A pan-Nordic clinical consent framework for genetic testing

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Nordic Alliance for Clinical Genomics

- Independent NGO, not-for-profit Nordic association
- Work together and learn from each other to lift performance standards
- Aim at responsible sharing of trustworthy data for improved diagnosis and treatment, and as a resource for research

NORDIC PERMED LAW

- Independent NGO, not-for-profit, voluntary Nordic organisation
- Nordic cooperation with respect to legal issues and jurisprudential research on personalised medicine
- Build bridges between legal, medical and technological communities and across sectors
- Create arenas for public debate

Why consent for genetic testing?

Needs that are unmet by today's consent approaches, including:

- Possibility of incidental and/or secondary findings
- Incomplete medical knowledge may need reanalysis and recontact
- Data sharing needed to provide best quality of care
- Potential ripple effects for family members

Exemplifies the paradigm shift that will come to many if not all disciplines of medicine

Motivation & aim

- Development and adoption of a harmonized consent framework as a mechanism to accelerate genomic data-sharing initiatives across the Nordic countries.
- Adoption may represent the first cross-border harmonized consent
- As the leading precision medicine initiative in the Nordics, NACG is well-positioned to influence the adoption of harmonized clinical consent practices across the Nordic countries in genetic testing.
- Develop partnerships across disciplines
- Develop Nordic legal collaboration
- Aligns with NPL aims and vision

