Statement of Principles for Genetic Research Involving Children*

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September 5th, 2007

*This project was made possible by funding provided by the Network of Applied Genetic Medicine (Réseau de médecine génétique appliqué-RMGA, affiliated with the Fonds de la recherche en santé de Québec (FRSQ), PHOEBE and the European Commission. Funding was also received from the Canadian Stem Cell Network and the Canadian Molecular Cytogenetics Platform (affiliated with Genome BC and Genome Canada).

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PREAMBLE

The Network of Applied Genetic Medicine ("Réseau de médecine génétique appliquée"; herein RMGA) of the FRSQ ("Fonds de la recherche en santé du Québec") proposes to the scientific community a *Statement of Principles for Genetic Research Involving Children*.

This *Statement* is adapted to the Quebec legal framework governing research. It conforms with the principles of the World Medical Association's *Declaration of Helsinki*, the Council for International Organizations of Medical Sciences' *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada's *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, the FRSQ's *Guide d'éthique de la recherche et d'intégrité scientifique* (August 2003), and the *Civil Code of Quebec*.

Increasingly, children are solicited as participants for genetic research in order to discover more about childhood disease and/or to develop treatments. Since children are considered vulnerable in the eyes of the law, their participation in research projects is contentious. Thus, research involving children is framed to ensure that they receive special protection to reflect their variable physical and intellectual maturity before they reach legal capacity.

The ethical principles stipulated in this *Statement* will guide researchers in the planning and conduct of genetic research involving children. These principles support the inclusion of children in research that contributes to their overall health and well-being.

INTRODUCTION

1. Genetic research makes it possible to identify the role of genetic factors both in health and in the transmission of disease. Because of the legal incapacity of children to consent, genetic research involving children raises ethical challenges. The storage of biological samples and data in this type of research merits a framework specific to children.

   The proposed RMGA *Statement of Principles on Genetic Research Involving Children* is committed to internationally recognized ethical principles, such as respect for the person, benevolence, non-maleficence, and justice. Moreover, it takes into consideration the degree of maturity and understanding of children in order to adapt these principles to their individual situations.

2. In order to respect these fundamental principles, the RMGA intends to promote the importance of including children in genetic research. The challenge is to further

scientific knowledge of childhood health and disease and to develop treatments adapted to their physiology and needs.

3. For the purposes of this text, the term "child" refers to every person under the age of majority (in Quebec: 18 years of age) who is not legally emancipated. The term "parents" is consistent with the meaning of the *Civil Code of Quebec* and refers to the child's mother and father. The term "assent" refers to the willingness of the child to participate in a research project. The term "dissent" means the opposition of the child to participate in a research project.

4. This RMGA *Statement of Principles* is directed at researchers and clinicians who are planning or conducting research to identify genes that contribute to health or early onset diseases or who are developing treatments for such diseases.

5. Research projects can be undertaken individually or in collaboration with different national and/or international institutions and researchers through partnerships (academic, industrial, national, or international).

6. In order to assist researchers in conducting their research, the RMGA proposes principles and procedures intended to protect the rights of children who participate or who are considering participating in genetic research. The RMGA anticipates that this *Statement* will foster the development of a deontological approach for genetic research involving the participation of children.

PRINCIPLES AND PROCEDURES FOR GENETIC RESEARCH INVOLVING CHILDREN

The operating principles of this *Statement* are:

I. Inclusion
II. Consent
III. Assent
IV. Dissent
V. Confirmation of Assent
VI. Withdrawal of Consent
VII. Exemption
VIII. Risk of Harm and Potential for Benefit
IX. Confidentiality
X. Professionalism
XI. Contribution to Well-Being

I. INCLUSION

Principle

It is essential to include children in research projects to avoid unjustly depriving them, either individually or collectively (the paediatric population), of beneficial results.

Procedure

Research involving children is essential because of their significant differences from adults, both physiologically and psychologically. The many stages of children's development influence the possible limits and potential benefits of research. In addition, some diseases are found only in the paediatric population, further demonstrating the importance of including children in research. However, given that children are vulnerable, research requiring their participation should be subject to a rigorous framework of governance. Furthermore, it should respect the fundamental principles of research involving human subjects.

