals abnormal results, the research team should encourage the participant to consult a physician.

3. Individual results and incidental findings

3.1) Possible Categories
As presented previously (part II. A), in the case of individual results and incidental findings, the plan for managing information could distinguish among:
   a) Results that has scientific and clinical validity as well as clinical utility:
      - for the participant;
      - for the members of the participant’s biological family;
   b) Results whose consequences are validated and known, with no treatments or preventive measures, but which may affect substantive lifestyle choices;
   c) Results whose consequences are validated and known, with no treatments or preventive measures, but which may affect reproductive choices;
   d) Result for which the clinical repercussions are uncertain or unknown;
   e) Result concerning familial relationships (e.g. adoption, non-paternity).
Note that some of the categories may exist simultaneously (for e.g. category b and c).

3.2) In the case of whole genome or exome sequencing tools
Although genetic and genomic research calls for a plan for managing information that is as complete as possible, some research contexts require a particularly exhaustive plan. This is notably the case when research uses whole genome or exome sequencing. In these circumstances, researchers should predict the categories of information most likely to emerge from the research and specify the policy adopted for each of them in the plan for managing information. The same holds for banked tissues and the fact that in the future such tissues may reveal results.
DECIDING WHICH RESULTS TO RETURN

I. GENERAL RESULTS

**PRINCIPLE 1**

General results should be made easily accessible to the scientific community, to research participants, and to the general population.

**PROCEDURES**

A) Accessibility of results

General results should be made available and should be as complete and accessible as possible.

The scientific community should be able to access the general results within a reasonable waiting period and, if possible, in a format that is easily accessible and free.

General results should be offered to all participants who want them, with the mode of transmission and level of language adapted to the particular groups of participants. Moreover, these results should be offered in a timely way. To the extent possible, these results should be in the form of a simple summary for the public.

B) Modes of communication

The methods chosen for return of general results to participants should be appropriate to the subject matter, and can be addressed to individuals, to a group, or to the general population (e.g. letter, electronic bulletin, web site). Researchers could also offer participants information on how to obtain a copy of scientific publications issuing from the research in which they participated. An opportunity to ask questions about the results could be offered.

C) Notification of participants

The modalities anticipated for dissemination of general results should form part of the information offered and explained to prospective participants, at the time of the consent process (e.g. in the plan for managing information). More precisely, researchers should furnish reasonable explanations about timing, modes of publication or dissemination of the research results.

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51 TCPS 2, supra note 1 at art 3.2 (f).
52 Ibid at p. 32-33.
D) Protection of privacy and confidentiality

The publication of general results should be done so as to minimize the risks of stigmatization for the identified groups, the families, and the participants concerned. The researcher should take the necessary precautions to protect the privacy and confidentiality of each participant in the course of returning the results. If necessary, researchers should inform potential participants at the time of consent if the dissemination of research results might result in identification, direct or indirect, of participants.53

II. INDIVIDUAL RESULTS AND INCIDENTAL FINDINGS

A) THAT SHOULD BE OFFERED TO PARTICIPANTS

**PRINCIPLE 2**
Individual results and incidental findings **should be** offered to participants when:

1) they are material54, i.e. when the following conditions are met:
   1.1) they meet the generally accepted criteria of scientific55 and clinical validity56 (criteria widely recognised by the medical community);
   1.2) they have clinical utility57 for the participant, i.e.:
       - the benefits associated with the communication of the results outweigh the risks;
       - prevention or treatment is available; and
       - individual, familial and social particularities were considered;

2) exceptions and additional considerations related to the research context have been weighed;

3) REB approval has been obtained;

4) the participant has consented to the return of results; and

5) the research result has been confirmed.

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53 Ibid at art 3.2 (f)
54 Note that according to the TCPS 2, material incidental findings are those “that have been interpreted as having significant welfare implications for the participant, whether health-related, psychological or social,” and that must be returned to participants *(ibid at art 3.4).*
55 Among the common characteristics of evidentiary requirements for reviewing the scientific validity of a result, a researcher could assess measures such as precision, reliability, accuracy, sensitivity, and specificity of the result. However, the accuracy of the result should not be confirmed until the researcher ensures that the other conditions are met. In this way, only results that could be communicated to the participant will be confirmed, and clinical laboratory services will not be wasted.
56 Refers to both the “scientific validity” and “clinical validity” *(see the Glossary for more details).*
57 Refer to the definition of clinical utility in the glossary.
PROCEDURES

A) Diligence
When a research project yields individual results or incidental findings, researchers should analyze the situation with diligence:

- When they are not sure of their interpretation, they should consult colleagues;\(^{58}\)
- In the case of rare conditions, consultation with expert clinicians may be required.

The information provided by professionals should be transmitted to the REB (see Principle 2, point 3).

B) Approaches
Generally, since the context of research essentially aims to extract generalizable knowledge, the return of individual results and incidental findings is an exceptional situation. Therefore, this situation should meet certain specific conditions. To determine whether an individual result or incidental finding should be returned to a participant, the researcher should ask the following questions:

1. Is the result material?

1.1) Does the result meet the generally accepted criteria of scientific and clinical validity?
The results can be considered to have scientific validity and clinical validity when they meet generally accepted criteria\(^{59}\) (see glossary for definitions of these concepts).

