



# RESEARCH QUESTIONNAIRE

Consent to Participate in the Alpha-1 Research Registry

## PURPOSE

**We invite you to join the Alpha-1 Research Registry, a program of the Alpha-1 Foundation. The purpose of the research database is to identify a group of people who are interested in receiving information about research studies focused on Alpha-1 Antitrypsin Deficiency and possibly participating in these research studies.**

**Before you do, we want you to know that:**

1. Your participation is entirely voluntary.
2. If you choose to join the research registry now, you may withdraw at any time for any reason.
3. You may receive no benefit from taking part in the research registry. The only benefit that can be reasonably expected, at this time, is that research using information from the research registry may give us knowledge that may help persons with Alpha-1 Antitrypsin (AAT) Deficiency (or Alpha-1) in the future.

## CONFIDENTIALITY

No information about research registry participants will be given to the Alpha-1 Foundation or directly to any researcher(s). Only the contractor managing the database (the Data Management Center, located at the Medical University of South Carolina) and university/Federal auditors required by law can have access to confidential personal information. It will be up to you to choose whether or not to contact any researcher(s) seeking to recruit research volunteers from among participants in the Alpha-1 Research Registry.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, local, civil, criminal, administrative, legislative, or other proceedings. 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. 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. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project if the researchers hear something that would immediately endanger you, your child, or others.

## RISKS AND INCONVENIENCES

### Risks:

The physical risks of participating in this Research Registry are anticipated to be minimal. All that is required is the time to fill out this survey. The risks that require more serious consideration relate to keeping your name in a database connected to your personal health information.

Although every reasonable effort will be made to keep your information confidential, there can be no guarantees that errors in protecting this information will not be made. If it became known that you have Alpha-1-Antitrypsin (AAT) Deficiency, there may be risks to you related to your employment, or health or life insurance. Insurers have been known to cancel insurance policies of persons who they found out had a genetic disorder.

### Inconveniences:

The burdens associated with participation in the Research Registry are:

1. Being contacted by the Alpha-1 Research Registry about your willingness to participate in research projects approved by the Medical And Scientific Advisory Committee of the Alpha-1 Foundation.
2. Being sent additional survey questionnaires and follow-up surveys on a continuing basis.

## HIPAA AUTHORIZATION HR #9059

HIPAA is a federal law that requires the protection of health information that can identify you. Protected Health Information includes information that pertains to your past, present or future physical and mental health conditions or the provision of health care. You have to authorize the use of this information for any purpose.

As you know, you are sharing this Protected Health Information to participate in the activities of the Alpha-1 Research Registry as described to you in the application. The information you share on the Registry questionnaire and when you update the questionnaire is the Protected Health Information the Registry staff will use. The health information you have shared will not be disclosed to any one other than Dr. Charlie Strange and the Registry staff; they agree to protect your health information by using it only as permitted by you and as directed by state and federal law. Federal law does require that the MUSC Institutional Review Board and the federal Office of Human Research Protection be given access to any research data as required to protect research participants.

If you do not wish to authorize the use of your Protected Health Information, you will not be able to continue to participate in the Alpha-1 Research Registry. If you authorize the use of your Protected Health Information, you can change your mind at a later time. Protected Health Information that has already been used cannot be withdrawn. If you want

to withdraw your authorization, you must do so in writing to the investigator at the following address:

Dr. Charlie Strange  
Medical University of South Carolina  
Division of Pulmonary, Critical Care, Allergy & Sleep Medicine  
96 Jonathan Lucas St., Ste. 812-CSB  
MSC 630  
Charleston, SC 29425-6300

When you sign the consent to be a member of the Registry, you are also authorizing Dr. Charlie Strange and the registry staff to use the information you have shared for the purposes of the Registry. There is no expiration date for this authorization. You may copy the information on this form and all forms you complete for the registry.

If you have questions or concerns about your privacy rights, you should contact MUSC's Privacy Officer at 1-843-792-0021. MUSC's Privacy Notice can be found at <http://research.musc.edu/hipaa/final%20Notice.PDF>

If you have any questions about your rights as a participant in the Alpha-1 Research Registry, contact the Institutional Review Board for Human Research, Medical University of South Carolina at 1-843-792-4148. If you have questions related to harm suffered as a result of your participation, contact Dr. Charlie Strange at 1-843-792-0260.

## CONSENT

**By my signature below, I agree to participate in the Alpha-1 Research Registry.**

Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Signature of Legal Guardian: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

(If Participant is under 18 yrs of age)

**Minor Participation:** Minors enrolled in the Research Registry must reenroll upon turning 18 years of age by filling out a new questionnaire and signing the consent form. Minors who choose not to renew their membership upon turning eighteen will no longer be enrolled in the Research Registry.

