Diagnostics (U.S.) — Information Sheet

Dear Patient,

Your physician recommends a biochemical and/or genetic analysis ("**Analysis**") for you or the patient for whom you are the custodian or legal guardian ("**you**" or "**Patient**") for a possible diagnosis of the disease stated in the "Informed Consent Form" below.

CENTOGENE shall only perform the Analysis. It remains the sole responsibility of the treating physician to interpret the result(s) of such Analysis and to inform you or the Patient of the results of the overall genetic testing.

In the following we shall inform you or the Patient about the testing procedure, possible results, and potential risks. You or the Patient may wish to consult with a genetic counselor before signing the Informed Consent Form.

The Analysis aims to identify the cause of a suspected disease by analyzing biological material of the Patient, including but not limited to genetic material ("**DNA**") for an abnormal change ("**Variant**") which eventually could explain the disease that the Patient or family members are suffering from. DNA encodes the relevant genetic information necessary for the development, function, growth and reproduction of humans. Depending on the case, the Analysis will look for a single gene/variant responsible for a specific, suspected genetic disease, or Variants in multiple genes (gene panels, whole exome or genome sequencing) at the same time.

The sample required for the Analysis may be biological material, typically blood, but may also be purified DNA, tissue, saliva or buccal swab, or raw DNA sequencing data, representing the genetic information from such biological material and in which case CENTOGENE does not perform the processing of the biological material, but receives only the resulting raw data files (each, together or separately a "**Sample**") or a combination of Samples, e.g. biological material and raw DNA sequencing data.

For operational (technical and economic) reasons, in some cases, CENTOGENE will sequence a larger part of your genome although your Physician has ordered a targeted Analysis. In any case, the report that is provided to the Physician will only cover the ordered Analysis. As a consequence, if raw data results are requested by the Physician, the raw data results may contain more data than ordered, analyzed, and reported by CENTOGENE, including possibly relevant Variants.

Possible results and significance of the results

- A disease-causing Variant is identified which confirms the diagnosis by the physician or helps the physician to determine a diagnosis. The physician is solely responsible for determining a diagnosis and will discuss the results with you or the Patient and may suggest appropriate medical treatment if available.
- A Variant is identified but currently, there is not enough scientific and/or medical information available to determine whether this is a disease-causing variant or not. The physician will discuss the results with the Patient and will explain what further options may be available.
- The Analysis does not identify relevant Variants which can explain the symptoms. This might be due to current limitations in scientific and/or medical knowledge and/or technology. However, such results do not rule out in full the possibility of a genetic disease or predisposition to such a disease.

Family relationship findings

If several family members are tested, accurate interpretation of the results depends on the information provided concerning familial relationships. If the Analysis reveals that reported familial relationships are not true biological relationships, we will only report such findings in the results where it is necessary for the correct medical interpretation of the requested Analysis.

Reanalysis

Diseases, genes and Variants are subject to ongoing scientific research, thus it may be beneficial to re-evaluate your or your Patient's Sample ("**Reanalysis**"), when new findings have been discovered. Hence, if related to your or your Patient's health status, CENTOGENE may review your or your Patient's Sample for clinically relevant Variants, whereas only the raw DNA sequencing data will be subject to a Reanalysis. If any results are being found differently than in the original report, this information will be stated in an updated report to you or the treating physician. There is also a possibility to actively request a Reanalysis of the Sample by you or your Patient in the absence of new clinical information (whereas it is recommended to wait at least one year from the original Analysis) or any time when a Patient presents a new phenotype.

Only relevant for Whole Exome Sequencing (WES) and Whole Genome Sequencing (WGS)

When performing WES and WGS, numerous Variants in various genes are simultaneously analyzed. Due to the nature of this Analysis, it is possible that a pathogenic Variant discovered unintentionally is not related to the cause of the investigated disease but is still considered medically relevant due to its clear and immediate medical significance to you or the Patient's health or the health of family members. In this regard the following findings may occur:

(1) The American College of Medical Genetics ("**ACMG**") has published guidelines for the reporting of findings, which are known as "Secondary Findings" (formerly "Incidental Findings"). Please refer to the latest version of the "ACMG Recommendations for Reporting of Secondary Findings in Clinical Exome and Genome Sequencing" at www.acmg.net. These recommendations form the basis for CENTOGENE's reporting of Secondary Findings.
(2) In addition, CENTOGENE may consider reporting further non-ACMG recommended findings, which are called "Carriership Findings". Carriership Findings include mainly findings indicating carrier status for recessive disorders, provided these Variants have been subject to CENTOGENE's prior evaluation.

