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Pediatric Consent to Genetic Research: Clauses

Co-Chairs: **Bartha Maria Knoppers** (Centre of Genomics and Policy, McGill University), **Megan Doerr** (Sage Bionetworks), **Susan Wallace** (University of Leicester)

Coordinator: **Kristina Kekesi-Lafrance** (Centre of Genomics and Policy, McGill University)

Consent Task Force:

Alanna Crouse, Centre of Genomics and Policy (McGill University), Canada

Stephanie Dyke, Neurological Institute (McGill University), Canada

Claire Ellen Wegel, Indiana University, United States

Tony Handstad, Nordic Alliance for Clinical Genomics, Norway

Melissa Heidelberg, Genentech, United States

Jonathan Lawson, Broad Institute, United States

Bobbie Nicole Ray-Sannerud, Nordic Alliance for Clinical Genomics, Norway

Guro Meldre Pedersen, Nordic Alliance for Clinical Genomics, Norway

Anna Middleton, Wellcome Genome Campus, United Kingdom

Richard Milne, Wellcome Genome Campus, United Kingdom

Kat Pavlova, UHN, Canada

Samantha Palmer, UHN, Canada

Amicia Phillips, KU Leuven, Belgium

Maria Pilar Nicolas, EUCANCan, Spain

Laura Rodriguez, National Human Genome Research Institute, United States

Rosalyn Ryan, US Senate, United States

Emily Sarah Kirby, Centre of Genomics and Policy (McGill University), Canada

Saumya Shekhar Jamuar, SingHealth - PAEDS, Singapore

Christoph Schickhardt, Heidelberg University, Germany

Danesh Sundar, UCL Genomics (University College London), United Kingdom

Adrian Thorogood, Beyond the 1 Million Genomes, LCSB, Luxembourg

Eva Winkler, Heidelberg University, Germany



Special thanks to:

Bimal P. Chaudhari, Nationwide Children's Hospital, US

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Renee Rider, National Human Genome Research Institute (NHGRI), US

Pediatric Consent Clauses: Context and Use

Consents involving children and minors recognize their various developmental stages and their increasing capacity to understand as they reach maturity. In most countries, the legal age of majority constitutes the age where minors are considered sufficiently mature to understand the nature, risks, benefits and implications of involvement in biomedical and genomic research. Yet, some countries may set the legal age of consent to research earlier by statute or even rely on physician discretion to determine the necessary maturity for an informed consent (mature minor rule). Irrespective, in the domain of genetic and genomic research in particular, there are further limitations beyond maturity/majority in that genetic testing for conditions that have an adult onset is generally not recommended for children. Moreover, where findings (even incidental) reveal conditions that are preventable or treatable during childhood, they should be communicated as considered to be in the best interests of the child.

The consent process must conform to the varying levels of maturity and needs of the growing child and the particular socio-cultural context. The language used should be clear and comprehensible. If the minor does not have adequate proficiency for the language in which consent is offered, a translation must be provided in his / her mother tongue. If the minor agrees to be involved in the research, they should be encouraged to participate along with their parents while younger children (approx. 7-11) should be asked at a minimum, to verbally provide assent.

These generic pediatric consent template clauses for genomic research are situated in an ethico-legal context that recognizes the international human rights particular to the child ([*Convention on the Rights of the Child*](#), 1989). Children have the right to their interests being a primary consideration in all decisions concerning their well-being. They have the right to be heard and the right to the highest attainable standard of health.

The attributes of parental duties and rights are enshrined in national laws and ethics guidance. They include the duty to provide medical care and include the authority to involve their children in biomedical research. All parental duties and freedoms however are circumscribed by the State. Children have a right to privacy, to the protection of their physical integrity and personal data, and to



medical confidentiality. Where possible, some form of recontact at maturity/majority for further research or an ethics waiver thereof is encouraged if their data or samples will continue to be used.

We have drafted generic consent clauses particular to the pediatric research context for mature minors and for parents consenting on behalf of children. The general clauses offered here may serve both parental consents and those where minors can consent themselves. These simple clauses are based on different consent languages currently in use around the world. In addition to these pediatric consent clauses, the Consent Task Force of the Regulatory and Ethics Workstream (REWS) has prepared WGS template clauses for: [genomic research](#), [large scale initiatives \(biobanking and population studies\)](#) and [clinical genetic testing](#). A typology of clauses specific to [familial](#) testing, [rare diseases](#) and [pediatrics](#) has also been prepared. They all cross the categories listed above.

The **clauses below should be edited** as needed to fit the context of the study and according to the laws and cultural norms of the country/countries involved and the particular context. The terms in brackets are suggestions.

A generic [Assent Form and Information Sheet \(approx. age 7-11\)](#) are also provided.

