D011 / v 1.0: 20 January 2021

Familial Consent 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:

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 Lyman Rodriguez, Patient-Centered Outcomes Research Institute (PCORI), 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, German

Familial Consent Clauses: Context and Use

This Typology derives from a 2020 article describing familial consent clauses from studies around the world (Knoppers, Bartha Maria, and Kristina Kekesi-Lafrance, "The Genetic Family as Patient?" The American Journal of Bioethics 20.6 (2020): 77-80. doi.org/10.1080/15265161.2020.1754505).

We have drafted generic consent clauses for each category of the typology. These clauses are based on consent language currently in use around the world. We provide these clauses as an aid to researchers. The **clauses 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. The terms in brackets are suggestions; the author of the consent should select the most appropriate term for their context.

To date, 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.

Typology	Consent Clause(s)
1. A Legal Duty to Communicate: a public health interventionist approach where physicians will inform others of clinically actionable conditions upon patient refusal to do so (if approved to do so by medical authorities)	We will ask you if we can contact your [family members] if we find something that may be important to their health. However, if there is a [significant/serious] risk to your [family members], we will contact them based on [applicable public health legislation]. We will try to keep your identity private. Still, your [family members] may be able to identify you.
	[Public health legislation] tells us that we can contact your [family members] if we find a result that is important to their health. We do not need to ask your permission. We will only do this if the [ethics committee] approves. The [ethics committee] will weigh the benefit of sharing the results against your right to keep results private. We will tell you what the [ethics committee] decides.

2. Physician Discretion: ethical privilege to breach confidentiality and warn others	You get to decide if you want results. No matter what you decide, we will contact you if something really important is found. You will be asked again if you want the result. Even if you still do not want the result, we may ask you if we can contact your [family members] to tell them.
	We will not share your results with your [family members].
3. Patient Preference: supports patient autonomy	If you give us permission, we will share your results with your [family members'] healthcare providers. If you would like, we can try to keep your identity private. Still, your [family members] may be able to identify you.
	Use this form to tell us who you would like to share your results with. [The institution/We] will not give your results to anyone without your [written/electronic/verbal] consent.
	My DNA results may also be important to my [family members]. My healthcare providers will discuss with me if and how I might want to share my results.
	My best chance for a diagnosis is through testing my [family members]. I agree that you may contact them to help.
4. IRB Approved Plan: reliance on an IRB approved plan to return results (or not) to family members. Examples are provided for both large-scale and smaller projects.	Our policy is [to/to not] return results. This policy has been approved by the [ethics committee]. It complies with [law/guidance].
	We could find results that are very important to your health or the health of your [family members]. If this happens, we will contact the [ethics committee]. It will decide if we can contact you/your [family members] about this information.

	We will only share results that are very important to your health with: - the [ethics committee] - your healthcare provider - your [family members]
5. Intra-Familial Outreach: sharing of a minimum of genetic through a process that will not identify the patient	Sometimes the meaning of a person's DNA results depends on those of their [family members]. For this reason, my [family member's] results may be in my health records and my results may be in their health records.
	I give you permission to share my results if it might help my [family members]. I know that if I ask, you will try to keep my identity private.
	Even if you share my DNA results, I know you will try to keep my identity private. I may be able to be identified if there is public information about my DNA (or my [family members'] DNA) out there, such as on a family tree website.
6. Right to be Left Alone: not to be informed/not to share with family members	You get to choose if you want us to tell you important results.
	You get to decide if we can share your important results with your [family members].
	We will not share any results about you without your permission.
	[Applicable law] requires us to tell your results.
	[Applicable law] requires us to share your results with your [family members].
7. Disclaimer/Warning (stigmatization/discrimination)	If I [join/give a sample], my DNA will be studied. There is a risk that I may be able to be identified. This risk is bigger if there is public information about my health or DNA (or that of my [family members'] health or DNA) out there, such as on a family tree website.

	I may be distressed if I am identified. [Employers/Insurers/Family members] may be able to find out private information about my DNA or health.

Deliverable Revision History

Deliverable Number/Version	Date Effective	Summary of Revisions
D 011 / v. 1.0	January 2021	Original document