**Please mail when completed to:**

ALPHA-1 RESEARCH REGISTRY  
c/o Medical University of South Carolina  
Division of Pulmonary, Critical Care, Allergy & Sleep Medicine  
96 Jonathan Lucas St., Ste. 812-CSB  
MSC 630  
Charleston, SC 29425-6300

**For further information:**

Toll Free Phone: 1-877-886-2383  
Regular Phone: 1-843-792-0260  
Fax: 1-843-792-0297  
Email: alphaone@musc.edu

## PATIENT INFORMATION

**Patient name and address:**

Name: Last \_\_\_\_\_ First \_\_\_\_\_ MI \_\_\_\_\_

Address: Street \_\_\_\_\_ Apt.# \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_ Country \_\_\_\_\_

Social Security Number: \_\_\_\_\_

Phone: Area Code ( ) \_\_\_\_\_

**Do you currently have a physician who cares for your AAT Deficiency?**  Yes  No

**Who is your current physician?**

Name: Last \_\_\_\_\_ First \_\_\_\_\_ MI \_\_\_\_\_

Address: Street \_\_\_\_\_ Suite # \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_ Country \_\_\_\_\_

Phone: Area Code ( ) \_\_\_\_\_

## DEMOGRAPHICS

1. What is your date of birth? Month \_\_\_\_\_ Day \_\_\_\_\_ Year \_\_\_\_\_

2. What is your gender?  Male  Female

3. Race/Ethnicity (check all that apply)  African American  Asian  Native American/American Indian  
 Hispanic  Caucasian/White  Other

4. Are you currently employed?  Yes  No

5. Please identify your smoking behavior:  Nonsmoker (Less than 100 cigarettes in whole life)  
 Ex-Smoker  Smoker

## DEMOGRAPHICS (continued)

At what age did you start smoking?

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At what age did you stop smoking?

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Ex-Smoker: How many cigarettes did you smoke per day?

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Current use: How many cigarettes do you smoke per day?

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6. Please identify your alcohol use:  No alcohol - or -  Ex-alcohol consumer  
 Current consumer
- 

At what age did you start drinking?

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At what age did you stop drinking?

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Current use:  (occasional)  (1-3 drinks/wk.)  
 (4-15 drinks/wk.)  (16+ drinks/wk.)

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## ALPHA-1 DIAGNOSTIC INFORMATION

7. Have you been diagnosed with AAT Deficiency (includes all phenotypes)?  Yes  No
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8. What is your phenotype?  ZZ  MZ  SZ  
 Don't know or unsure  Other: (Please Specify)
- 

9. What was your most recent alpha-1 antitrypsin level? (µM) - or - (mg/dl)  I don't know
- 

10. How old were you when you were diagnosed with AAT Deficiency or your phenotype was identified?
- 

11. Have you ever had pulmonary function (breathing) tests?  Yes  No  I don't know

If yes, date of most recent FEV1: Month Day Year  I don't know

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12. What was your percent predicted FEV1?  Less than 30%  30-50%  50-80%  
 More than 80% - or -  I don't know

What was your last FEV1 in liters? - or -  I don't know

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13. Do you currently have elevated liver function or elevated liver enzyme levels?
- 

14. Please mark any of the following diseases/conditions that you have been diagnosed with:  Chronic liver disease  
 Chronic lung disease  Emphysema  Jaundice  Cirrhosis  
 Bronchitis  Asthma  Hepatitis  Panniculitis
- 

## TREATMENT

15. Are you currently receiving AAT replacement therapy?

I have never received AAT replacement.  I am currently receiving AAT replacement.  
 I am NOT currently receiving AAT replacement, but I did in the past.

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16. Have you ever had a liver transplant?  Yes  No
- 

17. Have you ever had a lung transplant?  Yes  No
- 

18. Have you ever had a lung volume reduction?  Yes  No
-

## PREVIOUS REGISTRY ENROLLMENT AND FUTURE SURVEYS

19. Did you participate in the National Institutes of Health, National Heart Lung and Blood Institute (NIH-NHLBI) Alpha-1 Registry in the period from 1989-1995?  Yes  No

20. Do you own a computer?  Yes  No

21. Would you be interested in responding to future surveys over the Internet?  Yes  No

22. If you answered "yes" to the previous question, what is your email address?

## FINAL CHECK

I have signed and dated the consent form on the front of the application.

I have filled the application out in full to the best of my knowledge.

If you have family members who have AAT Deficiency or the carrier phenotype and would like to join the Research Registry please encourage them to contact the Alpha-1 Research Registry at our toll free number, 1-877-886-2383, or by email at [alphaone@muscc.edu](mailto:alphaone@muscc.edu). We will be happy to assist them.

## FAMILY LINKAGE APPLICATION

In addition to your personal enrollment, you are invited to participate in the Registry as a family. Family members are invited to enroll if they carry the gene for AAT deficiency or have the disorder. To place a family member's name in the space below, you must discuss registry enrollment with that person and obtain their permission to be contacted by the Registry through the mail. Further information on Family Linkage is provided in the brochure "Family Linkage in the Alpha-1 Research Registry."

**I have contacted these family members who agree to participate in the Registry as a family:**

**My signature:** \_\_\_\_\_

My Name: First \_\_\_\_\_ Last \_\_\_\_\_

Address: Street \_\_\_\_\_ Apt.# \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Phone: Area Code ( ) \_\_\_\_\_

Current Registry Participant?  Yes  No

## RELATIVES

1. First Name \_\_\_\_\_ Last \_\_\_\_\_

Street \_\_\_\_\_ Apt.# \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Phone: Area Code ( ) \_\_\_\_\_

Relation: \_\_\_\_\_ Current Registry Participant?  Yes  No

2. First Name \_\_\_\_\_ Last \_\_\_\_\_

Street \_\_\_\_\_ Apt.# \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Phone: Area Code ( ) \_\_\_\_\_

Relation: \_\_\_\_\_ Current Registry Participant?  Yes  No

Other relatives can be listed on additional pages as needed.