The participation of children in genetic research is possible only when the research cannot be carried out with adults. When the participation of children in genetic research is necessary, the least vulnerable children—that is, older children—should be included in the project first, if possible.

In theory, healthy children should not be recruited as volunteers. However, some research might require their participation in order to determine, for example, the effect of diet or environmental factors on a predisposition they have. Again, if their participation is necessary, the least vulnerable children should be considered first. In addition, the probability and degree of harm should be negligible.

The research should relate to a disease that appears early in life, relate to an adult disease that is asymptomatic in children, or be relevant to the health of children. In addition, child participants should derive a direct or indirect benefit from their

participation in the research. When they have little chance of benefiting from the research, it should not expose them to a more than minimal risk (see Principle VIII – Risk of Harm and Potential Benefits).

II. CONSENT

Principle

The researcher should obtain free and informed consent from the parent or legal guardian of the child.

Procedure

Consent of the parent or legal guardian of the child should be voluntary: that is, obtained without manipulation, coercion or undue influence. It should also be informed, meaning that the researchers will provide the parent or legal guardian with all the information necessary for informed consent. This information should be stated in understandable language and be adapted to the abilities of the parent or legal guardian. In particular, the information should describe:

a) the goal and nature of the research, the research methods, and the length of the child's participation in the genetic research project;
b) the name of the researcher;
c) the risks and benefits resulting from the child's participation in the genetic research;
d) the right to withdraw consent for participating in the research at any time, without the child suffering any harm;
e) the possibility of commercializing the results of the genetic research;
f) the existence of any actual, potential or perceived conflict of interest involving the researchers participating in the genetic research project.

The parent or legal guardian should be given sufficient time to provide consent. They should also have the opportunity to ask the researcher questions and to discuss their child's participation in the genetic research with others.

The consent of the child's parent or legal guardian should be obtained in writing before enrolling the child in genetic research (see Appendix 1 – Consent Form for the Parents and Legal Representative).

Consent is a continuing process that should be maintained throughout the research project. If there are significant changes to the research project, research ethics board approval and consent should both be renewed.

III. ASSENT

Principle

To the extent possible, the researcher should obtain the assent of the child regarding his/her participation in the genetic research project, according to his/her development and degree of understanding.

Procedure

Assent derives from the principle of respect for the person and makes it possible for children to exercise autonomy within the limits of their capacity to do so. Thus, including the child in the decision-making process respects his/her developing maturity. The assent of the child should be obtained after the consent of the parent or legal guardian. Though it is insufficient in itself to allow for the participation of the child in research, assent is a corollary to the consent of the child's parent or legal guardian.

Like consent, assent is a continuing process that requires confirmation over the course of the research project. It should be re-obtained when the research project undergoes significant changes.

The researcher should take into account the age and ability of the child to understand what participation in the genetic research project involves. To do this, the researcher will have to inform the child about the method, the procedure, the risks and benefits resulting from participation, and the right of withdrawal. This information should be provided in language appropriate to the age of the child and to his/her level of understanding and stage of development.

Newborns and Preschoolers

At this stage of development, it is impossible to obtain assent. However, since preschoolers have some ability to understand, they should be informed in language adapted to their age, their degree of understanding and their stage of development.

School-age Children (around 7 years old)

At this stage of development, the ability of the child to make and understand decisions is emerging. School-age children can understand the risks and benefits resulting from research, but might have difficulty understanding conflicting or abstract information or long-term implications and consequences. This should be taken into consideration during the writing of the assent form.

The researcher should have the child sign an assent form (separate from the consent form of the parent or legal guardian) when the child is able to write. This form should be phrased in clear and understandable terms according to the child's age, level of understanding and stage of development (see Appendix 2 – Assent Form).

Adolescents

At this stage of development, adolescents generally have acquired an ability to make decisions akin to that of adults. Their right to auto-determination should be respected as much as possible.

The researcher will have to disclose to the adolescent the same information as that disclosed to the parent or legal guardian during the process of obtaining free and informed consent. Thus, the assent form should contain essentially the same information as the consent form of the parent or legal guardian.