Nordic
Permed Law

Healthcare
institutions

Industry

Patient
groups

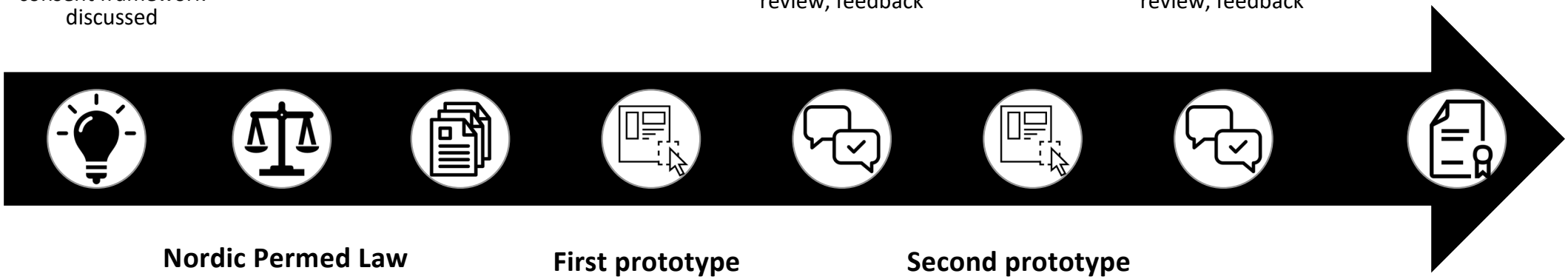
Development timeline

Nov 2019
NACG Workshop
Value of a harmonized consent framework discussed

Mapping
Nordic legislations, policies & best practices

May 2020
NACG Workshop
Multidisciplinary review, feedback

Nov 2020
NACG Workshop
Multidisciplinary review, feedback



Nordic Permed Law partnership

First prototype
Legal and clinical review

Second prototype
Legal, ethical, clinical and patient group review

Survey

Jan 2021
Publish on NACG webpage
Open for review

NACG Pan-Nordic clinical consent framework for genetic testing

1. Adult information packet

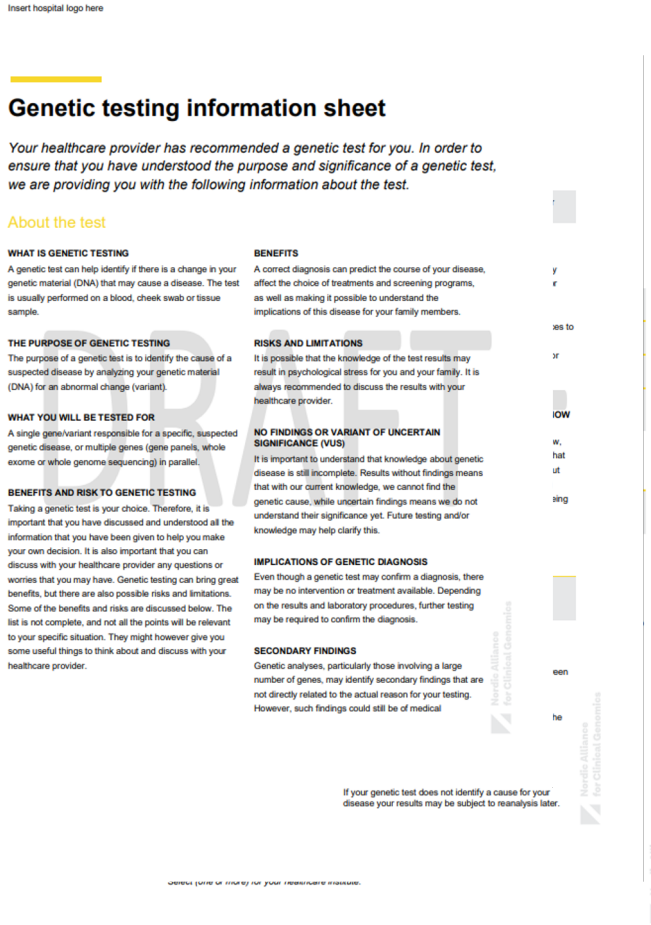
1. Adult consent form

1. Guidance to the process of delivering consent

Information packet

3-page document including the following sections:

- What is genetic testing and its purpose
- Benefits, risks and limitations of genetic testing
- Voluntary nature of the genetic test
- Implications of genetic diagnosis including uncertain and secondary findings, and for relatives
- Right to know and not to know
- Delivery of results
- Reanalysis and recontact
- Data sharing and privacy
- Withdrawal and modification of consent



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Genetic testing information sheet

Your healthcare provider has recommended a genetic test for you. In order to ensure that you have understood the purpose and significance of a genetic test, we are providing you with the following information about the test.

About the test

WHAT IS GENETIC TESTING
A genetic test can help identify if there is a change in your genetic material (DNA) that may cause a disease. The test is usually performed on a blood, cheek swab or tissue sample.

THE PURPOSE OF GENETIC TESTING
The purpose of a genetic test is to identify the cause of a suspected disease by analyzing your genetic material (DNA) for an abnormal change (variant).

WHAT YOU WILL BE TESTED FOR
A single gene/variant responsible for a specific, suspected genetic disease, or multiple genes (gene panels, whole exome or whole genome sequencing) in parallel.

BENEFITS AND RISK TO GENETIC TESTING
Taking a genetic test is your choice. Therefore, it is important that you have discussed and understood all the information that you have been given to help you make your own decision. It is also important that you can discuss with your healthcare provider any questions or worries that you may have. Genetic testing can bring great benefits, but there are also possible risks and limitations. Some of the benefits and risks are discussed below. The list is not complete, and not all the points will be relevant to your specific situation. They might however give you some useful things to think about and discuss with your healthcare provider.

BENEFITS
A correct diagnosis can predict the course of your disease, affect the choice of treatments and screening programs, as well as making it possible to understand the implications of this disease for your family members.

RISKS AND LIMITATIONS
It is possible that the knowledge of the test results may result in psychological stress for you and your family. It is always recommended to discuss the results with your healthcare provider.

NO FINDINGS OR VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)
It is important to understand that knowledge about genetic disease is still incomplete. Results without findings means that with our current knowledge, we cannot find the genetic cause, while uncertain findings means we do not understand their significance yet. Future testing and/or knowledge may help clarify this.

IMPLICATIONS OF GENETIC DIAGNOSIS
Even though a genetic test may confirm a diagnosis, there may be no intervention or treatment available. Depending on the results and laboratory procedures, further testing may be required to confirm the diagnosis.

SECONDARY FINDINGS
Genetic analyses, particularly those involving a large number of genes, may identify secondary findings that are not directly related to the actual reason for your testing. However, such findings could still be of medical

If your genetic test does not identify a cause for your disease your results may be subject to reanalysis later.