While the Carriership Findings are not included within the ACMG recommendations, these findings can still help to prevent or significantly reduce morbidity and mortality. Interpretation of the Variants/carrier status is based on information available at the time of the Analysis and may change in the future as medical knowledge advances. We are unable to guarantee that the Analysis will find all medically actionable conditions for which a pathogenic or likely pathogenic Variant might exist. Secondary and/or Carriership Findings will only be reported if consent is given by you or the Patient.

Potential risks

(1) If a blood sample is provided, there can be transient secondary bleeding and pain at the spot of the puncture and, rarely, local allergic reactions; the puncture can also result in bruising. However, these effects usually go away quickly. In very rare cases, the needle can damage a blood vessel or injure a nerve. Nevertheless, the spot of the puncture usually heals with no permanent effects. There are no further health risks associated with the Analysis.
(2) The communication of the results of the Analysis may result in psychological stress for you or the Patient and family members.
(3) If (optional) consent has been provided accordingly below, your or the Patient's biochemical, genetic, and health data, including results of the Analysis may be shared with external doctors, scientific institutions, and/or (pharmaceutical) companies for their own scientific (including commercial) research, but solely in de-facto anonymized form. Nevertheless, the risk of re-identification of you or the Patient as a person cannot be completely excluded in theory, due to the uniqueness of genetic information. Such risk increases if and to the extent more information about you or the Patient is publicly available and can be linked to you or the Patient. Therefore, we recommend to handle such information with care, and not to publish in freely accessible databases or elsewhere on the internet (e.g. for ancestry research), particularly not with any direct information or link to you or the Patient.
(4) Genetic non-discrimination laws prevent insurance companies from using your or the Patient's genetic information to deny health insurance coverage. However, these protections may not apply to life insurance, disability insurance, and long-term care insurance. Insurers may ask to provide genetic information indicating a disorder if this information is available to you or the Patient.

Privacy Notice

CENTOGENE US, LLC, 45 Prospect St, 5th Floor, Cambridge, MA 02139, USA and CENTOGENE GmbH, Am Strande 7, 18055 Rostock, Germany ("**CENTOGENE LLC**", "**CENTOGENE GmbH**", and jointly "**CENTOGENE**", "**we**" or "**us**") are jointly responsible for the collection, use, storage, or disclosure ("**processing**") of your or the Patient's personal data. "**Personal data**" means any information relating to an identified or identifiable natural person. If you have any questions on CENTOGENE's data processing or want to make use of your or the Patient's data protection rights, you can contact our data protection officer directly at the address above with the addition: Attn: Data Protection Officer, or via email at dataprivacy@centogene.com.

Data processing
We collect a Sample and other personal data, including first name, last name, address, date of birth, gender, family relations, ethnicity, nationality, insurance information, Patient code number (CGXXXXXXXX), disease, symptoms, and other medical information, including image material if provided (Art. 6 para. 1 a); Art. 9 para. 2 a) GDPR), which will then be processed in our databank. The Sample is analyzed using state-of-the-art scientific methods and the extracted data is processed with the collected data in our databank. We then provide the results containing biochemical, genetic and health data to you or the treating physician. Unless you consent otherwise as set out below, this data will be anonymized, which means that it will not be possible to reidentify you or the Patient. However, the data may be of scientific importance when improving diagnosis and treatment of rare diseases, including scientific publications.

Data storage
We archive the personal data and Sample for up to 10 years after the last result has been reported. We delete or anonymize the personal data and destroy the biological material thereafter if this has not already happened. You or the Patient also have/has the option to process the personal data and donate the Sample for scientific (including commercial) research purposes. Then, personal data and Sample will be stored for up to 20 years after the last result has been reported. After 20 years at the latest, the Sample may be anonymized and stored in our archive in anonymized form for further scientific (including commercial) research purposes.

