



Are you interested in getting vaccinated against COVID-19?

We are looking for volunteers for a COVID-19 vaccine research study.

The Systemic Allergic Reactions to SARS-CoV-2 Vaccination study is recruiting volunteers to receive one of the two mRNA vaccines - Pfizer BioNTech COVID-19 Vaccine or Moderna COVID-19 Vaccine. These are the same vaccines that have received emergency use authorization by the FDA and are being used at public vaccination sites.

You may qualify if you are 12*-69 years of age and:

- You have a history of Severe Allergies, **OR**
- You have been diagnosed with a Mast Cell Disorder, **OR**
- You have a history of No Severe Allergies.

***If you are the parent or legal guardian of a 12-17 year old who may qualify, your permission and the permission of your child will be needed. When “you” appears in this form, it refers to your child except where it says otherwise.**

We are doing this trial because some people (about 2 to 10 out of every million people vaccinated) have had severe allergic reactions to these vaccines. This reaction is called anaphylaxis.



1. How do I know I have severe allergies?

If you needed an injection of epinephrine because you ate a food you were allergic to or were stung by a bee, you may have severe allergies. Or, you may have severe allergies if you had an allergic reaction within minutes after taking a medication.

2. How do I know if I have a Mast Cell Disorder?

You may have been diagnosed with a mast cell disorder by a doctor, if you have more of a certain type of cell than is normal. Symptoms of this kind of disease include flushing, itching, diarrhea, and severe reactions that look like anaphylaxis.

3. Am I a person with no allergies?

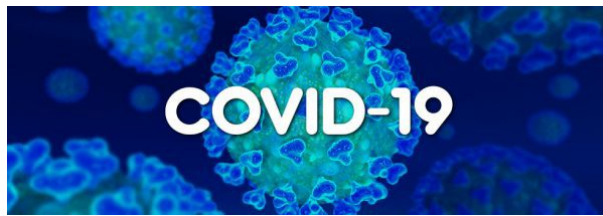
If you do not have hay fever, chronic hives, or you have no current history (within the past 10 years) of asthma or eczema, you likely have no allergies. To be in this group, you also cannot have a mast cell disorder.

4. Can I volunteer if I am currently pregnant?

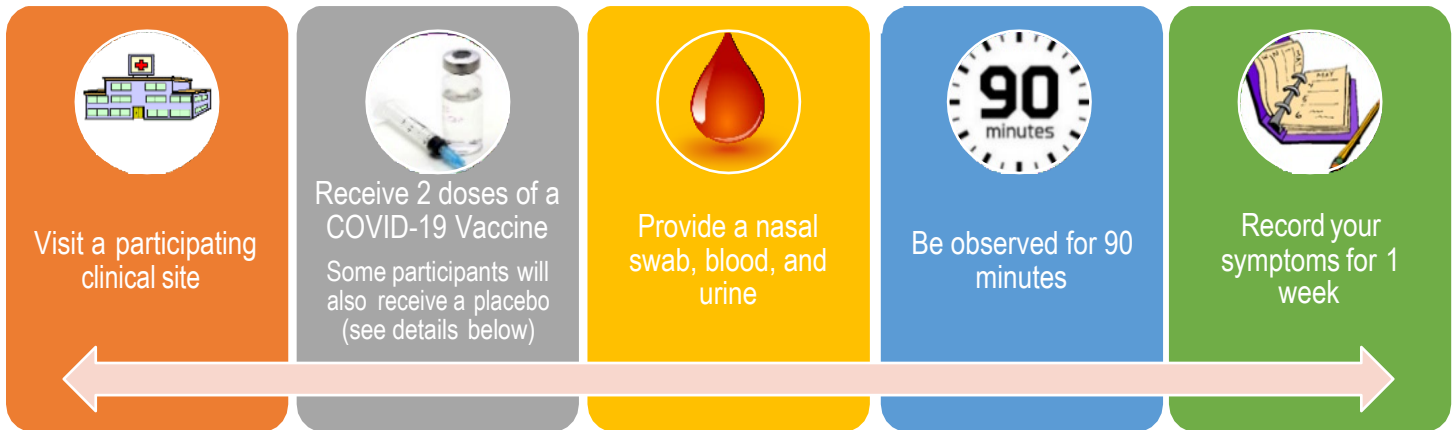
If you are currently pregnant or are planning to get pregnant soon, you cannot volunteer for this study.

5. Is there any benefit if I volunteer?

You will receive either the Moderna or Pfizer-BioNTech COVID-19 vaccine. Both vaccines are expected to be protective against COVID-19 infection. However, the vaccines may not protect everyone who receives them.



If you volunteer to participate and qualify for this study, you will:



These vaccines are administered in two doses. You, accompanied by your parent or legal guardian, if applicable, will need to visit the clinical site twice, to receive both doses. Before each dose is given, you will have a nasal swab collected for COVID-19 testing. You will also be asked to provide blood and urine samples before and after you receive each vaccine dose. We will watch you for 90 minutes after each dose, to see if you have an allergic reaction. If you have a reaction, the study doctors are trained to recognize and treat your reaction. Even if you do not have allergies, you have to stay the whole 90 minutes.

After each dose, you will also be asked to track your symptoms for 1 week. You can use a website to track your symptoms or the paper form we give you. Someone from the study team will also call you to see how you're doing.

One out of every 3 participants will receive a placebo (salt water) injection before they receive the first vaccine dose. You will not get to choose if you receive the placebo dose, or which vaccine you get. If you receive placebo first, you will still receive two doses of vaccine, per FDA guidelines. You will need to visit the clinical site a total of three times, if you receive placebo first.

After you receive your vaccination you may experience:

- Pain at the injection site
- Fatigue
- Headache
- Muscle pain
- Chills
- Joint pain
- Fever
- Redness or swelling at the injection site
- Axillary (armpit) swelling/tenderness
- Nausea/vomiting

These symptoms are temporary and usually resolve in a few days.

You might have an allergic reaction to the vaccine. The reaction could be mild or severe. Some symptoms of allergic reactions are rash, wheezing and difficulty breathing, dizziness and fainting, swelling around the mouth, throat or eyes, a fast pulse or sweating. A severe allergic reaction could lead to death. The study doctors are trained to recognize a reaction and will provide you treatment. If you experience any reactions after your visit, you will need to seek treatment immediately. We will give you a handcard and review what symptoms to look for in the event of a reaction.

Depending on which vaccine you receive and whether you get placebo first, your participation will end in as short as 4 weeks, or up to 9 weeks.

If you are interested in volunteering for this study and think you might be the kind of person we are looking for, please contact us at: (608) 263-6049 or allergyresearch@medicine.wisc.edu