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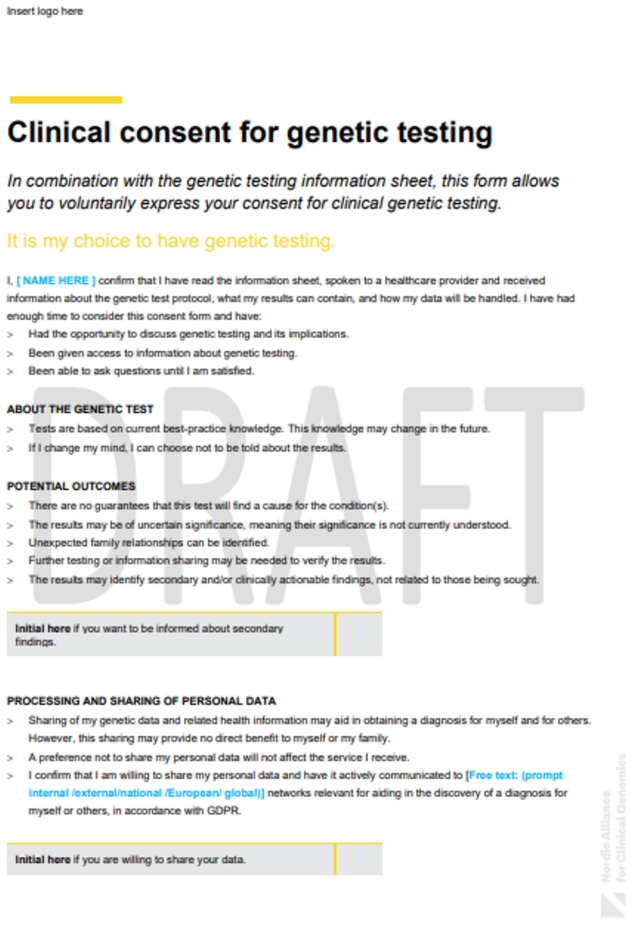
Consent form

2-page document including:

- consent to test
- about the test
- potential outcomes
- data sharing
- research
- signature



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Clinical consent for genetic testing

In combination with the genetic testing information sheet, this form allows you to voluntarily express your consent for clinical genetic testing.

It is my choice to have genetic testing.

I, [NAME HERE] confirm that I have read the information sheet, spoken to a healthcare provider and received information about the genetic test protocol, what my results can contain, and how my data will be handled. I have had enough time to consider this consent form and have:

- Had the opportunity to discuss genetic testing and its implications.
- Been given access to information about genetic testing.
- Been able to ask questions until I am satisfied.

ABOUT THE GENETIC TEST

- Tests are based on current best-practice knowledge. This knowledge may change in the future.
- If I change my mind, I can choose not to be told about the results.

POTENTIAL OUTCOMES

- There are no guarantees that this test will find a cause for the condition(s).
- The results may be of uncertain significance, meaning their significance is not currently understood.
- Unexpected family relationships can be identified.
- Further testing or information sharing may be needed to verify the results.
- The results may identify secondary and/or clinically actionable findings, not related to those being sought.

Initial here if you want to be informed about secondary findings.	

PROCESSING AND SHARING OF PERSONAL DATA

- Sharing of my genetic data and related health information may aid in obtaining a diagnosis for myself and for others. However, this sharing may provide no direct benefit to myself or my family.
- A preference not to share my personal data will not affect the service I receive.
- I confirm that I am willing to share my personal data and have it actively communicated to [Free text: (prompt internal /external/national /European/ global)] networks relevant for aiding in the discovery of a diagnosis for myself or others, in accordance with GDPR.

Initial here if you are willing to share your data.	