Recipients of personal data
In principle, we process personal data ourselves. Any transfer of personal data to a third party only takes place (1) with either explicit consent, (2) in order to fulfil a legal obligation or (3) if such transfer is permitted by law:

- We use third-party services, e.g. IT-service providers that maintain our systems or data centers which host such systems. Such third-party services are considered as data processors under GDPR. These data processors are carefully selected, contractually bound to comply with data protection laws, subject to our instructions and regular monitoring and only allowed to use the data they receive to fulfil their contractual obligations. We always conclude GDPR-compliant data processing agreements with such data processors.
- Your or the Patient's personal data may be shared with further third parties involved in your or the Patient's treatment or payment for healthcare services. These third parties may include, for example, phlebotomy services, billing service providers, and health insurance carriers.
- If consent has been provided accordingly, we may provide biochemical, genetic and health data, including results of the Analysis – solely in de-facto anonymized form – to external physicians, scientific institutions and/or (pharmaceutical) companies for their own scientific (including commercial) research.
- We provide the results of the Analysis and if requested the raw DNA sequencing data to the treating physician and/or eventually to the requesting laboratory and may provide the results of the Analysis to other health care professionals who are involved in your or the Patient's medical counseling and/or clinical care.

International data transfer
The Sample will be analyzed either in the USA or in Germany. In principle, we process personal data solely within the USA, Germany, the European Union, and the European Economic Area ("**EEA**") and may share personal data between our legal entities in the USA and Germany. We will provide the results of the Analysis to the treating physician located in the USA. If other recipients are located in a so-called third country outside the EEA where GDPR provisions do not apply, your or the Patient's personal data shall be transferred to this third country. Such transfer will only take place with your or the Patient's consent.

If we engage a data processor based outside the EEA, we may transfer the personal data to such third country, provided that, either (1) the European Commission has decided that this third country already provides an adequate level of data protection or (2) we establish appropriate data protection safeguards with the data processor, e.g. by concluding so-called "standard contractual clauses", respectively including supplemental clauses containing additional safeguards. In such cases, you or the Patient have/has a right to request a copy of these "standard contractual clauses". To do so, please contact our data protection officer.

Your/the Patient's Data protection rights under the GDPR

- Right to withdraw your consent regarding data processing with future effect
- Right of access
- Right to data portability
- Right to rectification
- Right to erasure
- Right to restriction of processing
- **Right to object**
- Right to lodge a complaint with a supervisory authority

Additional rights under the German Genetic Diagnostics Act (Gendiagnostikgesetz)

- Right to withdraw your or the Patient's consent to the Analysis (until such has been performed);
- Right to request destruction of the Sample (as long as it has not yet been anonymized);
- Until the moment you or the Patient has been given the results of the Analysis, the right not to be informed about such results in full or in part (right not to know); and the right to request destruction of all such results.

Further rights under the Health Insurance Portability and Accountability Act ("HIPAA") are outlined in our HIPAA Privacy Notice.

To exercise the rights, please contact our data protection officer.

Disclaimer:
Please note that biochemical and/or genetic analysis are not definitive. Due to limitations in technology and/or incomplete medical knowledge, some disease-causing variants may not be detected. Therefore, it is not possible to completely exclude all risks for all possible genetic diseases. Moreover, in some cases, the Analysis may indicate a genetic abnormality when you or the Patient are/is actually unaffected (false positive) or may indicate no genetic abnormality when you or the Patient are/is actually affected (false negative).

IN CASE OF THE UNDERLYING CAUSE OF A FALSE-POSITIVE OR FALSE-NEGATIVE FINDING COULD NOT BE IDENTIFIED BY CENTOGENE, CENTOGENE SHALL NOT BE RESPONSIBLE FOR THE INCOMPLETE, POTENTIALLY MISLEADING OR INCORRECT RESULT OF AN ANALYSIS.

HIPAA Privacy Notice

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW THIS NOTICE CAREFULLY.

1. Our Responsibilities

CENTOGENE US, LLC (hereinafter "**CENTOGENE**") is required by law to maintain the privacy of your identifiable health information ("**Protected Health Information**" or "**PHI**"). We are also required to provide you with this Notice of Privacy Practices ("**Notice**"), which describes our legal duties, privacy practices and your patient rights according to the Health Insurance Portability and Accountability Act ("**HIPAA**") of 1996. We are required to follow the terms of the Notice currently in effect and to notify affected individuals in the event of a breach involving unsecured protected health information.

