IRB Use Only
Approval Date: October 31, 2023
Expiration Date: October 31, 2024

ALLERGY & ASTHMA RESEARCH REGISTRY

Date and Time of Consent: ___/___/_____ Time_____

By clicking this checkbox, you confirm that you are 18 years of age or older: ☐

☐ I am an adult participant.

Print your name here:

_____

☐ I am the parent or guardian granting permission for a child participant (the use of "you" refers to "your child" or "your ward.")

Print child's name here:

_____

What is your relationship to the participant?

☐ Mother ☐ Father ☐ Legal Guardian ☐ Conservator

Note: The use of "you" may also refer to "your child" or "your ward."

DESCRIPTION: You or your child/ward are invited to become part of our registry and participate in research at the Sean N. Parker Center for Allergy and Asthma Research at Stanford University, looking at how allergies and asthma affect the immune system and why the prevalence of these conditions is on the rise. The researchers are collecting information about persons with asthma and/or allergies, as well as healthy participants because this information provides the researchers with a comprehensive picture of the trends and causes of allergies, asthma, and other immunologic disorders. If you would like to participate in a clinical trial,

please understand that while the information you provide may be used in the future to assess your eligibility for one of our research trials, responding to a questionnaire does not guarantee your enrollment into one of our studies. The Sean N. Parker Center for Allergy and Asthma Research and the National Institutes of Health (NIH) are providing financial support for this study.

You will be asked to answer a series of questions about your demographics, contact information, and medical history. We may also ask you follow-up questions about your dietary and lifestyle habits, environmental exposures, your family allergy history, and other details, based on the answer you give in the initial questionnaire. If you previously participated in a study at our Center, we may additionally follow-up with you to ask about your long-term dosing patterns, quality of life, and other questions. By agreeing to this consent form, you are giving us permission to add you to our registry and collect and use your information in our research.

RISKS AND BENEFITS: The risks associated with completing the questionnaire(s) are very small. All information you provide will be kept confidential and we will use safety measures to protect your privacy. However, despite our best efforts, there is a small risk that people outside of the research team could still learn this information. The information will be password-protected and available with limited access to qualified research staff. We cannot and do not guarantee or promise that you will receive any benefits from this study. There are no benefits to you for completing the questionnaire(s).

TIME INVOLVEMENT: You will be asked to complete 5-20 questionnaires. Each questionnaire will take approximately 5-10 minutes to complete.

PAYMENTS: You will not receive payment for your participation.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in our research, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue

participation at any time without penalty or loss of benefits to which you are otherwise entitled. The alternative is to not participate. You have the right to refuse to answer particular questions. Your individual privacy will be maintained in all published and written data resulting from the study. The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed. We may continue to store and use your information for the duration of the registry. If you are consenting to your child/ward, when they turn 18, they will be given the option to consent for themselves as adults to continue participation. We will use the information stored in the database for studies approved by the Institutional Review Board (IRB). The IRB is a group that independently reviews and watches over research studies involving people.

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.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

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The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH which is funding this project 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Authorization to Use Your Health Information for Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your authorization. If you agree to this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully.

What is the purpose of this research study and how will my health information be utilized in the study?

Researchers at the Sean N. Parker Center for Allergy and Asthma Research at Stanford University are looking at how allergies and asthma affect the immune system and why both conditions are on the rise. The researchers are collecting information about persons with allergies and/or asthma, as well as healthy participants because this information provides the researchers with a comprehensive picture about the trends and causes of allergies, asthma, and other immunologic disorders.

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Do I have to agree to this authorization form?

You do not have to agree to this authorization form. But if you do not, you will not be able to participate in this research study.

If I agree, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

• Dr. Sharon Chinthrajah, 750 Welch Road, Suite 114, Palo Alto, CA 94304.

What Personal Information Will Be Used or Disclosed?

Information that you provide in your responses to the research registry questionnaires, including your demographics, contact information, and medical history.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

• The Protocol Director
• The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
• Research Staff

Who May Receive or Use the Information?

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:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The National Institutes of Health (NIH)
- Research collaborators outside of Stanford (if information is shared with researchers outside of Stanford, your name and other identifying information will not be disclosed).

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31, 2100 or when the research registry ends, whichever is earlier.

CONTACT INFORMATION:

Questions, Concerns, or Complaints: If you have any questions, concerns, or complaints about this research, its procedures, or risks and benefits, contact the Protocol Director, Dr. Sharon Chinthrajah at (650) 521-7237. You should also contact her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford IRB to speak to someone independent of the research team at (650) 723-5244 or toll free at (866) 680-2906. You can also write to the

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Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Please print a copy of this page for your records.

If you have read the full consent and agree to the terms, please select "Yes, I agree to participate" to be taken to the Contact Information and questionnaire form.

☐ **Yes,** I agree (or I agree for my child/ward) to participate, and would like to become part of the registry and fill out the requested information

☐ **No,** I do not wish (or do not wish for my child/ward) to participate and I do not want to be added to the registry and/or research