- Characteristics for reviewing scientific validity
Among the common characteristics of evidentiary requirements for reviewing the scientific validity of a result, a researcher could assess measures such as precision, reliability, accuracy, sensitivity, and specificity of the result.\(^{60}\) However, the accuracy of the result should not be confirmed by a clinical test until the researcher ensures that the other conditions are met (e.g. clinical utility of the result, wish of the participant to be aware of this type of result, and REB agreement that a validated result may be sent to the participant, etc.). Indeed, the burden of confirming all research results would potentially have an impact on the operationalization of such recommendations. This is why the result obtained in the context of research should be confirmed in a clinical setting once all other conditions are met. In this way, only results that could be communicated to the participant will be confirmed, and clinical laboratory costs will not be wasted.

\(^{58}\) TCPS 2, supra note 1 at art 3.4.

\(^{59}\) While numerous evaluation frameworks for the assessment or adoption of genetic tests exist, there is no single, standardized process. The primary test performance measures include analytical validity (also called scientific validity) and clinical validity, as well as clinical utility. Some of these evaluation frameworks also consider ethical, legal, and societal implications. See A Morrison & R Boudreau, “Evaluation Frameworks for Genetic Tests” (2012) 36 Environmental Scan (Ottawa: Canadian Agency for Drugs and Technologies in Health), online: http://www.cadth.ca/en/products/environmental-scanning/environmental-scans/environmental-scan-37.

\(^{60}\) Morrison, ibid at 6.
- **Characteristics for reviewing clinical validity**
  The researcher could evaluate measures such as diagnostic specificity and sensitivity, as well as positive and negative predictive value.  

- **When tests of scientific and clinical validity are not met**
  Results not meeting generally accepted criteria of scientific and clinical validities should not be transmitted to the participant, because the potential risks then outweigh the benefits of return.

1.2) **Does the result have clinical utility for the participant?**
Taking into account the clinical utility of a result is an essential criterion in the decision to offer it to a participant. Criteria generally considered for determining the clinical utility of a result may be grouped in two large categories: those concerning the result and those concerning the situation of the person to whom the result is proposed.

The appreciation of the clinical utility should be considered according to the following elements:

- **Do the benefits of return outweigh the risks?**
  The “service rendered” by the act of disclosing the result should be considered (i.e. the benefits and potential risks of the knowledge of the result or possible interventions after return).

- **Is a treatment or preventive strategy available?**
  The value of the result to determine the possible medical measures, in terms of prevention or treatment, should be considered. More specifically, the researcher should determine if any action could be taken to improve the health of the participant, whether to prevent or treat the condition in question.

- **Have individual, familial and societal characteristics been considered?**
  According to the TCPS 2, researchers should disclose results or “findings that have been interpreted as having significant welfare implications for the participant.” Welfare refers, however, to the quality that it has in all aspects of her life, including factors such as physical, mental and spiritual health as well as family and social life. Consequently, the researcher

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61 Ibid.
63 Council of Europe, supra note 22 at art 57.
64 It is essential to emphasize that the TCPS 2 defines the material character of a research result by consequences that are "interpreted as having significant welfare implications for the participant, whether health-related, psychological or social" (supra note 1 at art 3.4).
65 Ibid.
66 Yet, the TCPS 2 also states that "[t]he welfare of a person is the quality of that person's experience of life in all its aspects. Welfare consists of the impact on individuals of factors such as their physical, mental and spiritual health, as well as their physical, economic and social circumstances. Thus, determinants of welfare can include housing, employment, security, family life, community membership, and social participation,"
should take into account the individual, familial and social particularities to assess the utility of a result. An individual result or incidental finding may reduce uncertainty, or inform reproductive or lifestyle choices. This should be weighed in the balance of benefits and risks of the communication.

The TCPS 2 gives no clear guidance on the level of impact required for the personal, familial or social dimension of return of the results.  

However, the return of individual results and incidental findings for personal, familial or social welfare could have a substantial impact on the health system (e.g. costs of further testing, genetic counselling services). Operational difficulties relating to the return of individual results and incidental findings for reasons related to personal, familial or social welfare, should be considered in the potential risks of the return of the result. The decision whether to return results with “personal, familial or social” utility for the welfare of the participant should be evaluated on a case by case basis according to the most favourable possible balance between benefits and potential risks, and should be approved by the REB. The potential systemic impact of such an extended obligation is an important consideration.

2. Have exceptions and additional considerations related to the research context been weighed?

It is impossible to use a single approach for all research contexts. Consideration of the research context will help determine whether an individual result or incidental findings should be returned to the participant.

2.1) Exceptions

Research participants’ vulnerability can modify the general principles of return of results (see supra Principles 5 and 6). More precisely, when participants are legally incapable of consent (i.e. in the case of minors or incapacitated adults), the general principles of return of individual results and incidental findings are different, as the best interests of the vulnerable individual must prevail.

2.2) Additional considerations related to research context

In certain research contexts, for example when the research is conducted using anonymized biological samples or anonymized genetic or medical data, the return of individual results and incidental findings, even material ones, is impossible.

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among other aspects of life. [...] A person’s or group’s welfare is also affected by the welfare of those who are important to them” (ibid at 10).