CENTOGENE's current Notice will always be available on our website at www.centogene.com/hipaa-notice or you can request a paper copy by contacting our Privacy Office as indicated below.

If you have any questions about this Notice or would like additional information, or to exercise your privacy rights as described below, please contact our Privacy Office at the following email: dataprivacy@centogene.com or by phone at (+1)617-580-2102.

We will not use or share your information other than as described in this Notice unless you tell us we can in writing. If you tell us we can, you may change your mind at any time. Let us know in writing if you change your mind by contacting our Privacy Office.

2. Your Rights

When it comes to your health information, you have certain rights. This section explains your rights and some of our responsibilities to help you. To exercise any of these rights, contact our Privacy Office at the contact information listed above.

Get an electronic or paper copy of your medical record
You can ask to see or get an electronic or paper copy of your medical record and other health information we have about you.
We will provide a copy or a summary of your health information, usually within 30 days of your request. We may charge a reasonable, cost-based fee.

Ask us to correct your medical record
You can ask us to correct health information about you that you think is incorrect or incomplete.
We may say "no" to your request for certain reasons, but we'll tell you why in writing within 60 days.

Request confidential communications
You can ask us to contact you in a specific way (for example, home or office phone) or at a specific location (for example, to send mail to a different address).
We may ask you, to confirm your identity first, but will agree to all reasonable requests.

For certain health information, you can tell us your choices about what we share
If you have a clear preference for how we share your information in the situations described below, talk to us. Tell us what you want us to do, and we will follow your instructions.
In these cases, you have both the right and choice to tell us to:
- Share information with your family, close friends, or others involved in your care
- Share information in a disaster relief situation
- Include your information in a hospital directory

Example: If you are not able to tell us your preference, for example if you are unconscious, we may go ahead and share your information if we believe it is in your best interest. We may also share your information when needed to lessen a serious and imminent threat to health or safety or where otherwise permitted or required by applicable law.

Ask us to limit what we use or share
You can ask us not to use or share certain health information for treatment, payment or our operations. We are not required to agree to your request, and we may say "no" including if it would affect the results of our diagnostic services or the care / treatment options of your physician.
If you pay for a service or health care item out-of-pocket in full, you can ask us not to share that information for the purpose of payment or our operations with your health insurer. We will say "yes" unless applicable law provisions require us to share that information.

Get a list of those with whom we've shared information
You can ask for a list (accounting) of the times we've shared your health information for six years prior to the date you ask, who we shared it with, and why.
We will include all the disclosures except for those about treatment, payment, and health care operations, and certain other disclosures (such as any you asked us to make). We'll provide one accounting a year for free but will charge a reasonable, cost-based fee if you ask for another one within 12 months.

Get a copy of this Notice
You can ask for a paper copy of this Notice at any time, even if you have agreed to receive the Notice electronically. We will provide you with a paper copy promptly.

Choose someone to act for you
If you have given someone medical power of attorney or if someone is your legal guardian, that person can exercise your rights and make choices about your health information.
We will make sure the person has this authority and can act for you before we take any action.

File a complaint if you feel your rights are violated
You can complain if you feel we have violated your rights by addressing us by email at dataprivacy@centogene.com or by mail at CENTOGENE US, LLC, 45 Prospect St, 5th Floor, Cambridge, MA 02139, USA.
You can file a complaint with the U.S. Department of Health and Human Services Office for Civil Rights by sending a letter to 200 Independence Avenue, S.W., Washington, D.C. 20201, calling 1-877-696-6775, or visiting www.hhs.gov/ocr/privacy/hipaa/complaints/.
We will not retaliate against you for filing a complaint.

3. Our Uses and Disclosures

How do we typically use or share your health information?
The following categories describe different ways that we are permitted to use and disclose your health information. For each category of uses or disclosures, we will explain what we mean. Not every use or disclosure in a category will be listed. However, all of the ways we are permitted or required to use and disclose medical information without your permission will fall within one of the categories. State laws and regulations may impose further limits or requirements on our ability to use or disclose your medical information or certain categories of your medical information, such as genetic information. We will follow more stringent state laws and regulations that apply to us and your medical information. For more information about your state's laws and whether they limit any of the activities described in this Notice, contact the Privacy Office at the contact information listed above.

