

INFORMED CONSENT- GENETIC COUNSELING

Last Updated: [05/08/22] DNA ALLY, Inc provides genetic counseling services through telehealth technologies. This Consent for genetic counseling describes your rights and responsibilities with respect to accessing and receiving healthcare services via telehealth technologies. DNA ALLY's Terms and Conditions (<https://dnaally.com/terms-of-use/>) and Privacy Policy (<https://dnaally.com/privacy-policy/>) apply to all users. By engaging in a video or phone consult you certify that you are the user or the user's parent/legal guardian, can provide valid consent, and that you agree to the terms of this Consent.

Telehealth involves the use of secure electronic communications, information technology, or other means to enable a genetic counselor and a user at different locations to communicate and share individual health information for the purpose of providing consultations. This "Consent" informs the user ("user," "you," or "your") concerning the methods, risks, and limitations of using a telehealth platform as well as some of the means by which communication may occur.

Services Provided:

Telehealth services offered by DNA ALLY, its affiliates, and/or network of independent contractors, (collectively "Genetic Group") may include a consultation and/or a referral to in-person care, as determined appropriate (the "Services"). Your Genetic counselor will be licensed in the state where you are located at the time of your consultation, or otherwise meet a professional licensure exception under applicable state law.

Electronic Transmissions:

The types of electronic transmissions that may occur using the telehealth platform include, but are not limited to:

- Appointment scheduling;
- Completion, exchange, and review of healthcare forms and other relevant information (for example: health records; images; output data from medical devices; sound and video files; diagnostic and/or lab test results) between you and your Genetic counselor via:
 - o asynchronous communications;
 - o two-way interactive audio in combination with store-and-forward communications; and/or
 - o two-way interactive audio and video interaction;
- Consult notes by your genetic counselor based upon such review and exchange of information;
- Other electronic transmissions for the purpose of genetic consultation

Expected Benefits:

- Improved access to care by enabling you to remain in your preferred location while your genetic counselor consults with you.
- More efficient care evaluation and management.

Service Limitations:

- The primary difference between telehealth and direct in-person service delivery is the inability to have direct, physical contact with the user. Accordingly, some needs may not be appropriate for a telehealth visit and your Genetic counselor will make that determination.
 - If you are not experiencing an emergency or do not require immediate or urgent care, you can communicate with Genetic counselors through the service. If a technical failure prevents you from communicating with your Genetic counselors, please email us immediately at yourfriends@DNAally.com.
 - Our Genetic counselors are an addition to, and not a replacement for, your local primary care provider. Responsibility for your overall medical care should remain with your local primary care provider, if you have one, and we strongly encourage you to locate one if you do not.
 - Genetic Group does not have any in-person locations.

Security Measures:

The electronic communication systems we use will incorporate network and software security protocols to protect the confidentiality of user identification and imaging data and will include measures to safeguard the data and to ensure its integrity against intentional or unintentional corruption.

All the Services delivered to the user through telehealth will be delivered over a secure connection that complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").



Possible Risks:

- Delays in evaluation and treatment could occur due to deficiencies or failures of the equipment and technologies, or genetic counselor availability.
- In the event of an inability to communicate as a result of a technological or equipment failure, please contact DNA ALLY at (844) 362-2559 AND yourfriends@DNAAlly.com.
- In rare events, your Genetic counselor may determine that the transmitted information is of inadequate quality, thus necessitating a rescheduled telehealth consult or an in-person meeting with your local primary care doctor.
- In very rare events, security protocols could fail, causing a breach of privacy of personal medical information.

