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Month Day Year

COPD Foundation

Research Registry

Please read the Registry description below and be sure to sign the bottom of page 4.

Study title:	COPD Foundation Research Registry
Principal Investigator:	James Crapo, MD
Phone number:	1-866-915-COPD (2673)
Sponsor:	COPD Foundation
HS#:	2357

What is the COPD Foundation Research Registry?
The COPD Foundation Research Registry is considered a research study . The development of this COPD Foundation Research Registry in conjunction with the COPD Foundation will help study this common and disabling disease. The aims of the study are as follows:

1) Create and maintain a registry of up to 50,000 people with COPD or who are at risk for developing COPD that are willing to be contacted to ascertain their interest in participating in clinical research.
2) Use the Registry as a source of possible subjects for the COPDGene® Study.
3) Use the Registry as a source of possible subjects for future clinical research studies that require people with COPD or people who are at risk for developing COPD.
4) Use the Registry to determine demographic data and clinical characteristics of a broad cross section of people with COPD or at risk for developing COPD.

Participation in the COPD Foundation Research Registry will not limit treatment options available to you. Participation in the Registry is voluntary and the alternative of not participating is always an available option. There are no investigational facets to the Registry and nothing about participation is experimental. Participation in the COPD Foundation Research Registry does not involve treatment of COPD using traditional or alternative treatments. Refusal to participate in the COPD Foundation Research Registry will involve no penalty or loss of benefits to which a participant would otherwise be entitled. Participants may stop participation at any time without penalty or loss of benefits to which a participant would otherwise be entitled.

How can I help promote research?
While it is estimated that 600 million individuals worldwide have COPD, there is no resource to locate these individuals for clinical research. The COPD Research Registry is intended to serve as a resource for researchers studying COPD.

Completion of the questionnaire provides valuable information about the number of patients diagnosed with COPD and their clinical symptoms. Also, the ability to contact a large number of COPD patients for their interest in clinical research studies will speed up the process of finding suitable research subjects for COPD research.

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Who is eligible to enroll?
Individuals over the age of 18 who have COPD or may be considered to be at increased risk for development of COPD are encouraged to enroll in the COPD Research Registry.

How do I participate?
To participate in the Registry, individuals are asked to complete the attached questionnaire. Questionnaires must be signed and dated in order for forms submitted through the mail to be accepted. For questionnaires submitted through the website, your name must be typed in the signature box with a signature date for the form to be accepted. If you do not offer your consent by signing and dating this form, you will not be enrolled in the Registry.You are not required to complete all questions. However, if missing or conflicting data is found on the questionnaire, you may receive a telephone call, an e-mail, or a mailed contact attempting to correct the information.

What are the risks and discomforts involved in participating in the Registry?
Enrollment in the Registry requires the completion of a series of questions concerning health history with a focus on lung health and COPD status. There is a potential risk that some questions may make you feel uncomfortable. At the COPD Registry your health and personal information privacy are of utmost importance to us. Though we maintain a highly secure database and strictly limit the number of individuals who have access to this information, there remains a small risk of inadvertent information disclosure. Should this occur, it is not expected that social or economic consequences will result with regards to a potential loss of health coverage or an increase in healthcare costs.

What happens after I enroll?
Once you are enrolled in the Registry, the COPD Foundation Registry will keep your information in a database.

Researchers interested in using the Registry must make a request to the COPD Foundation Registry Oversight Committee. The researchers must show a certificate of approval from an institutional review board (a group that approves research methods that are safe and humane). The committee will review the application and approve or decline the researchers' request to use the Registry. If the application is approved, the type of information requested will then determine the next step.

If the request concerns basic information about the patients enrolled in the Registry, the information will be provided from the Registry database. Contact information or other identifying information will not be provided to researchers.

If the request concerns contacting people for participation in a research study, the COPD Foundation Research Registry Coordinating Center will search the database for participants who closely match the criteria of the researcher. The COPD Foundation Research Registry will then send out invitation letters explaining the basics of the project, along with contact information for the researcher(s).

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If a Registry participant is interested in the research study, it is the responsibility of the participant to contact the researcher directly. Contact information will not be provided to researchers by the COPD Foundation Research Registry.

Participant information will be stored in the database for twenty years unless you request that it be removed. You may be contacted about research studies during that time.

How confidential is this database?
Your completed survey will go directly to the Registry Coordinating Center at National Jewish Health in Denver, Colorado. NJH strictly adheres to established confidentiality procedures that are intended to protect the identity of those who participate. The database is password-protected and secure and all hard copies of personal information are kept under lock and key. Only the Principal Investigator, Registry staff and the Registry Coordinating Center have access to a participant's personal information. Institutional regulatory oversight for the COPD Foundation Research Registry is provided by the National Jewish Institutional Review Board (IRB). As part of the responsibilty to ensure that clinical studies are carried out in accordance with internationally agreed standards, representatives of government agencies such as the Food and Drug Administration, or the IRB may inspect research records. Medical information will be kept as confidential as possible in accordance with local, state and federal law.