Treat you
We may use or disclose your Protected Health Information for treatment purposes.
Example: We may use your Protected Health Information to perform our testing services and disclose your genetic testing results to your physician and other healthcare providers involved in your care.

Run our organization
We can use and share your health information to run our practice, improve your care, and contact you when necessary.
Example: We use health information about you to review and improve our services, such as through quality assessment activities, and to provide customer service.

Bill for our services
We can use and share your health information to bill and get payment from health plans or other entities.
Example: We give information about you to your health insurance plan so it will pay for your services.

Business Associates
We may provide your PHI to other companies or individuals that need the information to provide services to us. These other entities, known as "business associates," are required to maintain the privacy and security of PHI.
Example: We may provide information to companies that assist us with billing of our services. We may also use an outside collection agency to obtain payment when necessary.

De-identified or Partially De-identified Information
We may use and disclose your health information for other purposes if we have de-identified it in accordance with applicable law. We may also use and disclose health information about you for research, public health and certain healthcare operations if information that directly identifies you is removed and the recipient signs an agreement to protect the privacy of the information as required by applicable federal and state law.

How else can we use or share your health information?
We are allowed or required to share your information in other ways – usually in ways that contribute to the public good, such as public health and research. We have to meet many conditions in the law before we can share your information for these purposes.

Help with public health and safety issues
We can share health information about you for certain situations such as:
- Preventing disease
- Helping with product recalls
- Reporting adverse reactions to medications or products
- Reporting suspected abuse, neglect, or domestic violence
- Preventing or reducing a serious threat to anyone's health or safety

Do research
In accordance with your consent, we may use or share your data for health research.

Comply with the law
We will share information about you if state or federal laws require it, including with the Department of Health and Human Services if it wants to see that we are complying with federal privacy law.

Respond to organ and tissue donation requests
We can share health information about you with organ procurement organizations or other entities engaged in the procurement, banking or transplantation of cadaveric organs, eyes or tissues for donation or transplantation.

Work with a medical examiner or funeral director
We can share health information with a coroner, medical examiner, or funeral director when an individual dies.

Address workers' compensation, law enforcement, and other government requests
We can use or share health information about you:
- For workers' compensation claims
- For law enforcement purposes or with a law enforcement official
- With health oversight agencies for activities authorized by law
- For special government functions such as military, national security, and presidential protective services

Respond to lawsuits and legal actions
We can share health information about you in response to a court or administrative order, or in response to a subpoena, discovery request, or other lawful process in certain situations.

In these cases, we never share your information unless you give us written permission or we are otherwise permitted by applicable law:
- Marketing purposes
- Sale of your information
- Most sharing of psychotherapy notes

4. Changes to the Terms of this Notice

We reserve the right to amend the terms of this Notice to reflect changes in our privacy practices, and to make the new terms and practices applicable to all PHI that we maintain about you, including PHI created or received prior to the effective date of the Notice revision. Our Notice is displayed on our website and a copy is available upon request.

This version of this Notice is effective from June 2022.
Rostock, June 2022

Informed Consent Form

Suspected Disease: (to be completed by the treating physician)

With my signature below, I confirm or confirm on behalf of the Patient for whom I am the custodian or legal guardian (hereinafter, "I" or "the Patient") that I or the Patient have/has received, read and understood the preceding written explanation about the biochemical and/or genetic analysis ("**Analysis**"). I or the Patient have/has been adequately informed regarding the purpose, scope, type and significance of such analysis, its possible results and possible risks. The responsible physician has informed me or the Patient about possible prevention/treatment measures of the suspected disease. Furthermore, I confirm that I have had sufficient opportunities to ask questions and such questions were answered in an understandable manner and to my or the Patient's full satisfaction.

