ALPHA-1 FOUNDATION

Research Registry Questionnaire

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. This 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 error in protecting this information will not be made. If it became known that you have Alpha-1 Antitrypsin 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.

HIPPA 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 anyone 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 and Sleep Medicine
96 Jonathan Lucas St., Suite 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://www.muschealth.com/siteinfo_footer/privacy/NPP%20English%209%202013.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 re-enroll 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 18 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 and Sleep Medicine
96 Jonathan Lucas St CSB 812 MSC 630
Charleston, SC 29425

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
Website: www.alphaoneregistry.org

PATIENT INFORMATION

Name: Last First MI

Address: Street Apt.#

City State Zip Country

Email: Phone: Area Code ( )

Soc. Sec. #

Have you visited a Clinical Resource Center? **Yes** ☐ **No** ☐

CRC:

Doctor's Name:

DEMOGRAPHICS

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

2. What is your gender? ☐ Male ☐ Female

3. What is your race? ☐ White ☐ African American ☐ American Indian/Alaska Native ☐ More than one race
☐ Hispanic ☐ Asian ☐ Native Hawaiian ☐ Other

4. Are you currently employed? ☐ Yes ☐ No ☐ Retired

5. Please identify your smoking behavior: ☐ Non-smoker (Less than 100 cigarettes in whole life -or- ☐ Ex-smoker ☐ Smoker

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

At what age did you start smoking? _____

At what age did you stop smoking? _____

Current Smoker: At what age did you start smoking? _____

How many cigarettes did you smoke per day? _____

DEMOGRAPHICS continued

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

   At what age did you start drinking? _____

   At what age did you stop drinking? _____

   Current use: ☐ Occasional (<1 drink/wk) ☐ (1-3 drinks/wk) ☐ (4-15 drinks/wk) ☐ (16+ drinks/wk)

ALPHA 1 DIAGNOSTIC INFORMATION

7. Have you been diagnosed with AAT deficiency? ☐ Yes ☐ No

8. What is your phenotype? ☐ MZ ☐ ZZ ☐ SZ

   ☐ Unknown ☐ 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? _____

11. Have you ever had pulmonary function (breathing) tests? ☐ Yes ☐ No

    ☐ I don't know If yes, date of most recent FEV1: (Month, Date, Year) _____

12. What was your percent predicted FEV1? ☐ Less than 30% ☐ 30-50% ☐ 50-80%

    ☐ More than 80% ☐ I don't know

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

    ☐ Yes ☐ No ☐ I don't know

14. Do you now or have you ever had any lung or liver symptoms from your Alpha-1?

    ☐ Liver Symptoms ☐ Lung Symptoms ☐ No Symptoms

15. Are you currently prescribed oxygen for your Alpha-1?

    ☐ Yes ☐ No

16. Please mark any of the following diseases/conditions that you have been diagnosed with:

    ☐ Chronic Obstructive Pulmonary Disease (COPD) ☐ Bronchitis ☐ Asthma
    ☐ Emphysema ☐ Jaundice ☐ Hepatitis
    ☐ Chronic Liver Disease ☐ Cirrhosis ☐ Panniculitis

TREATMENT

17. Are you currently receiving AAT replacement therapy:

    ☐ I have never received therapy
    ☐ I am currently receiving therapy
    ☐ I am NOT currently receiving therapy, but I did in the past

18. Have you ever had a liver transplant?

    ☐ Yes ☐ No

19. Have you ever had a lung transplant?

    ☐ Yes ☐ No

20. Have you ever had a lung volume reduction?

    ☐ Yes ☐ No

Please confirm you have signed and dated the consent form located at the top of page 2 of this application.