Categories	Consent Clause(s) for Mature Minors / Parents
Assent/Dissent (by child/minor, verbal or written)	If you want to be in the study, tell us. If you do not, tell us. [See the Assent Form and Information Sheet (approx. age 7-11)]
Confidentiality	[Your/Your child's] identity will only be shared with the doctors, nurses, and authorised members of the research team.
Data sharing	We will gather [your/your child's] samples and anonymized/coded information and share them with other researchers in [country] [and internationally]. [Your/Your child's] data will be stored at [name of institution] and can be accessed as follows: [describe the access process in place]. We may put what we learn from studying [your/your child's] sample, including the entire DNA sequence, in a database. This database will only be accessible to researchers who are approved to use [your/your



	<p>child's] anonymised/coded samples and/or anonymised/coded data. This research may advance scientific and medical understanding. [Your/Your child's] data will be stored at [name of institution] and can be accessed as follows: [describe the access process in place].</p>
	<p>We may/will share [your/your child's] anonymised study data with public research databases. [Your/Your child's] anonymised data will be stored at [name of institution] and can be accessed as follows: [describe the access process in place].</p>
Financial benefits	<p>Commercial company(ies) is/are part of the research team for this study.</p>
	<p>[Neither] [you [nor] your child] will receive any financial benefit if this research leads to new treatments, devices, drugs or medical tests.</p>
Future Studies	<p>In the future, we may contact [you/your child] to invite [you/your child] to be in other studies. If [you/your child] [are/is] invited to be in another study, we will provide [you/your child] [and your family] with full information about the study. [You/Your child] [are/is] free to decide whether or not you want to be in another study. [You/Your child] [don't/doesn't] have to if [you/your child] [don't/doesn't] want to.</p>
Parental/Guardian/ Mature Minor Consent (Signature clause)	<p>This study was explained to me. All of my questions were answered.</p>
	<p>If [you/your child] want to be in this study, please sign [your/your child's] name below.</p>
	<p>I, the undersigned, am the parent or legally authorized representative of the child/minor named below. I have the authority to sign this Consent Form on behalf of the child/minor.</p>
Recontact (upon maturity/legal age)	<p>At [number] years old [age of presumed maturity/legal age], we will contact [you/your child] to ask if [you/they] still want to be in this study. [You/They] will be given the option to participate or not.</p>
	<p>At [number] years old, we will contact [you/your child]. At that time, we will notify [you/your child] that we will continue to use [your/their] samples/data unless [you/they] object.</p>



Return of Results: communication of results	<p>A doctor [or other health care provider] will review the results. They will tell [you/your child] about anything for which there is childhood prevention or treatment available.</p>
	<p>We may identify genetic changes unrelated to [your/your child's] condition. These may suggest [you/your child] will develop another genetic condition in the future. We will only tell you about these results if prevention or treatment in childhood is available.</p>
	<p>Your child's [study] doctor [or other health care provider] will tell you about any other conditions that we identify that could change how to best manage the health of your child.</p>
	<p>In accordance with local law, we will return results from [your/your child's] DNA test to [you/your child], even if the results are not related to [your/their] condition and regardless of whether there is prevention or treatment available.</p>
	<p>We will/will not tell [you/your child] about DNA changes that are not related to [your/your child's] condition.</p>
	<p>We will/will not tell [you/your child] about DNA changes that could affect [your/your child's/your family's] future health.</p>
	<p>You can decide if you want us to tell you (or not) if we find a DNA change that is known to cause an adult-onset condition for which prevention or treatment is available. This information may be important to [your/your child's] health as an adult, or the health of other family members.</p>
	<p>We may learn that [you/your child] [are/is] a carrier for/at high risk of developing a genetic disorder other than the one(s) targeted by this study. Some people would like to know this information, others may find it stressful. A genetic counsellor can explain what these results mean for [you/your child] and your family before [you/your child] decide[s] if [you/they] want to be informed or not.</p>
Risk to relatives	<p>If the laboratory identifies a gene change in a gene known to cause a medically actionable disease with onset in adulthood, the laboratory will/will not report it if reporting could prevent serious harm to the health of a relative [or], if the release of this information is desired by you.</p>



Withdrawal / Voluntariness	[Your/Your child's] participation in this study is voluntary.
	[You/Your child] [are/is] free to withdraw from this study at any time.
	[You/Your child] [are/is] free to withdraw [your/their] assent, at any time without giving any reason. [Your/Their] medical care and legal rights will not be affected in any way.
	Upon withdrawal, [your/your child's] samples and data will be destroyed/no longer be used. However, data that has already been shared cannot be retrieved.
	Should you decide to withdraw [your child], we will stop using [your/their] data. Upon recontact at majority, the final decision will be made by [you/your child].

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