Consent to the Biochemical and/or Genetic Analysis and Related Data Processing

By signing this Informed Consent Form, I consent or consent on behalf the Patient for whom I am the custodian or legal guardian
(1) to an Analysis of my or the Patient's Sample by CENTOGENE US, LLC, 45 Prospect St, 5th Floor, Cambridge, MA 02139, USA and/or CENTOGENE GmbH, Am Strande 7, 18055 Rostock, Germany (jointly "("CENTOGENE") – including shipment of the Sample to Germany – for a possible diagnosis of the disease specified above; (2) to any necessary processing of my or the Patient's personal data to perform such Analysis, as specified in the Information Sheet; (3) to provide the results of the Analysis to the treating physician and to be informed by the treating physician of the results of the Analysis; (4) to provide the results of the Analysis to health care professionals, who are involved in my or the Patient's medical counseling and/or clinical care, if so requested by the treating physician; (5) to provide the results of the Analysis to the requesting laboratory, as instructed by the treating physician; (6) to provide raw data of the Analysis, upon request, to the treating physician and/or the requesting laboratory; and (7) to store the personal data and the Sample for up to 10 years after CENTOGENE has reported the last result and to anonymize the personal data. Furthermore, I consent to the transfer of my or the Patient's personal data between the USA and Germany and/or – if the following recipients are located in a so-called third country outside the European Economic Area, where GDPR provisions do not apply – to the transfer of my or the Patient's personal data between Germany and this third country, in particular (1) to share my or the Patient's personal data within CENTOGENE's legal entities; (2) to provide the results of the Analysis and the raw data to the treating physician and/or the requesting laboratory; and (3) to provide the results of the Analysis to the health care professionals who are involved in my or the Patient's medical counseling and/or clinical care. I acknowledge that the USA and such other third country may not provide a level of data protection equivalent to the GDPR and may grant fewer or less enforceable data protection rights and no independent data protection supervisory authority to assist in exercising these rights. Finally, I consent to the disclosure of my or the Patient's personal data – but only to the extent necessary in each case – with further third parties involved in my or the Patient's treatment or payment for healthcare services, in particular (1) to acquire the blood sample (phlebotomy service); (2) to organize a health insurance review and possible insurance payment through a billing service provider; and (3) if selected by me or the Patient, to bill the costs of the Analysis to my or the Patient's health insurance carrier, or other third party.

Optional Consent for Reporting of Secondary (Incidental) and/or Carriership Findings

Only relevant for Whole Exome Sequencing (WES) and Whole Genome Sequencing (WGS)
I understand the significance of Secondary and/or Carriership Findings and consent, that CENTOGENE

(1) reports the ACMG recommended Secondary Findings.	☐ YES
(2) reports further non-ACMG recommended Carriership Findings.	☐ YES

I am aware that CENTOGENE — at its own discretion — may refrain from reporting the Secondary and/or Carriership Findings.

Optional Consent to Further use of the Sample and Personal Data

I understand that my or the Patient's Sample and personal data may enable CENTOGENE to develop and improve diagnostic methods and therapeutic solutions for genetic diseases in general. This may help myself, my family members, and other patients in the future. However, such voluntary consent is not necessary to conduct the Analysis as specified above. I acknowledge that I or the Patient will not receive any compensation for the donation of the Sample and provision of personal data. I waive any claims for compensation, royalties, or other financial benefits that may arise from scientific (including commercial) research usage of the Sample and personal data.

(1) I consent to the usage of my or the Patient's Sample and personal data by CENTOGENE for scientific (including commercial) research, which focuses on the cause, early detection and/or treatment of rare diseases in general. I acknowledge that the Sample and data will be used in the interest of the greatest possible benefit to the general public for research which aims to improve the prevention, detection and treatment of rare diseases. Such includes but is not limited to disease areas such as metabolic disorders, neurodegenerative disorders, cardiac disorders and malformations as well as to diseases and genetic relationships that are still unknown today. In any research on rare diseases – particularly due to the latest findings in genetic diagnostics – it is usually not possible to predict in detail which research questions and matters will be addressed in the future. Therefore, the specific research purpose cannot be detailed herein, and the Sample and data may also be used for medical research projects that cannot be foreseen today. (2) I consent that CENTOGENE shares my or the Patient's biochemical, genetic, and health data, including the results of the Analysis – solely in de-facto anonymized form – with external doctors, scientific institutions, and/or (pharmaceutical) companies for their own scientific (including commercial) research. I acknowledge that "de-facto anonymized" means that the data available at CENTOGENE is altered in such a way, including redaction and removal of any pseudonyms, that re-identification of me or the Patient as a person for any further recipient of the data is practically impossible. However, the confidentiality risks described in the Information Sheet persist. (3) I consent that CENTOGENE stores my or the Patient's Sample and personal data for up to 20 years after the last result has been reported and I hereby donate and transfer ownership of my or the Patient's Sample to CENTOGENE for further scientific (including commercial) research, which focuses on the cause, early detection and/or treatment of rare diseases in general. I acknowledge that after 20 years at the latest – once the identifying data was deleted – the Sample will become anonymized and will remain in CENTOGENE's archive – in anonymized form – for such scientific (including commercial) research. In anonymized form means, that CENTOGENE cannot identify me or the Patient as a person from such Sample anymore.	☐ YES

