

Consent for genetic counseling and telehealth

1. This consent is for the provision of genetic counseling by the genetic counselors and pharmacists that are utilizing the DNAvisit platform.
2. Genetic counseling is the process of discussing genetic information and concerns, including personal and family history, genetic disease concerns, and the benefits and limitations of both genetic testing and potential test results, with a trained clinical genetics professional.

Genetic testing is any analysis that looks at your genetic makeup.

3. During a genetic counseling session, you and your clinician may:
 1. Review your personal health history and family history.
 2. Discuss questions you have about possible genetic conditions or the risk of a genetic condition in you or your family.
 3. Explore genetic testing options by helping you understand what tests are available and what testing can and cannot tell you, and provide guidance to help you decide if you would like to pursue genetic testing.
 4. Discuss the risks and benefits of genetic testing related to prevention or therapeutic medical treatment to reduce the risk of disease, including the potential psychological and social impact of genetic conditions or genetic test results.
 5. Explain results of any genetic testing you have had and what the results mean for you and your family.
 6. Discuss the Genetic Information Nondiscrimination Act (GINA) of 2008 that prohibits discrimination based on genetic testing from health insurance and employment with some exceptions. Your clinician can clarify any concerns you have about genetic testing (ginahelp.org).
4. Genetic counseling is voluntary. You are seeking genetic counseling either based on your own interest, or because your healthcare provider recommended you do so. Some insurance companies may require genetic counseling before they cover the cost of genetic testing.
5. You should share complete and accurate medical history and details regarding any conditions you may have or may be aware of in your family. You will also need to provide access to your medical records and any genetic test results. The recommendations from your genetic consultation will depend on the accuracy of your family history. Issues of non-paternity (for example, named father is not the biological father) will affect the evaluation of your family history. We may request that you obtain genetic test results or medical records from a family member.

6. Genetic counseling consults are provided through telehealth technologies and telephone and video consultations.
7. If the telemedicine session is interrupted due to a technological problem or equipment failure, alternative means of communication may be implemented, such as a telephone consultation, or the appointment may be rescheduled.
8. While telehealth may improve access to care and lead to more efficient diagnosis, treatment, and care management, there are potential risks associated with telehealth, as there are with any medical treatment or procedure. The potential risks associated with telehealth include, but are not limited to: insufficient transmission of information that does not allow for appropriate decision-making and diagnosis by the health care provider; delays in diagnosis, consultation, and/or communication due to deficiencies or failures of equipment or systems; failure of security protocols, resulting in a breach of privacy of personal health information; or adverse results or reactions due to lack of access to complete medical records.
9. Under certain circumstances, telehealth may not be as appropriate as face-to-face interaction, and your genetic counselor may refer you to another provider for follow-up or additional care.
10. The details of your telehealth interaction, which may include oral, visual, and electronic communications between you and your health care provider, may become part of your medical records, as such details would for any other type of face-to-face interaction with a health care provider.
11. Genetic consultations and testing results are confidential to the extent allowed by law. They are released to other physicians or parties only with your written consent or as permitted under applicable laws.
12. The information provided by genetic counselors, pharmacists and doctors are not intended to replace the medical advice and recommendations of your existing healthcare team who are responsible for your overall care. If you have non-genetic concerns about a current health condition, you should consult your local healthcare provider.
13. The clinicians are not affiliated with and do not receive direct payment from commercial genetic laboratories, and will assist you in selecting the best test based on your personal history. Genetic testing may require a separate consent form discussing the risks and benefits of a specific test.
14. The clinician may provide an evaluation and recommendations based on your unique medical history and genetic test results based on the clinical testing and knowledge available at the time of the consultation. Genetic testing is evolving rapidly and the significance of certain genetic changes on your health or family's health may not be known at the time of your evaluation. Management guidelines for genetic conditions can also change based on new information. It is important for you to contact your healthcare provider if there are changes in your medical or family history that would warrant further genetic consultation.

15. Your privacy is important to DNAvisit. Details about DNAvisit's policies governing patient privacy and health information, including patient rights regarding such information, may be found in DNAvisit's [Terms of Service](#), [HIPAA Notice of Privacy Practices](#), and [Privacy Notice](#), which may also be made available to you upon request by emailing support@dnavisit.com. DNAvisit complies with the applicable federal and state laws, including but not limited to HIPAA.
16. You may discuss any questions regarding this consent form with the staff at DNAvisit (hello@dnavisit.com).

