



Banner Health.

APR-001: Alzheimer's Prevention Registry  
GeneMatch Program  
PI: Jessica Langbaum Ph.D.  
Consent and Authorization

APPROVED  
AS MODIFIED  
Oct 20, 2016  
WIRB®

### Informed Consent and Authorization

**TITLE:** Alzheimer's Prevention Registry GeneMatch Program

**PROTOCOL NO.:** APR-001  
WIRB® Protocol #20151808

**SPONSOR:** Banner Alzheimer's Institute

**PROJECT DIRECTOR:** Jessica Langbaum, PhD  
901 East Willetta Street  
Phoenix, Arizona 85006  
United States

**STUDY-RELATED  
PHONE NUMBER(S):** Jessica Langbaum, PhD  
1-888-STOP-ALZ (24 hours)

Banner Alzheimer's Institute, through the Alzheimer's Prevention Registry, developed the GeneMatch program for adults interested in participating in research studies. Joining the GeneMatch program is voluntary. Please read this consent form carefully before making your decision. If you agree to participate in this project, your information will be securely stored and you may be contacted about future research studies. To print or email yourself a copy of this consent form, see the links on this page. To request a copy be emailed to you, email [GeneMatch@endALZnow.org](mailto:GeneMatch@endALZnow.org). If you have any questions about GeneMatch or the information in this consent form, email [GeneMatch@endALZnow.org](mailto:GeneMatch@endALZnow.org).

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Banner Alzheimer's Institute may receive compensation to cover costs associated with conducting this study.

#### **What is the purpose of GeneMatch?**

Our goal is to identify a large group of people interested in participating in research studies or clinical trials based on their genetic background. GeneMatch will test for a specific gene called APOE. GeneMatch may use your APOE test results to match you to research studies. It is your choice whether or not to pursue these research studies.



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### **What do I have to do to join GeneMatch?**

Participating in GeneMatch will determine which copies of a gene (known as the APOE gene) you have. Every person has two copies of this APOE gene. The APOE gene can occur in slightly different forms, called “alleles”.

After you sign the consent form, you will be given or mailed a genetic sample kit. The kit will contain instructions, a de-identified bar coded cheek swab in a plastic container, laboratory requisition form, and mailing/shipping envelope. GeneMatch will also send you emails about the kit. If you have any questions after you receive the kit, email [GeneMatch@endALZnow.org](mailto:GeneMatch@endALZnow.org).

When you receive the kit, you will be asked to remove the cheek swab from the container, and collect the sample according to the instructions. You should allow the swab to dry for 5 to 10 minutes before placing back in the container. You will be asked to place the closed container along with the completed laboratory requisition form in the pre-addressed and postage paid return envelope and send to the lab within approximately 5 business days of sample collection.

You may also be asked to complete online questionnaires, surveys, or watch informational or educational videos. You may be asked questions about the videos and your answers may be recorded and tracked by GeneMatch.

You will not receive information about the results of your APOE test from GeneMatch. GeneMatch may use your APOE test results to match you to research studies; those studies may or may not require you to learn your APOE test results. When you are matched to a study, the study may ask GeneMatch to share your APOE test results and contact information with them. GeneMatch will only release this information with your permission. It is your choice whether or not to pursue another study. Your interest and response to study information may be recorded and tracked by the GeneMatch.

You will be added to the Alzheimer's Prevention Registry mailing list if you had not joined prior to enrolling in GeneMatch. The Registry sends emails with news and information about Alzheimer's prevention research. You may unsubscribe from the mailing list at any time.

### **What if I no longer want to be part of GeneMatch?**

If you wish to end your participation in this program for any reason, please contact the GeneMatch staff at 1-888-STOP-ALZ or send an email to [GeneMatch@endALZnow.org](mailto:GeneMatch@endALZnow.org).

### **What are the risks of joining GeneMatch and how will you keep my information confidential?**

Your information will be kept private but there is always the risk of loss of privacy. Click here to read our Privacy Statement.



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Participation in GeneMatch involves submitting a cheek swab to test for the APOE gene. The APOE genetic test performed has not been established as a diagnostic tool to predict future development of Alzheimer's disease. You will not receive information about the results of your APOE test from GeneMatch. The results of your APOE test will be kept safe and secure.

Participation in GeneMatch involves sending a cheek swab to a commercial lab and the research procedures require submitting responses via the internet. Due to these requirements, there may be increased confidentiality risks associated with participating in GeneMatch. We take every step possible to ensure the information you provide GeneMatch is kept safe and secure. Data from GeneMatch may be shared with other researchers. All links with your identity will be removed from the data before they are shared. However, absolute confidentiality cannot be guaranteed.

We may present the findings from GeneMatch at meetings or in publications; however, neither your name nor identity will be disclosed in those presentations.

### **Certificate of Confidentiality**

To help us protect your privacy, the study staff has obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

### **Are there any alternatives to participation in this study?**

This is not a treatment study.

### **What are the benefits of GeneMatch?**

There is no direct benefit to you for joining and you will not receive any healthcare services. We hope the knowledge gained will be beneficial to society in improving our understanding of database registries, their role in research studies and clinical trials, and their ability to help enrollment into research studies and clinical trials.



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### **What is the cost of GeneMatch?**

There is no cost to join GeneMatch. You will not be paid for joining GeneMatch.

### **What about compensation and treatment for injury?**

We do not anticipate any injuries as the result of your participation in GeneMatch. This does not waive your rights in the event of negligence. You have all rights to which you are entitled as a research subject.