67 Supra note 1 at art 3.4.
In other circumstances, the duration and nature of the relationship between researcher and participant could influence expectations. The closer research is to the clinical context, the higher the expectations may be that individual results and incidental findings be returned.

In the same vein, if a researcher conducts a longitudinal study over twenty years with a very limited number of participants (e.g. research on a rare disease) and has regular contact with the participants in question, this could also intensify the expectations of the return of individual results and incidental findings to the participants.

3. Has REB approval been obtained?
The researcher should have a plan for managing information that may be revealed through genetic research approved by the REB, and should provide a policy for the return of material individual results and material incidental findings. The return of the material individual result or material incidental finding should be done in conformity with the plan for managing information approved by the REB. Also, any deviation from the plan or any difficulty in implementing the plan for managing information should be evaluated by the REB. In particular, researchers unsure of whether to communicate a result should consult their REB.

In the absence of such plan for managing information (for example, when the research in question was approved by the REB before the publication of the TCPS 2), the researcher who identifies a material individual result or a material incidental finding should submit the case to the REB to determine whether or not, in the circumstances, the researcher should contact the participant anew. If this is the case, the return should be conducted in conformity with the REB’s approved procedure.

4. Has the participant consented to be informed of the result?
Voluntary and informed consent constitutes the expression of the participant’s autonomy. This consent is only valid if the participant is informed of the research’s scope and limits, notably concerning the return of individual results and incidental findings.

4.1) Participant choice and the right not to know
When researchers anticipate the return of results or incidental findings, participants should be allowed to make an informed choice about whether or not to receive results\(^{68}\). Respect for individual autonomy requires that the participant’s opinion be sought during the consent process.

Moreover, as consent is an ongoing process\(^{69}\), research participants should have the option of refusing the return of individual results and incidental findings that concern them at all times\(^{70}\). Following this principle, if a participant has indicated a wish to receive

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\(^{68}\) Ibid at art 13.3(a).

\(^{69}\) Ibid at art 3.3.

\(^{70}\) Supra note 12.
individual results and incidental findings, the researcher should nevertheless confirm the desire to receive results before returning them.

In the case of refusal, the right not to know should be respected. Participants who initially refused to be informed of the individual results and incidental findings might change their minds during the research and notify the research team. However, researchers should not be normally obliged to accept changes of mind beyond the funding period of the research.

4.2) What to do when the initial consent does not address the issue of return research results?

When the initial consent does not address the issue of return of individual results or incidental findings to participants (e.g. when the consent was obtained before the publication of the TCPS 2\(^{71}\)) and the researcher identifies a material individual result or a material incidental finding (refer to the criteria above under Principle 2), the researcher should submit the case to the REB to determine whether or not, in the circumstances, the researcher should contact the participant anew in order to return the material results.

5. Has the result been confirmed?

Because errors in the results of genetic tests can have serious and sometimes irreversible consequences, the researcher should develop mechanisms to reduce or manage the risks involved by inexact testing and to ensure scientific validity of the result. Although the validity of a test is judged on the evidence and not on the type of laboratory that performed the test, the results obtained in a research laboratory should be confirmed by an accredited clinical diagnostic laboratory before return.\(^{72}\) However, in order to minimize the operational impact of this condition on clinical laboratories, confirmation of the results should only be performed when the result satisfies the four conditions set out above.

In this regard, an action plan should be developed in the initial research protocol indicating that research results will be confirmed, where necessary.

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\(^{71}\) This could be the case, for example, when a researcher uses data or samples stored in a biobank that was created before the publication of the TCPS 2 and the initial consent did not address the issue of individual research results or incidental findings.

B) THAT MAY BE OFFERED TO PARTICIPANTS

**PRINCIPLE 3**

Individual results and incidental findings that do not meet the criteria set out in Principle 2 (hereinafter called non-material individual results and non-material incidental findings) may be offered to participants (i.e. at the researcher's discretion) when:

1) they meet the generally accepted criteria of scientific and clinical validity;

2) the benefits of return surpass the risks;

3) REB approval has been obtained;

4) the participant consented to the return; and

5) the research result has been confirmed.

**PROCEDURES**

Non-material individual results and non-material incidental findings may be returned to participants (i.e. at the researcher's discretion) when the following five conditions are met:

1) **Does the result meet generally accepted criteria of scientific and clinical validity?**

   Results can be considered to have scientific validity and clinical validity when they meet generally accepted criteria (see glossary for definitions of these concepts and explanations under point 1.1 of Principle 2 for more details).

   Results that do not meet generally accepted criteria of scientific and clinical validities should not be return to the participant, because the potential risks may outweigh the benefits of return.

2) **Do the benefits of returning results outweigh the risks?**

   Researchers can transmit individual results and incidental findings that are non-material if the benefits of the return outweigh the risks. The benefits and the risks to consider are those affecting the participant as well as his family, the community, and society in general. It remains to be determined how to weigh benefits for the participant against risks to society (e.g. increased costs).

   Results that do not have scientific and clinical validity should not be transmitted to the participant, because the potential risks then outweigh the benefits of return.

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73 *Supra* note 17 (commentary).