User Acknowledgments:

I further acknowledge, understand, and agree to the following:

1. I am at least eighteen (18) years of age.
2. I am the individual who provided the sample for the Test(s).
3. My health information and results may be shared with other health care professionals including, but not limited to, physicians and counselors for purposes of providing Services.
4. I have read and understand the benefits, risks, limitations and other information about the Test(s).
5. The information I have provided in connection with Services is correct to the best of my knowledge. I will not hold DNA ALLY, Group, affiliates, or network of independent genetic counselors responsible for any errors or omissions that I may have made in providing such information.
6. Services do not constitute treatment of any condition, disease or illness.
7. While DNA ALLY, Group, and the laboratories implement safeguards to avoid errors, as with all laboratory tests, there is a chance of a false positive or false negative result.
8. I will not make medical decisions without consulting my primary care or disregard medical advice from my primary care or delay seeking such advice based on information as a result of the use of the Services.
9. The scope of Services will be at the sole discretion of the genetic counselor conducting the Services, with no treatment or diagnosis. The genetic counselor will determine whether or not the Services being rendered are appropriate for a telehealth encounter.
10. Genetic counseling is a service used to evaluate and understand a person or family's risk of an inherited medical condition. During a genetic consultation, you and your genetic counselor may review your personal family health history, explain your genetic test results and what it means for you and your family, and provide other genetic testing recommendations.
11. Genetic services are voluntary. You are seeking genetic services either based on your own interest, or because your healthcare provider recommended you do so. You can end your consultation at any time.
12. If I am experiencing a medical emergency, I will be directed to dial 9-1-1 immediately and my Genetic counselor is not able to connect me directly to any local emergency services.
13. I may elect to seek services from a medical group with in-person clinics as an alternative to receiving telehealth services.
14. I have the right to withhold or withdraw my consent to the use of telehealth in the course of my care at any time without affecting my right to future care or treatment.
15. Federal and state law requires health care genetic counselors to protect the privacy and the security of health information. I am entitled to all confidentiality protections under applicable federal and state laws.
16. Genetic Group will take steps to make sure that my health information is not seen by anyone who should not see it. Telehealth may involve electronic communication of my personal health information to other health practitioners who may be located in other areas, including out of state.
17. Dissemination of any user identifiable images or information from the telehealth visit to researchers or other educational entities will not occur without my affirmative consent.
18. There is a risk of technical failures during the telehealth visit beyond the control of Genetic Group. I AGREE TO HOLD HARMLESS GROUP AND ITS EMPLOYEES, CONTRACTORS, AGENTS, DIRECTORS, MEMBERS, MANAGERS, SHAREHOLDERS, OFFICERS, REPRESENTATIVES, ASSIGNS, PARENTS, PREDECESSORS, AND SUCCESSORS FOR DELAYS IN EVALUATION OR FOR INFORMATION LOST DUE TO SUCH TECHNICAL FAILURES.
19. In choosing to participate in a telehealth visit, I understand that some parts of the Services involving tests (e.g., labs or bloodwork) may be conducted at another location such as a testing facility, at the direction of my Genetic counselor.
20. Persons may be present during the telehealth visit other than my Genetic counselor in order to operate the telehealth technologies. If another person is present during the telehealth visit, I will be informed of the individual's presence and his/her role and I have the right to request the following: (i) omit specific details of my medical history/examination that are personally sensitive to me; (ii) ask non-medical personnel to leave the telehealth consultation; and/or (iii) terminate the consultation at any time.

21. I am responsible for checking for results notification and logging on to my account to view my results when available.
22. I am responsible for downloading and forwarding any results or records to my primary care or other personal physician and for initiating follow up, without delay, with such physician for care, diagnosis or medical treatment. I should not make medical decisions without consulting my personal physician.
23. There is no guarantee that I will be treated by a Group genetic counselor. My Genetic counselor reserves the right to deny care for potential misuse of the Services or for any other reason if, in the professional judgment of my Genetic counselor, the provision of the Services is not appropriate.
24. I agree to receive invitations, notifications, reminders and other communications from my Genetic counselor, DNA Ally, Inc. ("DNA Ally") and any of its affiliates or agents) through the websites, technology, or by email, text message (including any short message service), fax, phone or other method of communication. I agree and authorize my Genetic counselor and DNA Ally to make such communications through use of an automatic telephone dialing system and/or an artificial or prerecorded voice message system ("Automated Messages") at any of the contact information provided to DNA Ally or my Genetic counselor or to other service genetic counselors who are working with DNA Ally or the Group. I will immediately notify my Genetic counselor if there are any changes to my mobile phone or other contact information.
25. I understand that I may receive Automated Messages and may receive multiple messages per day, and that I am responsible for any message and data rates charged by my mobile carrier. These communications may not be secure (not encrypted). Unsecured communications may pose a risk to the confidentiality and privacy of the information being sent because they might be intercepted by a third party. I also understand that my consent to receive Automated Messages is optional. I can opt out of receiving Automated Messages at any time, including contacting DNA Ally at yourfriends@DNAAlly.com or replying "STOP" to an automated text message.

