

## COVAAR Brief Synopsis:

We are excited to share that the National Institute of Allergy and Infectious Diseases (NIAID) is now actively enrolling for the clinical trial titled **COVID Vaccine Allergy Reaction** (COVAAR).

This study aims to address the critical questions related to allergic reactions to the mRNA COVID-19 vaccines, such as:

- a) What is the risk of recurrence of allergic reactions in individuals who had anaphylaxis or a systemic allergic reaction after receiving the 1<sup>st</sup> dose of an mRNA COVID-19 vaccine?*
- b) What is/are the underlying mechanism(s) of these reactions and are there any specific biochemical, molecular, or genetic factors that influence these reactions?*
- c) How likely is skin testing to predict a systemic reaction to the mRNA COVID-19 vaccines?*
- d) How is the immune response to mRNA vaccines impacted by variable dosing?*

To answer these questions, we are conducting a randomized, double-blinded, placebo-controlled crossover study, where **eligible individuals who developed a systemic allergic reaction to the 1<sup>st</sup> dose of the Moderna or Pfizer-BioNTech mRNA COVID-19 vaccine will receive the 2<sup>nd</sup> dose of a COVID-19 mRNA vaccine in the intensive care unit (ICU) at the National Institute of Health (NIH)**. Any reactions will be treated according to current standards of care. Multiple blood and urine samples will be obtained at different timepoints to investigate the mechanisms behind these reactions. After receiving the second dose of the vaccine, participating individuals will be evaluated at 8-10 weeks and 6-months with skin testing and blood tests to further investigate allergic and immune responses to the vaccine.

We believe this study will provide crucial information to allergists and providers to guide their patients regarding allergic reactions to the mRNA COVID-19 vaccines and will address the general public anxiety related to these reactions.

If you would like to know more about our trial, please visit <https://go.usa.gov/xFRBN> or contact us directly at NIAIDFARS@nih.gov or 240-627-3677.