The assent of adolescents should be obtained through a separate form from the consent form of the parents or legal guardians (see Appendix 2 – Assent Form).

IV. DISSENT

Principle

The dissent of the child regarding participation in the research project should be respected.

Procedure

The dissent of the child should be respected if it is not harmful to his/her health, even if the parent or legal guardian consented to his/her participation in the research project. However, the consent of the parent or legal guardian could override the opposition of the child when: i) the child is too young, too immature, or incapable of understanding; or, ii) involvement in the research project constitutes the only possible intervention and offers the hope of some benefit for the child.

Objections raised by the child during the research project should also be considered and his/her wishes should be respected if the choice is not harmful to his/her health.

V. CONFIRMATION OF ASSENT

Principle

Where appropriate and feasible, when a child reaches the age of majority—in Quebec, 18 years old—the researcher should obtain confirmation of the child's initial decision through a free and informed consent.

Procedure

The procedures stated under Principle II – Consent apply.

VI. WITHDRAWAL OF CONSENT

Principle

The parent or legal guardian can, at any time, withdraw consent for the child's participation in research.

Procedure

The parent or legal guardian should be informed of the possibility of withdrawing consent at any time during the genetic research project with no obligation to explain this choice. (See Principle II – Consent, Procedure d)

The withdrawal of consent by the parent or legal guardian of the child should not affect the medical care received by the child.

The child should also be informed of the possibility of withdrawing from participating in the genetic research project.

VII. EXEMPTION

Principle

In exceptional circumstances, the researcher can receive an exemption from the obligation to obtain consent from the parent or legal guardian. To do so, he/she should obtain the approval of a research ethics committee.

Procedure

An exemption from obtaining the consent of the child's parent or legal guardian is a rare and exceptional procedure that should always be explicitly approved by a research ethics committee.

Exceptional situations that could give rise to such exemptions are cases in which the child is the victim of abuse or neglect. A research ethics committee may approve a consent procedure that set aside certain constituent elements of free and informed consent. The following requirements have to be met: "i. The research involves no more than minimal risk; ii. The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects; iii. The research could not practicably be carried out without the waiver or alteration; iv. Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and v. The waiver or altered consent does not involve a therapeutic intervention" (*Tri-Council Policy Statement*, s. 2.1 (c). Such an exemption should be subject to continuing oversight by a research ethics committee.

VIII. RISK OF HARM AND POTENTIAL FOR BENEFIT

Principle

The participation of children in research should offer the possibility of a direct benefit to their health. If not, the results should benefit other children who are the same age and have the same disease or handicap, and the child should not be exposed to more than minimal risk.

Procedure

The anticipated benefits from the participation of a child in a research project should exceed the possible risks. Following article 21 of the *Civil Code of Quebec*, a child cannot be subjected to an experiment that involves a serious health risk. The participation of the child in the research should offer hope of direct benefits for the child or indirect benefits for other children of the same age, with the same illness or handicap.

If he/she does not benefit directly, the child should not be exposed to more than a minimal risk, i.e. a risk comparable to that which he/she is exposed to in everyday life or during a routine medical exam. This acceptable level of risk of harm could be slightly increased when there is major scientific or medical significance or where there is research ethics committee approval. Potential risks of harm include, harms both to individuals and communities and can be physical, psychological, social or financial harms.

In such a situation, the evaluation criteria stated in Guideline 9 of the Council for International Organizations of Medical Sciences (CIOMS, 2002) relating to the "[l]imitations on risk when research involves individuals who are not capable of giving informed consent" apply. Therefore, the research ethics committee should ensure "1) that the research is designed to be responsive to the disease affecting the prospective subjects or to conditions to which they are particularly susceptible; 2) that the risks of the research interventions are only slightly greater that those associated with routine medical or psychological examination of such persons for the condition or set of clinical circumstances under investigation; 3) that the objective of the research is sufficiently important to justify exposure of the subjects to the increased risk; and 4) that the interventions are reasonably commensurate with clinical interventions that the subjects have experienced or may be expected to experience in relation to the condition under investigation" (CIOMS, Guideline 9).

IX. CONFIDENTIALITY

Principle

Respect for privacy is a fundamental principle. Due to the personal and familial character of genetic information, the researcher should establish protective measures to ensure the highest degree of confidentiality.

