

Lakeland volunteers sought for COVID-19 vaccine study starting in December

LAKELAND — <u>Accel Research Sites</u> is recruiting Lakeland volunteers for a COVID-19 vaccine trial study that will launch in December.

With Florida on the verge of surpassing 1 million confirmed cases, including more than 27,600 people in Polk County, the DeLand medical research company is searching for individuals willing to help test a vaccine's effectiveness as the area's rate rises.



Dr. James Andersen, principal investigator for Accel Clinical Research in Lakeland, said the company will launch a Phase 3 study of Novavax, Inc.'s potential coronavirus vaccine in early December. Lakeland will be one of approximately 125 sites nationwide seeking to enroll hundreds of volunteers, age 18 and older, in an effort to reach 30,000 participants in the upcoming weeks.

"There are over 200 vaccines being investigated worldwide and many of the ones you hear about have more money behind them," Andersen said. "I'm glad there are different ones out there, as they all have their pluses and minuses."

Novavax is a smaller Maryland-based biotechnological company, according to Andersen, which has been engineering vaccines for more than a decade. Anderson said the COVID-19 vaccine is entirely synthetic with a unique protein cap designed to help it better penetrate into a person's bloodstream while causing less unwanted side effects.

"There's nothing infectious in it, so you cannot catch anything from it," he said.

Novavax's vaccine is a two-shot series that requires individuals get a first dose followed by a booster shot three weeks later. Anderson said the Lakeland study will use what's called a 2:1 ratio, or two volunteers receiving the active vaccine to every one person who receives a saline water injection as a placebo.

"They are looking for people likely to have the worst health problems with COVID-19," he said. "There is no upper age limit."

The trial is particularly looking for individuals with:

- Chronic health conditions such as high blood pressure, heart disease, emphysema or other respiratory issues;
- People likely to come in frequent contact with the virus such as law enforcement, first responders, health care workers or nursing home residents;
- Older individuals who are likely to be more susceptible to the disease

Andersen said the Lakeland study will also include volunteers of diverse backgrounds looking to accurately reflect national demographics in race, color and ethnicity. Ideally, researchers hope to have 25% of volunteers over age 65, with 10% to 15% coming from the Hispanic, Latino and Black communities, and 1% Native Americans.

All participants will be asked to undergo a preliminary medical screening. Andersen said anyone who has already contracted COVID-19 cannot take part and those with recent changes in their medical condition will be asked to get approval from their treating physician.

Those selected will be asked to download an app to their phone to take and record their temperature daily as well as report any symptoms they might experience.

"It makes collecting all the information the FDA needs from home easier," Andersen said. "If someone is not following up, they will be contacted to ensure they follow through."

All volunteers will be monetarily compensated for their participation in the study, though the amount has not yet been finalized. The study has started taking a waitlist of interested participants as it awaits final procedural approvals from the U.S. Food and Drug Administration.

Anyone interested can call 863-940-2087 for more information and add their name to the waitlist or visit covidorlando.com.

"The more people in the study, the more information we gather, the quicker it goes," Andersen said. "It looks like a good thing."

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