### **Who can answer my questions?**

If you have any questions, concerns or complaints regarding this program, or if at any time you feel you have experienced a study-related issue, you should contact Jessica Langbaum, Ph.D. at 1-888-STOP-ALZ (24 hours) or send an email to [GeneMatch@endALZnow.org](mailto:GeneMatch@endALZnow.org).

If you have any questions about your rights as a GeneMatch member or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)  
1019 39<sup>th</sup> Avenue SE Suite 120  
Puyallup, Washington 98374-2115  
Telephone: 1-800-562-4789 or 360-252-2500  
E-mail: [Help@wirb.com](mailto:Help@wirb.com)

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the study staff cannot be reached or if you wish to talk to someone other than the study staff.

### **What is the GeneMatch volunteer statement?**

Your participation in GeneMatch is entirely voluntary. You have the right to refuse to participate, refuse to answer specific questions in an interview or on a questionnaire or may refuse to participate or discontinue participation in this program at any time without a penalty, loss of benefits, or jeopardize the medical care you receive at this institution.

## **Authorization to Use Your Health Information for Research Purposes**

### **What is the purpose of this form?**

The federal medical HIPAA Privacy Rule protects your personal health information (PHI). The purpose of this form is to inform you about how your PHI will be used or disclosed (given out) in this research study. In order for the study staff to use and give out your PHI, your written permission, called your "authorization", is needed.



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If you sign this form, you give permission to the study staff to use and/or disclose your PHI as described in this consent form. Please consider the important information in this form prior to making your decision.

If you have any questions or concerns about this authorization you should contact Sue Colvin, Banner Research Regulatory Affairs Program Director, at (602) 839-4583 or sue.colvin@bannerhealth.com. You may also request and will be provided a copy of the Notice of Privacy Practices.

**What PHI will be obtained, used or disclosed?**

The following is a description of your PHI you are authorizing to be used and/or disclosed in connection with this program:

- Demographic Information
- Questionnaires
- Genetic Testing
- Surveys

Information related to this program that identifies you and your PHI will be collected from you. Your demographic information to be disclosed may include, but is not limited to, your name, address, or phone number.

By signing this form you are also giving permission to use and/or disclose PHI related to genetic information (e.g., genetic testing). Your information will only be used and/or disclosed in connection with this program.

**Who will use and/or disclose your PHI?**

The following parties are authorized to use and/or disclose your PHI for the research described in the attached consent form:

- a) Banner Alzheimer's Institute
- b) Banner Health
- c) GeneMatch

**Who may receive your PHI?**

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- a) Banner Alzheimer's Institute and companies working with Banner Alzheimer's Institute on the GeneMatch study who may create and maintain the database, website, and process the genetic samples.
- b) Banner Health
- c) GeneMatch
- d) Locations near you that may have research studies or clinical trials that you may qualify to participate in



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- e) Western Institutional Review Board (WIRB)
- f) U.S. Department of Health and Human Services (HHS); HHS Office for Human Research Protections (OHRP); HHS Office of Research Integrity (ORI); and the U.S. Food and Drug Administration (FDA), or other regulatory agency in the event of an inspection or audit.

Some of these parties are required to sign agreements which include data privacy and confidentiality guidelines consistent with the intent set forth by the HIPAA privacy rule prior to receiving any information. However, your PHI may no longer be protected under the HIPAA privacy rule once it is disclosed by the GeneMatch staff to these other parties.

**What purposes are you authorizing the use and/or disclosure of your PHI?**

- a) To conduct the study described earlier in this document
- b) Oversight, audit and monitoring of the study

**When will my authorization expire?**

There is no expiration date or event for your authorization. Therefore, unless you cancel this authorization (as instructed below) this authorization will continue to be effective.

**Do I have to sign this authorization form?**

You do not have to sign this authorization. However, if you decide not to sign, you will not be able to participate in this program. If you do not sign, it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or benefits.

**What do you need to know if you decide to cancel your authorization?**

After signing the authorization, you may decide to cancel your permission to use your PHI. If you cancel the authorization, you will no longer be able to participate in the GeneMatch program.

Any PHI collected before you cancel the authorization may still be used by the study staff and recipients described above to maintain the integrity or reliability of the research study. The study staff is required by law to report any bad side effect you experience even if you have canceled your authorization.

**How do you cancel your authorization?**

To cancel this authorization you must notify the Project Director or GeneMatch staff in writing at the following address:

Banner Alzheimer's Institute  
901 E. Willetta Street  
Phoenix, AZ 85006  
[GeneMatch@endALZnow.org](mailto:GeneMatch@endALZnow.org)

**Will access to your medical record be limited during the study?**



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To maintain the integrity of this program, you may not have access to any health information developed as part of this program until it is completed.

**What other information do you need to know?**

If you choose to sign this Authorization the disclosure or transfer of your PHI will result in payment/compensation to Banner Health. Additionally, the disclosure or transfer of your PHI by any person or entity identified above will also result in payment/compensation to such person or entity.

You are the study subject who is making a decision whether or not to participate in the research program described above. You have had the opportunity to read this information and ask questions regarding this Consent and Authorization. By signing this document you agree to take part in this study, as set out in this information sheet and consent form and authorize the use and/or disclosure of your PHI. You will receive a copy of this form.

In giving my consent:

- I acknowledge my participation in this research project is voluntary and I may refuse or withdraw from participation at any time without penalty or loss of benefits to which I am otherwise entitled.
- My signature below means I have read this consent form and all of my questions have been answered.
- I understand that I will not lose any of my legal rights as a study subject by signing this consent form.
- I may print and/or save a copy of this consent form.
- By signing below, I agree that I would like to participate in the program and authorize use of my personal health information.

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Printed Name of Study Subject

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Electronic Signature of Study Subject

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Date