I have read this document carefully and understand the risks and benefits of the telehealth consultation and have had my questions regarding Services explained and I hereby give my consent to participate in a telehealth consultation and communicate/receive communications under the terms described herein. I hereby state that I have read, understood, and agree to the terms of this document.

INFORMED CONSENT- LABORATORY TESTING

This form reviews the benefits, risks and limitations of exome screening offered by your healthcare provider. Your test will not be processed without your permission. The choice to undergo testing is yours.

GENERAL INFORMATION: The test that is being pursued is the Exome Sequencing test. This test will be used in an attempt to identify a genetic cause for my/my child's medical condition. Genes carry information about heredity that determines how a body functions and develops. It is estimated that humans have about 20,000 genes. Half of an individual's genetic material comes from the biological mother and the other half from the biological father. The collection of the entire set of genes is called the genome and consists of exons and introns. Exons are the functional parts of the genome that make proteins. "Exome" refers to the parts of the genome formed by all the exons. The exome test will analyze approximately 95% of an exome in order to find a change in the DNA that is causing an individual's medical condition.

TEST RESULTS: I understand that the exome test is not 100% sensitive and does not identify every DNA change. The comprehensiveness of a exome result will depend on the accuracy of family history and the amount of relevant clinical information an individual and their ordering healthcare provider are able to provide.

Confidentiality: Your results will only be disclosed to the ordering healthcare provider, unless otherwise authorized by you. Information obtained from this test may be used in scientific publications or presentations, but the identity of individuals will never be revealed. To contribute to the advancement of scientific research, Gene by Gene will keep raw data and an open-access database of mutations found in various ethnicities, but no personal identifying information will be included. Laws have also been put in place by the US government to protect you against discrimination of health insurance and employment. More information is available at www.genome.gov/10002077 and www.genome.gov/11510216. Please speak with your healthcare provider regarding any additional concerns.

RISKS/LIMITATIONS: There is a possibility that an individual has a genetic condition even though the exome result may be negative. Due to limitations in technology, some types of DNA changes will not be detected by this test. In addition, some disease-causing variants that do not occur in an exon will not be detected.



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A healthcare provider may decide that additional genetic testing is needed to obtain a molecular diagnosis. Due to incomplete knowledge of some DNA changes, there is a possibility that the test result may be a variant of unknown significance (VUS). This means that a DNA change was identified; however, it is unknown whether the variant is responsible for an individual's medical condition.

Genetic knowledge is constantly changing. The interpretation of an exome sequencing test will be based on the most currently available information. As further discoveries are made this interpretation may change. A re-interpretation of a exome result at a future date may lead to a molecular diagnosis that may impact an individual's healthcare management. A request for a re-interpretation of a exome result may be submitted by a healthcare provider.

The accuracy of the test depends on correct family history. An error in diagnosis may occur if the true biological relationships of the family members involved in this study are not as they have been stated. In addition, testing may inadvertently reveal non-paternity or non-maternity. This means that the biological father or biological mother of an individual is not the person stated to be the father or mother. It may be necessary to disclose this finding to the ordering healthcare provider. This is due to the fact that an erroneous diagnosis in a family member can lead to an incorrect diagnosis for other related individuals.

SPECIMEN RETENTION: DNA specimens are retained and stripped of identifying information to be used for quality assurance, test validation and/or research purposes. Please check the box below to consent to this possibility. If you do not consent your sample will be discarded within 60 days of completion of the testing. You may decline consent at any time and request that your specimen be destroyed by calling Gene by Gene at 713-474-2401, option #5. Your consent will not affect your results.

I have read the consent and have been explained the benefits, risks and limitations of whole exome sequencing offered by Gene by Gene. I have had the opportunity to consult with a healthcare professional. I agree to undergo whole exome sequencing testing.