I understand that the consent(s) is/are voluntary and valid until such time as I choose to withdraw consent. The consent with regard to the Analysis and the optional consent for Secondary and/or Carriership Findings can be withdrawn until such has been performed; and (2) the processing of the personal data can be withdrawn at any time. Furthermore, the destruction of the Sample can be requested as long as it has not yet been anonymized, in each case with effect for the future. Until the moment the results of the Analysis have been provided to me or the Patient, I understand that I have the right (1) not to be informed about such results (so called right not to know); and (2) to request the destruction of all such results. To withdraw the consent and/or to exercise the rights, I may contact CENTOGENE's data protection officer.

Date	Name and date of birth (DD.MM.YYYY) of the Patient	Signature of the Patient, and/or custodian/legal guardian
.....	.....	.....

For Duo and Trio (only applies to additional Patient(s) 2 and 3)

Please read the detailed information on the optional consents as described above.
Optional consent to further use of the Sample and personal data

	Patient 2	Patient 3 (if applicable)
(1) I consent to the usage of my or the Patient's Sample and personal data by CENTOGENE for scientific (including commercial) research, which focuses on the cause, early detection and/or treatment of rare diseases in general.		
(2) I consent that CENTOGENE shares my or the Patient's biochemical, genetic, and health data, including the results of the Analysis – **solely in de-facto anonymized form** – with external doctors, scientific institutions, and/or (pharmaceutical) companies for their own scientific (including commercial) research.		
(3) I consent that CENTOGENE stores my or the Patient's Sample and personal data for up to 20 years after the last result has been reported and I hereby donate and transfer ownership of the Patient's Sample to CENTOGENE for further scientific (including commercial) research, which focuses on the cause, early detection and/or treatment of rare diseases in general.	☐ YES	☐ YES

Optional Consent for Reporting of Secondary (Incidental) and/or Carriership Findings

Only relevant for Whole Exome Sequencing (WES) and Whole Genome Sequencing (WGS)
I understand the significance of Secondary and/or Carriership Findings and consent, that CENTOGENE

	Patient 2	Patient 3 (if applicable)
(1) reports the ACMG recommended Secondary Findings.	☐ YES	☐ YES
(2) reports further non-ACMG recommended Carriership Findings.	☐ YES	☐ YES

I am aware that CENTOGENE — at its own discretion — may refrain from reporting the Secondary and/or Carriership Findings.

Date	Name and date of birth (DD.MM.YYYY) of the Patient 2	Signature of the Patient 2, and/or custodian/legal guardian
.....	.....	.....
Date (if applicable)	**Name and date of birth (DD.MM.YYYY) of the Patient 3 (if applicable)**	**Signature of the Patient 3, and/or custodian/legal guardian (if applicable)**
.....	.....	.....

Notice to the treating physician:
The applicable law requires informed consent from your Patient to be able to perform a biochemical and/or genetic analysis. Please ask your Patient to sign the informed consent form. Alternatively, please confirm with your signature that the Patient has consented accordingly and that you have such consent on file. Subsequently, please send the completed and signed informed consent form together with the information sheet and Sample(s) to CENTOGENE.

Physician's Confirmation

I acknowledge that (1) the consent as shown above has been declared by the Patient and/or the Patient's custodian/legal guardian, (2) I have the Patient's and/or custodian's/legal guardian's signature on file if it is not shown above, (3) the Patient and/or custodian/legal guardian is capable of giving consent, (4) all questions of the Patient and/or custodian/legal guardian have been answered, (5) the Patient and/or custodian/legal guardian had the necessary time to consider the decision, and (6) the Patient and/or custodian/legal guardian until now have not exercised the right not to be informed of genetic testing results. I understand that (1) the Patient and/or custodian/legal guardian may exercise any of the rights specified in the Information Sheet and (2) I shall forward such requests to CENTOGENE without undue delay.

Date	Name of the treating physician	Signature of the treating physician
.....	.....	.....