Laboratory of Personalized Genomic Medicine
Department of Pathology and Cell Biology

COLUMBIA UNIVERSITY MEDICAL CENTER

630 West 168th Street
P&S 11th Floor, Room 453
New York, NY 10032
Tel: 212-305-9706
Fax: 212-342-0420

Internal Use Only CUMC MRN:_____ Acc #:_____

Informed Consent for APOE Genotyping (Symptomatic) Testing

Please read the following form carefully and discuss with your ordering physician/genetic counselor before signing this consent.

1. This is a genetic (DNA-based) test for genotyping of the APOE gene.

2. The purpose of this analysis is to determine your APOE genotype.

This information may be used by your physician to inform about the risk of adverse reactions to certain medications used to treat Alzheimer's disease (AD). The APOE genotype informs regarding the risk of development of AD in asymptomatic individuals. APOE genotyping is not clinically recommended for asymptomatic individuals but may be considered at your clinician's discretion.[1]

3. You (or the person for whom you are signing) may want genetic counseling before signing for consent.

4. This is a test for genetic susceptibility ("genetic predisposition"), the risk of actually having AD depends upon other genetic factors, and on environmental conditions. If the testing shows that you are at increased risk for AD, you may wish to have further independent testing, consult your physician, or have genetic counseling.

5. APOE genotype is associated with risk for AD. AD is the most common form of dementia; it is characterized by progressive memory loss. Other common features include confusion, poor judgment, language disturbance, visual complaints, agitation, withdrawal, and hallucinations.[2]

6. There are 3 common APOE gene alleles: E2, E3 and E4. The APOE E4 allele is a risk factor for AD, but it is neither necessary nor sufficient to cause AD.[1] A person may have one or two copies of the APOE E4 risk allele. The presence of the E2 allele is associated with decreased risk for AD.[3]

If you have a diagnosis of AD and are found not to carry an APOE E4 risk allele, there may be other genetic factors contributing to your disease.

7. A normal ("negative") test results do not exclude the possibility that you may be at risk, as this test only looks at two variants, while there are other risk factors for AD.

8. The results of this test will become a part of the patient's medical record, and may be made available to individuals/organizations with legal access to the patient's medical record, on a strict "need-to-know" basis, including, but not limited to, the physicians and nursing staff directly involved in the patient's care, the patient's current and future insurance carriers, and others specifically authorized by the patient/authorized representative to gain access to the patient's medical records. Columbia University, NewYork-Presbyterian and Weill Cornell Medicine, and their related entities participate in an Organized Health Care Arrangement (OHCA). This allows us to share health information to carry out treatment, payment and our joint health care operations, including integrated information system management, health information exchange, financial and billing services, insurance services, insurance, quality improvement, and risk management activities. Organizations that will follow this Notice include Columbia University, NewYork-Presbyterian sites, Weill Cornell Medicine and their related entities.

9. I have been given the opportunity to ask questions about the ordered tests and I have been told how I will obtain the test results.

Laboratory of Personalized Genomic Medicine
Department of Pathology and Cell Biology

COLUMBIA UNIVERSITY MEDICAL CENTER

630 West 168th Street
P&S 11th Floor, Room 453
New York, NY 10032
Tel: 212-305-9706
Fax: 212-342-0420

10. No additional test shall be performed on the biological sample and the sample will be destroyed at the end of the testing process or not more than sixty days after the sample was taken, unless a longer period of retention is expressly authorized in the consent or unless consent is given for additional purposes.

11. Medicare/Insurance Carriers may not pay for the test, in which case, the patient/responsible party will be billed for the test.

12. Upon completion of testing, a portion of my specimen may be made anonymous and used for test validation, research or educational purposes. Once the material has been made anonymous, its original source can no longer be identified.

I do not wish to allow my specimen sample to be used for test validation, research or education. Therefore, I am checking this box to indicate that the sample should be used only for the test specified above and should be destroyed after sixty (60) days. ☐

All of the above has been explained to me to my satisfaction, and my signature below attests to the same.

Patient (person being tested):

_____ _____ **Date:** _____

Print Name of Patient/Authorized Representative | Signature of Patient/Authorized Representative

Person obtaining consent:

_____ _____ **Date:** _____

Print Name of Person Obtaining Consent | Signature of Person Obtaining Consent

References:

1. Goldman JS, Hahn SE, Catania JW, LaRusse-Eckert S, Butson MB, Rumbaugh M, Strecker MN, Roberts JS, Burke W, Mayeux R, Bird T; American College of Medical Genetics and the National Society of Genetic Counselors. Genetic counseling and testing for Alzheimer disease: joint practice guidelines of the American College of Medical Genetics and the National Society of Genetic Counselors. Genet Med. 2011 Jun;13(6):597-605. doi: 10.1097/GIM.0b013e31821d69b8. Erratum in: Genet Med. 2011 Aug;13(8):749. PMID: 21577118; PMCID: PMC3326653.

2. Bird TD. Alzheimer Disease Overview. 1998 Oct 23 [Updated 2018 Dec 20]. In: Adam MP, Feldman J, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2024. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1161/

3. Stites SD, Vogt NM, Blacker D, Rumbaugh M, Parker MW; Advisory Group on Risk Evidence Education for Dementia (AGREED). Patients asking about APOE gene test results? Here's what to tell them. J Fam Pract. 2022 May;71(4):E1-E7. doi: 10.12788/jfp.0397. PMID: 35730709; PMCID: PMC10032667.