STATEMENT OF CONSENT, INCLUDING RELEASE OF MEDICAL RECORDS

I have read and fully understand this informed consent document relating to genetic counseling and telehealth and the risks described in this consent. I understand I will have the opportunity to discuss the genetic counseling service and the use of telehealth with my clinician and may discontinue the service at any time. This consent applies to all genetic counseling I receive through DNAvisit and its affiliated professionals and all telehealth interactions. I acknowledge that I am responsible to provide information about my medical and family history that is complete and accurate to the best of my ability. In order to facilitate the genetic counseling process, I voluntarily request and authorize the clinicians to access my applicable medical records and any genetic test results. I consent to be contacted by email, phone, or written letter by clinicians in the future.

I understand that electronic transmission of data, video images, and audio is a new and developing technology. I understand that telehealth-based services may not be as complete or appropriate as face-to-face interactions under certain circumstances, and my clinician provider may refer me to another health care provider for follow-up or additional care.

I understand that I may expect certain anticipated benefits of the use of telehealth by my health care providers, but that no outcomes or results are guaranteed.

I understand that the clinician (e.g. genetic counselor or pharmacist) may utilize all tools available that can search, find, and aggregate my patient history of care, to help provide me with the highest level of care.

I understand that nothing in this consent precludes me from seeking or receiving in-person care if I choose, even after consenting to receive services via telehealth.

CONSENT FOR GENETIC TESTING AT LAB

1. If genetic testing is being ordered by a healthcare professional, you acknowledge that you have requested the performance of the genetic test at the Laboratory

(Lab). You acknowledge that your submission of a specimen to be tested is voluntary.

2. The purpose of the Test is to look for mutations or genetic characteristics known to be associated with certain genetic diseases, conditions, or pharmaceutical therapies. You acknowledge that you have reviewed information specific to the Test and understand the test's risks, benefits, and limitations.
3. You acknowledge that you have been provided with information about obtaining genetic counseling prior to giving your consent, and you understand that you may seek consultation with a geneticist, genetic counselor, and/or physician after testing.
4. You will be asked to provide a blood, cheek swab, or saliva specimen in accordance with specified collection procedures. You will also be asked to provide certain health and other personal information, such as name, address, DOB, and certain medical history. In order for the Test to be performed as intended, the information provided must be accurate and complete.
5. Your specimen, along with your other personal information, will be sent for analysis to the Lab. DNA will be extracted from the specimen, and certain markers within regions of your genome relevant to the Test will be sequenced and analyzed. Upon successful completion of the Test, the results will be sent to the authorized person. No other tests will be performed using the specimen except as authorized herein or permitted by applicable law.
6. You hereby acknowledge that the Test results may become part of your permanent medical record and understand that some test results may impact your ability to obtain certain insurance benefits. You hereby acknowledge that genetic test results may have implications for your biological family members and unexpected family relationships may be identified through genomic testing.
7. The Test analyzes specific gene regions based on currently available information in the medical literature and scientific databases, as well as Lab informatics and algorithms that may be subject to change. As such, new information may replace or add to the information that was used to analyze your results that may impact the interpretation of results. As with any Lab test, there is a possibility of error. For example, with all medical tests, there is a chance of a false positive or a false negative result. A false positive result means a relevant marker or variant is incorrectly reported as present. A false negative result means that a variant of interest is not identified when it is in fact present and within the reportable range. Other sources of error, while rare, include specimen mix-up, poor specimen quality or contamination, inherent DNA sequence properties, and technical errors in the Lab. In addition, if you have certain rare biological conditions or have had certain bone marrow, kidney, liver or heart transplants, transfusions, or hematologic malignancies, these conditions may limit the accuracy or relevance of the results or prevent the Test from being completed. The Lab expressly disclaims any liability for the inaccuracy of the genetic test results due to such conditions or the failure to provide accurate, correct or complete information, and you hereby waive any claims against the Lab with respect thereto.

8. The Lab will obtain, retain, and use your personal information, specimen, and test information in compliance with applicable law and maintain the confidentiality thereof and protect from unauthorized disclosure or misuse. The lab may de-identify your discarded specimen and information for regulatory compliance purposes, internal quality control, validation studies, or research and development. Any use or disclosure of the specimen and any data will be done in an anonymized manner by either encrypting or removing personally identifiable information in accordance with applicable law.
9. Lab will retain your specimen for the maximum duration permitted under applicable law or regulation. In certain states you have the option of giving Lab permission to store any specimen that remains after testing has been completed.

My signature indicates that:

- I am of legal age to request the test services and consent hereto, or I am the parent, legal guardian, or person having legal authority to act on behalf of the individual who will receive the test services.
- I have read, or had read to you, and understand the above information.
- The decision to consent to, or to refuse, the above testing is voluntary and entirely mine.
- I have had the opportunity to discuss the testing, including the purposes, limitations, and possible risks, with my healthcare provider or genetic counselor of my choice.
- I have all the information I want, and all of my questions have been satisfactorily answered.