Message

From: Orme-Zavaleta, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C5A111DC377411595E5B24B5D96146B-ORME-ZAVALETA, JENNIFER]
Sent: 2/5/2021 7:00:40 PM
To: Rodan, Bruce [rodan.bruce@epa.gov]
Subject: RE: ORD-Chapel Hill Facility Collaboration with UNC-Chapel Hill on Coronavirus Vaccine

Thanks Bruce!

Jennifer Orme-Zavaleta, PhD
Acting Assistant Administrator, and
Principal Deputy Assistant Administrator
Office of Research and Development
US Environmental Protection Agency

DC Ex. 6 Personal Privacy (PP)
Cel

From: Rodan, Bruce <rodan.bruce@epa.gov>
Sent: Friday, February 5, 2021 1:48 PM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Cc: Diaz-Sanchez, David <Diaz-Sanchez.David@epa.gov>; Robbins, Chris <Robbins.Chris@epa.gov>; Nelson, Daniel K. <Nelson.Daniel@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Schmitt, Michael <Schmitt.Mike@epa.gov>
Subject: ORD-Chapel Hill Facility Collaboration with UNC-Chapel Hill on Coronavirus Vaccine

Jennifer,

As requested, following is a summary of the coronavirus vaccine research on which UNC-Chapel has requested the assistance of ORD's Chapel Hill laboratory and staff. As we discussed, this research with UNC-Chapel Hill – an emergency priority for NIH-NIAID – is consistent with the EPA Cooperative Agreement and Outside User's Agreement between EPA and the UNC Center for Environmental Medicine Asthma and Lung Biology (CEMALB) for the purposes of conducting research that furthers the goal of understanding the effects of environmental pollutants and agents on human health. ORD will ensure compliance with our Human Subjects Research protocols, including that no intentional dosing occur to any pregnant woman or child.

Background: Vaccines are a critical tool with which to bring the Coronavirus pandemic under control. There have been several reports of systemic allergic (anaphylactic) reactions in allergic individuals who have received either of the two vaccines currently approved in the United States. These reports are very rare (2.5-10 cases/ 1,000,000 vaccine doses) however, they have been reported widely in the media and concern regarding the safety of the vaccine is contributing to vaccine hesitancy.

The NIH National Institute of Allergy and Infectious Disease (NIAID) has sponsored an emergency clinical trial to establish whether the risk for a systemic allergic reaction induced by the two COVID-19 vaccines in a population of individuals with a history of severe allergic reactions is higher than in a non-atopic population. The University of North Carolina, Chapel Hill has been selected as one of the 30 sites in the country to address this critical question. The Principal Investigator is Dr. David Peden who is co-located at the EPA Human Studies Facility (HSF) in Chapel Hill and the head of the Centre for Environmental Medicine, Asthma and Lung Biology (CEMALB).

UNC-CEMALB has requested the use of space in the Human Studies Facility to conduct some aspects of the NIAID emergency trial. An Outside User Agreement between EPA/ORD and CEMALB permits the use of space for research on environmental agents' effects on human health. In addition, UNC-CEMALB has requested the assistance of EPA staff in

the conduct of some aspects of the study that would be conducted at the HSF. An EPA-UNC/CEMALB Co-Operative Agreement allows for EPA investigators to be substantially involved in research projects with CEMALB investigators.

The emergency trial will involve research volunteers who will undergo the 2-stage vaccination with the Pfizer-BioNTech or Moderna vaccines or will receive placebo. 60% of participants will be people who have a history of anaphylaxis (high risk for a reaction) and 40% healthy volunteers. Placebo patients will get an actual vaccine 3 days later. The target for the UNC site is to recruit 10 people/week for 8 weeks. Approximately two-thirds of participants enrolled in each of the groups will be female. The primary endpoint is the proportion of participants who experience a systemic allergic reaction within the 3-hour post-vaccination observation period. The research participants will be followed for 30 days to record any other changes. Exploratory endpoints will be changes in blood markers following vaccination. The total study duration is estimated to be 14 weeks.

Specific Request to EPA Facilities: EPA is being asked to host and provide support staff for the second round of vaccinations in our Chapel Hill facility, in order to relieve pressure on other UNC-CH COVID research. The research will remain under the control of the UNC-CH investigators, representatives of which will be present during the second round vaccinations in the EPA CH facility. A major benefit of this research being conducted in a staffed health research facility is that, in the unlikely event of a substantive adverse reaction, trained response staff and equipment will be available onsite. UNC-CH and ORD will ensure that the relevant IRB approval is submitted to EPA's HSRRO, whose approval is necessary prior to commencement of this work in EPA facilities and/or with EPA staff. Consistent with EPA regulations, there will be no intentional dosing of any pregnant woman or child as part of this research.

Dr. Bruce Rodan
Associate Director for Science
EPA Office of Research and Development