### Examples of benefits
- Improvement of general health, prevention
- Informed decisions about reproductive choices
- Participant's feeling of reciprocity
- Maintenance of participant's trust of researchers
- Financial savings for the health system

### Examples of risks
- Anxiety for the participant and the participants family
- Frustrations caused by uncertainty of results
- Human and financial resources required to return
- Risk for insurance and employability
- Difficulty accessing resources for follow-up care
- Impact of supporting participant on the health system

#### 3) Has the agreement of the REB been obtained?
When a researcher wishes to return non-material individual results and non-material incidental findings, this should be indicated in the plan for managing information submitted to the REB. Where applicable, the return of non-material individual results and non-material incidental findings should be consistent with the plan for managing information approved by the REB. Any deviation from the plan for managing information or any difficulty in applying the plan should be evaluated by the REB. In particular, the researcher who has a doubt as to whether or not to communicate the result in the circumstances should consult an REB.

The researcher could legitimately choose not to provide non-material individual results and non-material incidental findings to participants. The policy of non-return of non-material individual results and non-material incidental findings should be clearly stated in the plan for managing information and be approved by the REB.

In the absence of a plan for managing information revealed through genetic research (e.g. when a research was approved by the REB prior to the publication of the TCPS 2), the researcher should not return non-material individual result or non-material incidental findings.

#### 4) Has the participant consented to return?
Researchers are not required to return non-material individual results or non-material incidental findings. Voluntary and informed consent constitutes the expression of the participant’s autonomy. This consent is only valid if the participant is informed of the research’s scope and limits, notably concerning the possibility of being informed (or not) of non-material individual results and non-material incidental findings.
4.1) **Participant choice and the right not to know**
When the researchers provide a policy where the return of non-material individual results or non-material incidental findings is possible, participants should make informed choices about whether they wish to receive information or not\(^\text{75}\). Respect for individual autonomy requires that the participants’ opinion be sought during the consent process.

Moreover, as **consent is an ongoing process**,\(^\text{76}\) participants should have the opportunity to refuse to be informed of individual results and incidental findings at any time during the research\(^\text{77}\). Following this principle, if a participant has indicated in the plan for managing information a wish to receive individual results and incidental findings, the researcher should nevertheless confirm the participant’s willingness before returning the results.

In the case of refusal, **the right not to know** should be respected. Participants who initially refused research results might change their minds during the research and notify the research team. Researchers are not obliged to accept changes of opinion beyond the funding period of the research.

4.2) **What happens when the initial consent does not address the return of research results issue?**
When initial consent does not address the issue of return of individual results and incidental findings (e.g. when the research consent was obtained before the publication of the TCPS 2\(^\text{78}\)), the researcher should not return non-material individual research results and non-material incidental findings to participants.

5) **Has the result been confirmed?**
Because errors in the results of genetic tests can have serious and sometimes irreversible consequences, the researcher should develop mechanisms to reduce or manage the risks involved by inexact testing and to ensure scientific validity of the result. Although the validity of a test is judged on the evidence and not on the type of laboratory that performed the test, the results obtained in a research laboratory should be confirmed by an accredited clinical diagnostic laboratory before the return of the individual results or incidental findings to the participant\(^\text{79}\). However, in order to minimize the operational impact on clinical laboratories, **confirmation of the results should only be performed when the result satisfies the four conditions set out above.**

In this regard, an action plan should be developed in the initial research protocol indicating that research results will be confirmed, where necessary.

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\(^{75}\) TCPS 2, *supra* note 1 at art 13.3(a).

\(^{76}\) Ibid at art 3.3.

\(^{77}\) *Supra* note 12.

\(^{78}\) More specifically, this could be the case, for example, when a researcher uses genetic data or stored biological samples in a biobank created before the publication of the TCPS 2 where the initial consent did not address the issue of individual results or incidental findings.

\(^{79}\) *Supra* note 12. See also *supra* note 72.
C) THAT HAVE IMPLICATIONS FOR FAMILY MEMBERS

**PRINCIPLE 4**

It is possible that individual results and incidental findings have implications for the participant’s **BIOLOGICAL RELATIVES**. Under certain circumstances, these results may be returned (i.e. *at the researcher’s discretion*) to family members when:

1) they meet the generally accepted criteria of scientific and clinical validity;
2) the benefits of the return outweigh the risks;
3) REB approval has been obtained;
4) the research result has been confirmed;
5) the participant agrees to share the result with biological relatives; and
6) the biological relatives concerned agree to receive the results.

**PROCEDURES**

1) **Is the result meeting generally accepted criteria of scientific and clinical validity?**

Researchers could consider returning individual results and incidental findings with implications for family members if the result meets the generally accepted criteria of scientific and clinical validity (see glossary for definitions of these concepts and refer to the explanations under Principle 2 for more details on these criteria).

Results that do not meet generally accepted criteria of scientific and clinical validity should not be returned to a family member, because the potential risks then outweigh the benefits of return.

2) **Do the benefits of returning results outweigh the risks?**

Researchers could consider returning individual results and incidental findings with implications for family members if the benefits of the return outweigh the risks. As specified above, the benefits and risks to consider are those that affect the participant, family members, and society in general. To consult a table of specific examples of benefits and risks, see the procedure section of Principle 3.