Efforts will be made to keep your information confidential. Persons who receive a participant's health information may not be required by Federal privacy laws to protect it and may share the information with others without the participant's permission, if permitted by laws governing them. Your personal and medical information may be disclosed if required by law. Organizations that may inspect and/or copy your research and medical records for quality assurance and data analysis include, but are not necessarily limited to:

- The National Institutes of Health or other government agencies
- The Food and Drug Administration
- Department of Health and Human Services
- The National Jewish Health Institutional Review Board

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

If you have concerns about research subject rights, please contact the Institutional Review Board (IRB) for National Jewish Health at:

Institutional Review Board
National Jewish Health
1400 Jackson Street, Room M211
Denver, CO 80206
303-398-1477

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What if I no longer want to participate in the Registry?
If you choose to discontinue participation, the Registry will remove your information from the database and you will not be contacted about future clinical studies. However, if you have consented to participate in a particular study and wish to withdraw, it is your responsibility to contact the study investigator to have your data removed. The Registry and its personnel are not responsible for the discontinuation of data collected by a Registry-affiliated study. The Registry will be able to aid you in discontinuing participation in affiliated studies by providing contact information to the investigators, whom you may contact in order to discontinue participation.

A common exception applies in cases where consent is withdrawn and participation is discontinued. If an investigator has already "acted on the authorization," meaning that data has been analyzed, presented or published, it is no longer possible to remove a participant's individual data.

If you have questions or would like to withdraw from the COPD Foundation Registry, please contact the COPD Foundation or the Principal Investigator. All requests to discontinue participation must be submitted in writing.

COPD Foundation
2937 SW 27th Avenue, Suite 302
Miami, FL 33133
1-866-316-COPD (2673)

James Crapo, MD
1400 Jackson Street, Room K701c
Denver, CO 80206
1-866-915-COPD (2673)

Authorization

By signing or typing your name and the date in the space provided you give authorization to the COPD Foundation Research Registry to use your information until the end of the research study or for up to twenty years, whichever comes first. You acknowledge that you were provided with the opportunity to ask questions of the COPD Foundation or Dr. Crapo. You also acknowledge that the Principal Investigator, his/her staff, the COPD Foundation and/or regulatory agencies may access your information after the study is complete to review data, as necessary. If you do not enter your name and date in the space provided on the questionnaire, your questionnaire will not be accepted into the system and you will not be an enrolled participant in the COPD Foundation Research Registry.

Please print and retain a copy of this form for your records.

Sign ☐ *Date* ☐

Questionnaires must be signed and dated in order for forms submitted through the mail or website to be accepted.

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Today's Date ☐☐ / ☐☐ / ☐☐☐☐
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Contact Information

Name First Name ☐☐☐☐☐☐☐☐☐ M.I. ☐ Last Name ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Address Street ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

City ☐☐☐☐☐☐☐☐☐☐☐☐☐☐ State ☐☐ Zip ☐☐☐☐☐

Phone Daytime (☐☐☐) ☐☐☐ - ☐☐☐☐ Evenings (☐☐☐) ☐☐☐ - ☐☐☐☐

Email ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Are you willing to participate in a study for people who have COPD or are at risk of developing COPD?

○ Yes ○ No

If **Yes**, are you willing to have someone from the *COPD Foundation* or *National Jewish Health* contact you so you can learn about how to participate in a study?

○ Yes ○ No

If **Yes**, how far are you willing to travel (only 1 trip needed) to participate in this study?

○ 20 miles ○ 100 miles ○ whatever distance is necessary

The questions on the following pages will help us identify your characterisitcs as a possible candidate for a study.

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Your initials ☐☐☐ Zip Code ☐☐☐☐☐

Today's Date ☐☐ / ☐☐ / ☐☐☐☐ (Month / Day / Year)

COPD

1. Do you have COPD?

   ○ Yes ○ No

   If **Yes**, answer the following:

   a. Who made this diagnosis? (check all that apply)

   ○ Family doctor ○ Specialist ○ Self ○ Family or friend

   b. In what year were you first diagnosed with COPD? ☐☐☐☐

2. Have you had any of the following studies? (check all that apply)

   ○ Lung function (PFT) or spirometry
   ○ Chest x-ray
   ○ Chest CT
   ○ Alpha-1 antitrypsin blood test

   a. Do you know the results of your alpha-1 antitrypsin test?

   ○ Normal ○ Abnormal ○ Don't know

   b. If you know your alpha-1 antitrypsin type, which is it?