Procedure

Professional Secrecy

The principal researcher as well as people authorized to access the child's medical file, familial files, and research files should be identified. All these people are implicated by professional secrecy.

Members of the team, as identified by the principal researcher, are subject to professional secrecy both inside and outside research laboratories and in the management and communication of data. It is important to emphasize that electronic communication, such as email or fax, does not ensure the confidentiality of the data transmitted.

Access to Genetic Information

Access to genetic information is dependent on the consent of the child's parent or legal guardian and, if applicable, to the assent of the child.

The principal researcher is responsible for controlling access to the genetic information. Control of this access is similar to the control exercised over delegated

medical acts. Thus, those authorized to access genetic information are under the supervision of the principal researcher.

Disclosure of Genetic Information

The principal researcher, as well as members of the research team, should never disclose personal information about the child to a third party unless the parent or legal guardian of the child consented to such a disclosure and unless the child assented, according to his/her degree of understanding.

In some situations, the principal researcher may have to disclose genetic information to members of the child's biological family, despite opposition from the child or refusal by the parent or legal guardian. If this is necessary, it is desirable to work with the treating physician so that he/she can discuss with his/her patient and the parent or legal guardian about the family follow-up and the consequences of refusing to communicate the information in question.

Three conditions should be present before considering possible disclosure of such information to the family despite the opposition of the child or the refusal of the parent or legal guardian: 1) non-disclosure could lead to serious and foreseeable harm for members of the biological family; 2) the members of the biological family are identifiable; and 3) the risk of harm could be avoided by prevention or treatment. The evaluation of disclosure or non-disclosure of genetic information to members of the child's biological family in such circumstances should take into account the fact that the harm resulting from disclosure should not be greater than the harm that the members of the family risk from non-disclosure. The decision to disclose or not is one of professional judgment

Moreover, in Quebec, article 23 of *An Act Respecting Health Services and Social Services* (R.S.Q., S-4.2) maintains that the principal researcher could also disclose genetic information to blood relations of a deceased child when this disclosure is necessary to confirm the existence of a genetic disease or a familial disease. Article 23 also specifies that "the holder of parental authority is entitled to be given communication of the information contained in the record of a user under 14 years of age even if the user is deceased." Moreover, the legal representatives of a deceased child have the right to access information contained in his/her file when it is necessary for the exercise of their rights in that capacity.

Other than in the exceptions foreseen by law, no genetic information can be transmitted to insurers, employers, educational institutions, or other public institutions, without the consent of the child's parent or legal guardian and the assent of the child, according to his/her degree of understanding.

The child's parent or legal guardian and the child should be informed about the consequences that could result from the disclosure of genetic information.

X. PROFESSIONALISM

Principle

Children participating in research and their parent or legal guardian have the right to expect competent and professional conduct on the part of researchers and members of the research team. Professionalism is based on the principle of reciprocity, which allows for an open exchange based on shared confidence between the participant and the researcher.

Procedure

Safeguards for Participants

Every researcher has the duty to ensure the respect for and protection of children participating in research projects. Every researcher should also respect the norms which aim to protect participants in genetic research.

It is strongly recommended that a physician-clinician be associated with every genetic research project and particularly so where the researcher is not a physician. They should have the skills required to provide the necessary support, advice, and help that could eventually be required by the child or by the parent or legal guardian. Deontological medical principles serve as a framework for researchers.

All research projects should be approved by a research ethics committee and be subject to ongoing ethical oversight.

Communication of General Results

When appropriate and possible, the principal researcher should publish in the shortest possible time the information relating to the general results of the research, whether they be positive or negative. This information should be as comprehensive as possible and should conform to current scientific principles.

The team should ensure a high level of precision in the information, according to the expertise of each member, clinical knowledge, and genetic advice.

Communication of Individual Results

The child who is participating in the research should always be treated with respect, whatever the results. When the researcher has doubts about the results of the analysis, he/she should consult other experts.

When results are scientifically valid and where there are either significant implications for the health of the participant or treatment or preventative measures are available, these results can be communicated to the child, according to his/her degree of understanding, and to the parent or legal guardian through their doctor, unless they had indicated that they did not want to receive the results.