3) **Has the agreement of the REB been obtained?**

In the context of medical or genetic research, the plan for managing information should address information likely to emerge from the research that could allow treating, preventing or alleviating a health condition likely to affect a participant’s family member.

When a researcher wishes to return individual results or incidental findings to biological relatives, he should obtain the agreement of the REB.

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80 *Supra* note 17. See also *supra* note 62.
4) Has the research result been confirmed?
As previously explained, researchers should try to ensure the scientific validity of the result. In the alternative, they should develop mechanisms to reduce or manage the risks created by inexact testing. The results obtained in a research laboratory should be confirmed by an accredited clinical diagnostic laboratory before return to the participant.\(^{81}\) However, in order to minimize the operational impact of this condition (cost and impact on clinical laboratories), *confirmation of the results should only be performed when the previous conditions set out above are met.*

5) Has the participant agreed to share the result with biological relatives?
At the time of the consent process, participants should be able to express their preferences with regard to the return of individual results and incidental findings to biological relatives, as well as to other persons with whom they share ties (family, community, or another group).\(^{82}\)

If a material individual result or material incidental finding is returned to a participant (see conditions under Principle 2) and this result has potential health importance for a biological relative, the researcher should encourage the participant to share the information with related biological relatives in explaining the importance of the information for them. If necessary, the participant should be supported by the researcher for the communication of the result to the concerned relatives.\(^{83}\) If the participant’s refusal persists, the researcher should consult the REB\(^{84}\) to determine the appropriate course of action in the circumstances.

6) Do the biological relatives agree to receive the results?

6.1) *Consent and the right not to know for biological relatives*
Biological relatives also have a “right not to know” genetic information that relates to them\(^{85}\). Consequently, when a participant or researcher approaches biological relatives to offer material results (or material incidental findings) that affect them personally, the person should present the situation with vigilance, keeping in mind that the biological relatives do not expect to receive such information, and being attentive to signs suggesting that they prefer not to be informed of the results.

\(^{81}\) Supra note 12. See also supra note 76.
\(^{82}\) TCPS 2, supra note 1 at arts 13.2 - 13.3.
\(^{83}\) See also above section Modalities of Communication.
\(^{84}\) TCPS 2, supra note 1 at art 5.2.
EXCEPTIONS - Principles 5 to 7

It is impossible to apply a single approach to all research contexts. It is particularly important to consider the specific circumstances of participants. The vulnerability of participants is a crucial element and leads to certain categories of exceptions.

A) MINORS

1) Justification Principle 5 - What is the best interest of the child?

The best interest of the child constitutes an essential consideration for all decisions concerning minors.86 The minor's parents should not refuse the communication of individual results or incidental findings when the child's immediate health is likely to benefit from return of results (e.g. early onset serious disease for which, according to the evidence-based, treatment or preventive measures must be initiated during childhood or adolescence). A refusal to receive this category of result could be considered as a refusal of care required for the health of a minor.

**PRINCIPLE 5**

Individual results and incidental findings concerning a MINOR should be returned when all the following conditions are met:

1. they meet the generally accepted criteria of scientific and clinical validity;
2. they have significant implications for the health of the minor;
3. effective treatment or prevention is available and should be initiated during childhood or adolescence;
4. REB approval has been obtained; and
5. the research result has been confirmed.

Under these circumstances, the parents should not refuse the return of results. A refusal to receive this category of result could be considered medical neglect.

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86 *Convention on the Rights of the Child*, 20 November 1989, 1577 UNTS 27531 at 3, s 3(1), online: [http://www.ohchr.org/Documents/ProfessionalInterest/crc.pdf](http://www.ohchr.org/Documents/ProfessionalInterest/crc.pdf); See also art 33 CCQ which reads: “Every decision concerning a child shall be taken in light of the child’s interests and the respect of his rights. [para 1] Consideration is given, in addition to the moral, intellectual, emotional and physical needs of the child, to the child’s age, health, personality and family environment, and to the other aspects of his situation. [para 2]”
2) Justification Principle 6 - Do the benefits of returning results outweigh the risks?

As in all research, paediatric research should allow a favourable balance between the benefits and the risks it creates.

When individual results or incidental findings concerning a minor do not meet the criteria stated in Principle 5, they generally should not be returned to the parents. In effect, the guidelines governing the use of genetic tests on minors stipulate that, even in a clinical context, genetic information on adult onset genetic conditions should not be returned, unless there is a treatment or a preventive measure that needs to be initiated and administered during childhood or adolescence to prevent harm. Divulging information about the future health of a child, when there is no treatment or preventive measure, could engender more harm than benefit, which would be contrary to the best interest of the child. This could create anxiety for the parents, engender psycho-social effects in the child, and restrain the possibility for the child to have an open future, i.e. the possibility of deciding for himself whether he wants to know certain genetic information (also designated the “right” of the child to an open future).

As a case in point, in the context of paediatric research, a large amount of data, even those that are clinically pertinent, concern the future health of children (e.g. information on carrier status, eventual development of late-onset diseases, likelihood of developing common diseases, etc.). Conforming to current norms, this information should not be divulged unless there is an effective treatment or preventive measure that can be commenced during childhood or adolescence.