   ○ MM ○ MS ○ SS ○ MZ ○ SZ ○ ZZ ○ other

3. If you know your percent predicted FEV1, enter the value: ☐☐☐ %

Lung Symptoms

1. For the last two years, have you had a cough for at least three months per year?

   ○ Yes ○ No

2. For the last two years, have you brought up phlegm from your chest at least three months per year?

   ○ Yes ○ No

3. Does your chest ever sound like it is wheezing or whistling?

   a. With a cold ○ Yes ○ No
   b. Apart from colds ○ Yes ○ No
   c. Most days ○ Yes ○ No

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Breathlessness

1. At the present time, are you limited in your activities because of breathing problems?
   ○ Yes ○ No
2. If you are limited, how much are you limited?
   ○ 100% ○ 75% ○ 50% ○ 25%
3. Do you have to stop for breath after you walk a few minutes on level ground (about 100 yards)?
   ○ Yes ○ No

Smoking History

1. Have you smoked at least 100 cigarettes (5 packs) in your entire life?
   ○ Yes ○ No ○ Uncertain
2. If you smoked, how old were you when you started smoking? ☐☐ years old
3. If you have quit smoking, how old were you when you quit smoking? ☐☐ years old
4. How many years did you smoke or have you smoked cigarettes? ☐☐ years
5. On average, how many cigarettes do you/ did you smoke per day?

Currently	*In the past*
○ 0 - quit	--
○ 1-5 cig/day	○ 1-5 cig/day
○ 6-10 cig/day	○ 6-10 cig/day
○ 11-20 cig/day	○ 11-20 cig/day
○ 1 pack/day	○ 1 pack/day
○ 1.5 packs/day	○ 1.5 packs/day
○ 2 packs/day	○ 2 packs/day
○ 3+ packs/day	○ 3+ packs/day

6. During the last year, have you stopped smoking for at least one day because you wanted to quit smoking?
   ○ Yes ○ No

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Medication

1. Have you used medications to treat your breathing problems?

○ Yes ○ No ○ Uncertain

If **Yes**, mark all that apply.

Currently	*In the past*	
		Corticosteroids
○	○	Aerobid / flunisolide
○	○	Azmacort / triamcinolone
○	○	Flovent / fluticasone
○	○	Prednisone, Medrol / methylprednisolone
○	○	Pulmicort Turbohaler / budesonide
○	○	Qvar, Vanceril / beclomethasone
		Inhaled anticholinergics
○	○	Atrovent / ipratopium
○	○	Spiriva / tiotropium
		Inhaled beta-agonists
○	○	Foradil / formoterol
○	○	Serevent / salmeterol
○	○	Ventolin, Proventil / albuterol
		Combination inhalers
○	○	Advair / salmeterol and fluticasone
○	○	Combivent / albuterol and ipratropium
		Other
○	○	Theo-Dur, Theolair-24, Uni-Dur, Uniphyl / theophylline
○	○	Singulair / montelukast
○	○	Mucomyst / N-acetyl-cysteine
○	○	guaifenesin / expectorant / cough syrup

2. Do you use oxygen at home?

○ Yes, daytime and nighttime ○ Yes, only at night ○ No

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Today's Date ☐☐ / ☐☐ / ☐☐☐☐

Respiratory History

1. What respiratory illnesses or diseases have you had? (Answer all that apply.)

	Age at onset		*Age at onset*		*Age at onset*
○ Asthma	☐☐	○ Bronchitis	☐☐	○ Pneumonia	☐☐
○ Bronchiectasis	☐☐	○ Emphysema	☐☐	○ Other lung disease	☐☐

2. Have you taken part in a formal pulmonary rehabilitation program?

○ Yes ○ No ○ Uncertain

Family History

1. How many siblings did you grow up with? ☐☐
2. How many children do you have? ☐☐
3. Do any of your family members have the following problems?

	Yes	*No*	*Uncertain*		*Father*	*Mother*	*Any Sibling*	*Any Child*
Smoking	○	○	○	If **Yes**, who?	○	○	○	○
COPD	○	○	○	If **Yes**, who?	○	○	○	○
Emphysema	○	○	○	If **Yes**, who?	○	○	○	○
Chronic bronchitis	○	○	○	If **Yes**, who?	○	○	○	○
Alpha-1 antitrypsin deficiency	○	○	○	If **Yes**, who?	○	○	○	○

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Exacerbations

1. Over the last year, how many times have you had breathing problems that required:

	None	*1*	*2*	*3*	*4+*
a. Antibiotics	○	○	○	○	○
b. Prednisone	○	○	○	○	○
c. Visit to a physician	○	○	○	○	○
d. Visit to an emergency room	○	○	○	○	○
e. Hospitalization	○	○	○	○	○
f. Intensive care unit	○	○	○	○	○

General

1. *Gender* ○ Male ○ Female
2. *Age* ☐☐ years
3. *Race (check all that apply)*
   - ○ White
   - ○ Black or African American
   - ○ Asian
   - ○ American Indian / Alaska Native
   - ○ Native Hawaiian / Pacific Islander
   - ○ More than one race
   - ○ Unknown or not reported
4. *Ethnicity (check only one)*
   - ○ Hispanic or Latino
   - ○ Not Hispanic or Latino
   - ○ Unknown
   - ○ Refused

Referrals

1. Do you know any smokers who have little or no lung disease who might be willing to participate in this study?

   ○ Yes ○ No

2. Would you be willing to ask them to fill out our questionnaire?

   ○ Yes ○ No