During the communication of the results to the child and to the parent or legal guardian, the choices available, the limitations of available clinical services, the accessibility of consulting services, and the familial implications should be taken into consideration.

XI. CONTRIBUTION TO WELL-BEING

Principle

Genetic research involving children should aim to promote children's health and to prevent disease among this particular population group.

Procedure

The research team should have recognized expertise in the area of research involving children.

The research should have the objective of acquiring scientific knowledge that will eventually allow for the improvement of children's health and the prevention of childhood diseases.

Collaboration with other researchers should be encouraged in order to allow an exchange of scientific knowledge and to encourage the advancement of genetic research involving children.

APPENDIX 1

INFORMED CONSENT FORM FOR PARENTS OR LEGAL REPRESENTATIVE OF THE CHILD[‡]

[‡] This template was prepared by Mireille Lacroix, Julie Samuël and Bartha Maria Knoppers of the Centre de recherche en droit public, at the University of Montreal.

Informed Consent Form for Parents or Legal Representative of the Child

Title of Study: *Insert lay title. Some institutions require the use of the official protocol title. In such a case, add a simplified title if the official one is complex.*
(*e.g. Genomic tools for diagnosis and evaluation of developmental delay or mental retardation*)

Investigators:
Names, qualifications and institutional affiliation of principle investigator and co-investigators.

Sponsors:
Funding sources for the research.
(*e.g. This research project is funded by the Canadian Institutes of Health Research.*)

Introduction
Short statement of invitation to participate in the specific study.
(*e.g. We are inviting your child to take part in this research study because he/she has a developmental delay or mental retardation for which a genetic cause has not been found*.)

Voluntary Participation
Indicate that the participation is voluntary.
(ex. Your child's participation is entirely voluntary. This consent form tells you about the study. Please take the time to read it and discuss it with other family members, friends, or doctor before you decide whether or not you wish that your child participates. Please ask the study staff to explain any words or information in this form that you do not clearly understand.

If you wish to participate, both parents or the legal representative of the child will be asked to sign this form. If you do not wish to participate, you do not have to give any reason for your decision, and your decision will not affect the medical care your child receives.)

What is the Purpose of this Study?
Describe the field of research in short sentences, in simple, easily understandable English. Describe progress to date.
Describe the specific purpose of the study.
(*e.g. The purpose of the research is to use a new method called microarray comparative genomic hybridization (mA-CGH) to look for small areas of chromosomal imbalance in people with developmental delay or mental retardation whose chromosomes appear normal on the karyotyping test.*)

Who Can Participate in the Study?
Describe inclusion criteria, e.g. recruitment of trios, etc.

What Does the Study Involve?
Describe what you need to do as a researcher, and any procedure the participant will undergo.
(ex. physical examination, taking a blood sample, taking a family history, access to medical records, etc.)

Will We Receive any Results From This Study?
Describe the policy adopted for your study, including who is responsible for keeping participants' contact information current.

If the Study Changes, Will We Be Informed?
Insert notification criteria.

How Long Does This Study Last?
Indicate the planned length of the specific study.
(e.g. This study will last 3 years.)

What Are the Possible Harms, Discomfort and Side Effects of Participating?
Describe potential physical harms and discomfort.
(ex. During the blood test, your child may experience brief pain or possible bruising. Like all medical information, the fact of participating in a genetic study and the results that may come out of this study or future studies may have implications for other family members and for your child's insurance or employment.)

What Are the Potential Benefits of Participating in this Study?
Describe the potential benefits of the study for the child and for others, if any (ex. future patients and families).

How Is Confidentiality Ensured in this Study?
Indicate for how long and where the samples and data will be kept. Indicate what will happen to the samples and data after the study (destruction, how, etc.). Indicate which measures will be put in place to protect confidentiality in the specific study.
(*ex. All information gathered about your child during this study will remain confidential. Information collected by the research will be kept in a safe place at the (insert place). No information that discloses your child's identity will be released or published without your consent, unless the disclosure is required by law. However, research records and medical records identifying you and your child may be inspected by representatives of the research ethics board or governmental health agencies for the purpose of monitoring the research. In this case, a member of the research team would be present. No records that identify your child by name or initials will be allowed to leave the researchers' offices.)*

Is Any Compensation paid?
Indicate whether any compensation will be paid to participants.
(ex. You will receive no compensation for taking part in this study. The results of the research may help create products or services that become available commercially, but you will not be able to obtain financial benefit from these.)