Nevertheless, under certain exceptional circumstances (refer below to Principle 6), it is possible that the revelation of a significant and valid genetic result may engender a favourable balance between benefits and risks, despite the absence of treatment or preventive measures possible during childhood and adolescence. This could be the case, for example, if a researcher notices that a minor is a carrier of a mutation in the genes BRCA1 or BRCA2. Although knowing this information will not lead to starting treatment or preventive measures during the participant’s childhood or adolescence, the information can have significant consequences for the health of the child’s parents and adult-aged sibling, for whom it will be possible to start effective preventive measures (cascade screening, regular follow-up, early intervention, etc.).
**PRINCIPLE 6**
Individual results and incidental findings concerning the future adult health of a **MINOR should not be offered.**

However, in *exceptional circumstances*, this principle *may be* outweighed and results may be returned to the minor’s parent when the following conditions are met:

1) the results meet the generally accepted criteria of scientific and clinical validity;

2) the results are important for the immediate health of a parent or adult-aged sibling, considering:
   - the probability of the risk occurring (for the parent or adult-aged sibling) is high;
   - the consequences for the parent’s or adult-aged sibling health is serious;
   - treatment or an effective method of prevention is available;

3) REB approval has been obtained;

4) the results have been confirmed;

5) parental consent has been obtained; and

6) when possible and appropriate, the assent of the minor participant should be obtained.

**PROCEDURES – PRINCIPLES 5 & 6**
The Procedures set out below are not exhaustive. They should be considered in addition to the Procedures of Principles 2 to 4 where applicable.

- **Information to communicate at the time of consent**
When paediatric research is likely to generate individual results and incidental findings, the minor’s legal representatives should be informed of the results at the time of the consent-obtaining process and when they are presented with the plan for managing information issued from the research project. Where possible and appropriate, the researcher should also inform an adolescent during the course of the assent-obtaining process.

Among the information that should be transmitted, researchers should explain that it is possible that individual results and incidental findings may reveal information significant for the immediate health of the minor, or other members of the family. The conditions and manner in which the return of research results should or could be made should be clearly explained.

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87 Article 13.2 of the TCPS 2 stipulates that the prospective participant should be informed of the plan for managing information, which gives the reader reason to believe that the plan should be presented to participants before they decide to participate (*supra* note 1 at s 13.2 (c)).
For example, the plan for managing information should explain the policy (to return or not) for each category of the following results:

1) material individual results and material incidental findings with importance for the immediate health of the child and for which the evidence-based is treatment or preventive measures during childhood or adolescence (mandatory policy of return of result);
2) individual results and incidental findings revealing information about the future adult health of the child for which there is no cure or preventive measure that can prevent the onset of disease in childhood or adolescents (mandatory policy of non-communication, except in exceptional cases (see conditions under Principle 6)); and
3) Exceptionally, results concerning the future adult health of the minor could be communicated to parents if they can have a significant impact on the health of the parents and there is an available effective intervention. The plan for managing information should present options and seek the parents’ preferences.

• **Duty to act**

When an individual result or incidental finding concerning a minor:

- Meets generally accepted criteria of scientific and clinical validities;
- Carries significant health implications for the minor; and
- Has an evidence-based method of prevention or treatment that should be initiated during childhood or adolescence;

researchers should act.

At first, researchers should consult their REB to obtain its agreement to return the result. The return of individual results and incidental findings should be done according to procedures established in the plan for managing information, or, if there is no plan (e.g. research begun before the publication of the TCPS 2), according to procedures established by the REB.

Researchers may return the results to parents and direct them toward appropriate resources. If the researcher does not have the necessary professional competence to return the result to the participant, then appropriate plans should be in place for timely clinical referral. In the plan for managing information, researchers may also delegate of the return of individual results and incidental findings to a designated health professional, for example, a doctor designated by the participant.

At the time of return of individual results or incidental findings, researchers or the people to whom this responsibility has been delegated (e.g. genetic counsellor), should provide parents (and the minor himself, if this is appropriate to the minor’s age and maturity level) clear explanations of the interpretation of the results in such a way as to address the distress that the results may cause. Researchers should also address the following elements:

- Possible preventative options or cures;
- The limits of extant clinical services;
- The results’ consequences for the participant’s family; and
- As necessary, the accessibility of genetic counselling services.
If the parents refuse to receive material individual results or material incidental findings, the researcher should then consult the clinical ethics committee. If the committee supports the researcher and proposes a course of action but the parents’ refusal persists, the researcher should refer the matter to child services, to obtain court authorization of another person to consent to healthcare that the minor requires, and to carry out the court order.

B) LEGALLY INCAPACITATED ADULTS
Québec civil law anticipates that the rules relating to minors’ exercise of civil rights also apply to adults under legal guardianship or trust, with some necessary adaptations. In the same way, the principles and procedures indicated in the section addressing paediatric research apply to research with incapacitated adult participants, with necessary adaptations. One exception could be if the incapacity is likely to be temporary and the sharing of the individual result or incidental findings is not deemed to be immediately necessary to prevent harm. In this case, the result could be withheld until the incapacitated individual recovers and can personally make an informed decision.

C) DECEASED PARTICIPANTS
The situation of participants deceased after their participation in a research project is a particular issue in genetics, because the individual results and incidental findings issue from the research can have implications for family members of the deceased.