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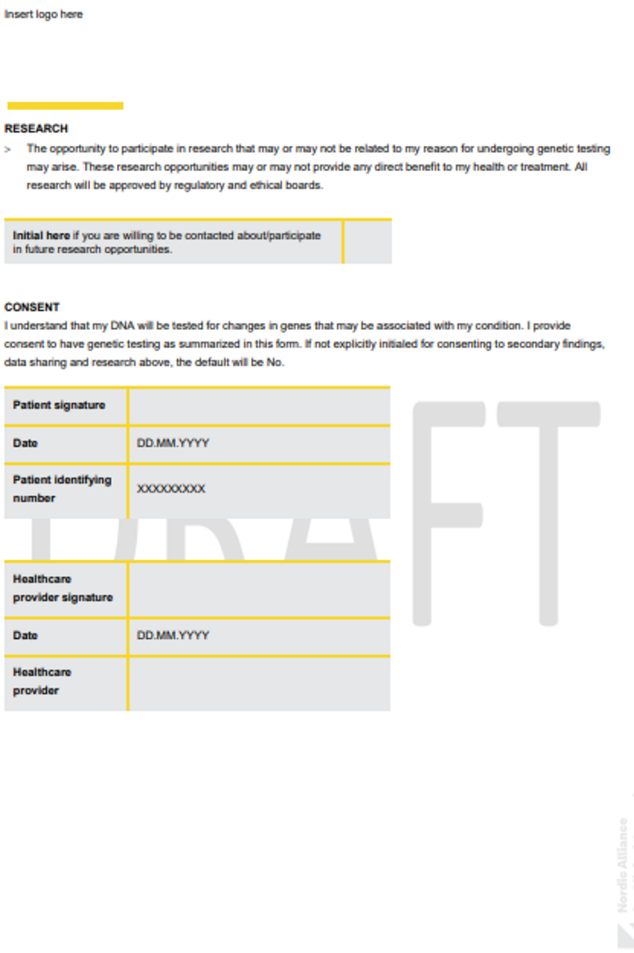

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RESEARCH

- The opportunity to participate in research that may or may not be related to my reason for undergoing genetic testing may arise. These research opportunities may or may not provide any direct benefit to my health or treatment. All research will be approved by regulatory and ethical boards.

Initial here if you are willing to be contacted about/participate in future research opportunities.	

CONSENT

I understand that my DNA will be tested for changes in genes that may be associated with my condition. I provide consent to have genetic testing as summarized in this form. If not explicitly initialed for consenting to secondary findings, data sharing and research above, the default will be No.

Patient signature	
Date	DD.MM.YYYY
Patient identifying number	XXXXXXXXX
Healthcare provider signature	
Date	DD.MM.YYYY
Healthcare provider	

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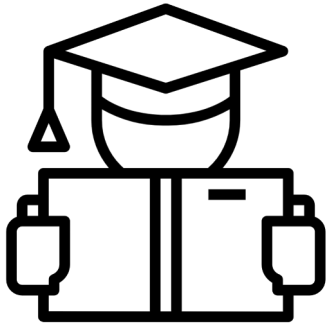
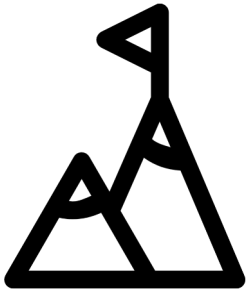


Learnings

- Inclusive process for co-development
- Guided customization options
- Different Nordic legal frameworks at different maturity levels for supporting precision medicine



Remaining challenges

- Implementation will require extensive dialogue, trust & buy-in
- Complex interplay of laws regulating healthcare and privacy that is different in each country
- Supporting legally compliant technical solutions for digital dynamic consent needed

Food for thought

Is it appropriate to use consent as the only legal basis for processing of genetic data?

Next steps and future perspectives

- Consent framework open for comment on https://nordicclinicalgenomics.org/resources
- Virtual NACG consent workshop 25th November 2020 https://nordicclinicalgenomics.org/events
- v1.0 to be published Jan 2021 for download, translation and implementation
- Implications beyond Nordics
- Expanded research focus synergies with GA4GH DUO
- Validated need for a trusted digital consent solution

Questions, feedback or interested in joining?

Questions?

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Both NACG and NPL are open for new members that will adhere to the organizations' guiding principles:

NORDIC PERMED LAW '/www.nordicpermedlaw.org/

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