What Happens if We Decide to Withdraw our Consent to Participate?

Your child's participation in this study is entirely voluntary. You may withdraw from the study at any time. There will be no penalty or loss of benefits to which you child is otherwise entitled. Your future medical care will not be affected.

If you wish to withdraw from this study, please contact (principal investigator or study staff) at (contact information).

It will be impossible however to eliminate your child's data from analyses conducted before your withdrawal.

Who Can We Call if We Have Questions?

Insert contact information.
(e.g. For more information about this study, or if you have any questions you can contact XYZ at (XXX)XXX-XXXX. For more information about your or your child's rights as a research subject or your family's experience while participating in this study, please contact ABC at (XXX)XXX-XXXX.)

Parents or Legal Representatives of theChild Consent to Participate

We have read and understood the information contained in this consent form. It was explained to us and to our child to the extent that he/she is able to understand it. All our questions have been answered.

We understand that our child's participation in this study is voluntary. We can refuse to participate and we can withdraw our child from this study at any time without affecting his/her medical care.

We understand that we are not waiving any of his/her legal rights by signing this consent form.

We understand that the information collected for this study will be kept confidential and will only be used for scientific objectives.

We have read this form and freely consent on behalf of *(add the name of the child)* to participate in this study.

Parent/Legal Representative *(Print)*	Parent/Legal Representative *(Signature)*	Date
Parent *(Print)*	Parent *(Signature)*	Date
Principal Investigator (*Signature*)	Witness (*Signature*)	Date

Investigator's Commitment

This study and terms of participation have been described to the participant. A member of the research team has answered the participant's questions and explained that the participation in this study is on a free and voluntary basis. Finally, the research team agrees to respect the terms of this consent form.

Principal Investigator (*Print*)	Signature	Date

APPENDIX 2

ASSENT FORM

(CHILDREN AGED 7-13 YEARS)[§]

[§] This template has been written by Karine Sénécal, Centre de recherche en droit public, University of Montreal, in a paper entitled « Document de réflexion sur l'information et l'assentiment des mineurs ».

Assent Form

Title: *Insert a simplified title*

If you want, an adult can read this sheet together with you.
Ask all the questions you want.

Introduction

You are invited to take part in a study of Dr _____.
Provide a simplified description of the reasons why you are seeking the child participation for this study.

During you reading, you can ask all the questions you want. After, you can take your time to think about the study and decide if you want to participate or no to the study. This is your decision.

If you like, an adult can read this sheet with you.

Why do the doctor and his/her team need you help?
Provide a simplified description of the study considering the age of the child and his/her level of comprehension and language. Do not use the terms "research objectives" or "research goals" because they are not well understood by children.

What do you have to do if you join the study?
Insert a simplified description by considering the age of the child and his/her level of comprehension and language.

Who will the study help?
Explain to the child who will benefit from the study.

How do you decide to join or not?
If some explanations are hard to understand, ask all the questions you want.

You can take all the time you need to think and decide if you want to participate or not in the study. You can also think about it at home. If you decide to think about it at home, we can answer your questions by phone. You can ask you parents. It will also be possible to meet with us again.

Once you decide, you have to tell your parents or a person in the medical team.

If you don't want to participate to this study, no one will be mad or upset. You can refuse.

If you choose to participate, you have to write your name on the line at the bottom of this sheet.

IMPORTANT: Even you decide to participate to this study and write your name on the line at the bottom of this sheet, **you can change your mind at anytime during the study**. No one will be mad or upset. You will have to tell your parents or a person in the medical team.

_____	_____	_____
Child's Name (*Print*)	Child's Signature	Date

Verbal assent of the child incapable to sign, but able to understand the nature of this study: yes _____ no _____

_____	_____	_____
Person who discussed with the child (*Print*)	Signature	Date

_____
Function of the person who discussed with the child