Since it is impossible to contact the participant in order to obtain his consent to the disclosure of personal information to members of his family, and since ethical research norms generally require respect of the participant’s previously expressed wishes, it is preferable to anticipate the post-mortem type of some research results, especially when the participants are likely to pass away during the project. For example, this category of results could be anticipated in the plan for managing results for research with end-of-life participants or cancer research. In such cases, the wishes of the participants for the post-mortem disclosure of material results for family members should be ascertained. In addition, the participant should be encouraged to seek the opinion of people who may be concerned (e.g. adult children of the participant or the spouse of the participant if the children are minors, brother(s) or sister(s) of the participant) and may consider designating a surrogate decision-maker. A means to contact these family members should also be registered in the plan for managing information.

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88 Art 16 CCQ para 1.
89 Art 266 CCQ.
**PRINCIPLE 7**

Individual results and incidental findings *should be* returned POST-MORTEM to members of the family when:

1) they meet generally accepted criteria of scientific and clinical validity;
2) they have significant implications for family members;
3) the participant has previously consented that they be transmitted to family members;
4) REB approval has been obtained;
5) the family (i.e. the persons directly affected by the results) have consented; and
6) the research result has been confirmed.

**PROCEDURES**

When it is appropriate (e.g. research with end-of-life participants), the plan for managing information should address return of post-mortem research results and ask about the wishes of the participant in this regard.

**ADDITIONAL CONSIDERATIONS RELATED TO RESEARCH CONTEXT - Principles 8 to 10**

It is impossible to apply a single approach to all research contexts. Therefore, it is important to take certain contextual elements into consideration to determine if an individual result or incidental finding should be returned to the participant.

The principles set out below are not exhaustive. They should be considered in addition to Principles 1 to 7 where applicable.

**A) BIOBANKS**

**PRINCIPLE 8**

When biological samples or medical/genetic data are deposited in a BIOBANK for future use, the question of research results management and return *should be* addressed in the biobank’s management policy, and more specifically in the agreement for the transfer of medical/genetic data or biological material.
PROCEDURES
Biobanks differ widely and, consequently, the responsibility of research results management can be accorded to different people depending on the biobank. Generally, the principal investigator or investigators have the duty to protect the confidentiality and, if need be, the return of research results. Nevertheless, in some research contexts, for example when research results are encountered by researchers using a genetic databank or biobank, the duty to return results may be framed by the management policies of the biobank and addressed specifically in the transfer agreements for the data or biological materials. The principles to be considered by the biobank should encompass those laid out in Principles 1-8, and, if applicable in the context of the concerned biobank, Principles 9 or 10.

B) POPULATION-BASED RESEARCH

PRINCIPLE 9
In POPULATION-BASED RESEARCH, some elements linked to the research context could render the return of individual results and incidental findings impossible or unreasonable.

The following elements may be considered in such an assessment and to request a REB waiver concerning the communication of research results:

1) the scope of research objectives;
2) the number of participants involved;
3) the nature or duration of the relationship between the researcher and the participants, especially:
   a) the number of meetings between the participant and the researcher;
   b) whether these meetings took place with the researcher himself or other personnel;
   c) the duration of the participant’s involvement in the project;
   d) whether the researcher is also the participant’s treating physician; and
4) whether the data or samples are readily accessible to the researcher.

PROCEDURES
When return of individual results and incidental findings appears impossible or unreasonable, the plan for managing information should clearly permit participants to make an informed decision as to their participation in the research. It is important that participants do not have unrealistic expectations with regard to return of individual results and incidental findings.
C) LONGITUDINAL RESEARCH

PRINCIPLE 10
In LONGITUDINAL RESEARCH, the nature of the relationship between the researcher and the participant could modify expectations for the return of research results. For example, expectations of communication of research results could be intensified if a participant was regularly recontacted.

To judge the nature of the relationship between researcher and participant, the following factors may be considered:

1) number of participants involved in the research;
2) the number of encounters between the researcher and the participant;
3) whether these encounters took place with the researcher himself or other personnel;
4) the duration of the participant's involvement in the project; and
5) whether the researcher is also the participant’s treating physician.

PROCEDURES
In the context of longitudinal research, it would be judicious to ask participants for the name and contact information of their treating physician.

When longitudinal research involves minors, the researcher should offer the results to participants when they reach the age of majority during the research.

MODALITIES OF COMMUNICATION

Communication modalities should be clearly outlined in the plan for managing information revealed through the research. Remember that the plans for managing information should form part of the explanation given to “potential” participants, therefore preferably at the time of consent, so that participants can make an informed decision as to their participation in the research. The right to be informed of a plan for managing information that may be revealed through research is an extension of the recognized right to free and informed consent.

I) Liability

Researchers should show caution when disclosing research results. In case there is doubt as to the most appropriate method for returning results to participants, they should consult with their REB, and may also consult their colleagues.

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90 TCPS 2, supra note 1 at art 13.3.
91 Ibid at art 13.2(c).
92 Ibid at art 3.4.
Liability for managing research results could fall to different people in different research contexts. Generally, the principal investigator or investigators are liable for protecting the confidentiality of information and, if need be, for the return of research results. Nevertheless, in certain research contexts, for example when research results are encountered by researchers accessing a genetic databank or biobank, liability for the return of research results could be framed by the biobank’s management policy, and addressed specifically in transfer agreements for the data or biological material. The failure to disclose material findings may also lead to legal liability.

II) Who returns the results?

a) The researcher or one of his colleagues

When individual results and incidental findings could be returned to participants and when prior consent for the return has been obtained, results should be explained by the researcher if he or she has the necessary competence, or by a member of the research team (e.g. a health professional or qualified professional, such as a nurse or genetic counsellor).

b) Genetic counselling

Researchers who envision returning individual results in genetic research and incidental findings should engage, where pertinent, genetic counselling services in order to explain the clinical significance or consequences of the information, notably the clinical significance of the information, the timeliness of an intervention or lifestyle changes, and the prospective implications of this information for members of the participant’s biological family.

When researchers return results to other family members or to members of a community or group, they should equally facilitate access to genetic counsellors for the affected parties.

The nature and scope of the genetic counselling should be defined with reference to the implications of the results and their particular significance for the individual concerned or for the members of his or her family, including prospective implications for reproductive choices. The counselling should be delivered in a non-prescriptive manner.

Genetic counselling should be given by a trained and experienced individual, although it is not necessary that he or she hold a diploma in genetic counselling.

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93 These duties are the same as those stated over ten years ago in the RMGA Statement of Principles: Human Genome Research (See Network of Applied Genetic Medicine (RMGA), Statement of Principles: Human Genome Research (2000), online: http://www.rmga.qc.ca/en/issues.html.)

94 TCPS 2, supra note 1 at art 13.4.

95 Ibid.
III. Time of return

Individual results and incidental findings should be returned at an opportune time, considering the category of the results and the circumstances. The plan for managing information should address these aspects clearly. In case of doubt, the researcher should consult his REB.

IV. To whom should results be returned?

Return of individual results and incidental findings could be done directly with the participant, a designated health professional, or a third party authorized to receive the information. The recipient of the information can vary given the context of the research. The plan for managing information should address this subject.

When the participant is an adult with capacity, the result could be returned directly to the participant, or to an authorized third party (e.g. designated health professional or biological relatives) (see Principles 4, 6, 7).

When the participant is an incapable adult, the result should be returned to the legal representative. When possible, the results should also be explained to the incapable adult, in a manner appropriate to his level of comprehension.

When the research project involves young children, results should be returned to his parents or the persons acting in their stead (person having parental authority). The Civil Code of Québec anticipates that one parent can give the other the mandate to represent her or him in acts relating to the exercise of guardianship and that this mandate is presumed to apply to third parties in good faith. In this way, return of results can be returned to either parent or to both.

When the research project involves adolescents, results should also be returned to them with the agreement of their parents, in a manner appropriate to their level of development, comprehension, and maturity. For certain individual results and incidental findings, it could be important to first divulge delicate information to the adolescent.

In the case of longitudinal research, researchers could offer to return results to participants when they reach the age of majority during the course of the research.

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96 Ibid at art 13.3.
97 Art 194 CCQ.
CONCLUSIONS

The research undertaken to develop this Statement has permitted us to identify certain issues that, in the current Québec context, do not allow a clear position.

What is the duration of the duty to return research results?
In numerous longitudinal studies, researchers collect and conserve data and biological samples in order to use them in research over several years, for example 25 or 50 years. A material individual result or a material incidental finding could come out after the analysis of tissue collected many years before and stored in a biobank. The validity of a result may also change with time. This situation raises the question of the duration of the duty to return research results to participants.98

There are few extant guidelines on this subject. The TCPS 2 specifies only that the divulgence of incidental findings is subject to the duty of the researcher to return research results to participants.99 The TCPS 2 has no disposition on the duration of this duty. The Industry - Pharmacogenetics Working Group, an association of pharmaceutical companies engaged in research, states that there would be reason to adopt practical limits to circumscribe the period of researcher liability.100 The working group of the American National, Heart, Lung and Blood Institute adopts a clearer position: researcher liability cannot persist beyond the period of project.101

In Québec, the absence of instructions on the duration of the duty to return results can be problematic both practically and financially. In this sense, other studies are to be anticipated. Until then, we recommend that the researcher responsibility not persist beyond the length of the project funding, unless there are special circumstances to justify a longer period of responsibility (e.g. when the researcher remains active in a project beyond the funding period).

What impact will return of results have on the healthcare system?
The return of research results risks a considerable impact on the Québec healthcare system because:

- Genetic and genomic research is an important part of health research;
- New sequencing tools are used more and more often; and
- The TCPS 2 puts forward considerable duties as to the return of incidental findings, and recommends the furnishing of genetic counselling services for the return of research results.

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98 Supra note 14 at 118.
99 TCPS 2, supra note 1 at art 3.4.
Consequently, the impact of these new realities on the healthcare system need to be considered and strategies identified to face them. This will have an immediate impact on the need for expertise in genetic counselling, as the volume of information to be interpreted for the medical community and participants will rapidly expand. In addition, there will be substantial impact upon the number of identified genetic conditions that may warrant monitoring, preventative strategies or therapy much earlier than if they had become clinically apparent with time. All these elements will need to be considered in designing appropriate support for research participants and their family.

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