JOHNS HOPKINS
CENTER FOR AMERICAN
INDIAN HEALTH

COVID-19 Vaccine Trials Overview

The Johns Hopkins Center for American Indian Health is evaluating whether an investigational vaccine, created by Pfizer/BioNTech, is effective in preventing COVID-19 disease. Currently, there is no licensed vaccine against the virus that causes COVID-19 and finding a safe and effective vaccine is critical to stopping the spread of COVID-19 and protecting our communities.

The Pfizer/BioNTech COVID-19 vaccine clinical trial is being conducted at more than 130 sites in 5 countries, including 39 U.S. States. Sites on Navajo Nation and White Mountain Apache Tribal lands will join the trial in September/October 2020.

Who is the Johns Hopkins Center for American Indian Health?

- Founded in 1991 at the Johns Hopkins Bloomberg School of Public Health, the Center works in partnership with Native Nations on public health interventions in over 140 Native communities in more than 20 states.
- The Center has partnered with the Navajo Nation, White Mountain Apache Tribe, Indian Health Service and Tribal Health Organizations on many studies aimed at reducing disease and improving the health and well-being of Native people. Past studies include successful Phase 3 clinical trials of vaccines that are now used as part of routine immunizations that all children around the world receive, including: the Hib vaccine (against a leading cause of meningitis), the Prevnar vaccine (against a leading cause of pneumonia) and the rotavirus vaccine (against a leading cause of infectious diarrhea that can have severe effects in infants). All studies have been done by research personnel who are trained in the conduct of clinical trials, with the guidance of the communities, and with the oversight of the Tribal IRBs.

Does a vaccine against COVID-19 already exist?

- There is no licensed vaccine against the virus that causes COVID-19. Scientists are working hard to develop vaccines and to determine whether they are safe and effective.
- Numerous vaccines, including the vaccine by Pfizer/BioNTech are in large-scale clinical trials to establish safety and efficacy.
- Phase 3 clinical trials are the last stage of testing before a vaccine can be approved by the FDA for use in the U.S.
- The Pfizer/BioNTech is enrolling ~44,000 people from around the world.

What is known about the Pfizer/BioNTech vaccine?

- The Pfizer/BioNTech COVID-19 investigational vaccine is a mRNA vaccine. mRNA is the code that tells cells what to build. The **vaccine tells the body to build coronavirus spike protein. This may help the body to produce antibodies to fight against the coronavirus.**
    - mRNA vaccines are made from synthetic (laboratory made) pieces copied from the coronavirus, SARS-CoV-2, not the whole virus. The vaccine doesn't contain human RNA.

The vaccine doesn't enter the nucleus of the cell. The vaccines CANNOT cause someone to get COVID-19.

- mRNA vaccines are **much quicker to make** than conventional vaccines, which means that they could be manufactured and produced quickly if licensed and recommended for use.
- The idea of making a vaccine in this way was developed more than ten years ago, because scientists knew that if an outbreak of a brand-new virus occurred, they would have to be able to make new vaccines quickly.
- Before advancing to human trials, vaccine candidates go through rigorous laboratory and animal testing. **Only when data show that a product appears safe and helps make a good response do studies move forward in people.**
- In studies conducted to date, the Pfizer/BioNTech COVID-19 vaccine has been shown to induce a **strong immune response**. So far, the reported side effects are similar to other vaccines and include temporary arm soreness, fever, headache muscle aches and pains. As with any vaccine given by injection, people may have an allergic reaction.
- All participants in vaccine trials are monitored very carefully for safety. The same is true for COVID-19 vaccines. No steps are being skipped. The studies are moving faster than in the past because some of the phases of research are overlapped. The support of the government has also allowed companies to move more quickly because they don't have to take all of the financial risks themselves.

What does this study involve?

- People 18 years and older who are healthy (or have stable underlying medical conditions) and have not had a prior diagnosis of COVID-19 may **volunteer** for this study. People who are pregnant or breastfeeding are excluded from participation.
- People who are interested in participating go through a thorough informed consent process to ensure they understand what the study entails, the risks and benefits, and that joining the study is a voluntary decision.
- Volunteers will be asked some questions and have a physical exam by a study physician to see if they are eligible based on the inclusion/exclusion criteria.
- People who consent and are eligible will be assigned to receive the study vaccine or a placebo. This is determined by chance, like flipping a coin. Half of the participants will get the vaccine, and half will get the placebo. Aside from the person who administers the dose, neither the study staff nor the participants will know who gets vaccine and who gets the placebo.
- Two doses will be given, three weeks apart.
- After the two vaccination visits, there are 4 more visits for a total of **6 visits over a two-year period**. A nasal swab will be collected at two visits and a blood sample will be collected at five visits. The nasal swabs will be tested for the COVID-19 virus and the blood samples will be tested to measure the level of antibodies to COVID-19 before and after vaccination. No other testing of specimens, beyond what is specifically stated at the time of enrollment, is allowed. Any residual specimens are destroyed when the study-specified testing is complete, in accordance with regulations. No genetic testing will be done.
- Participants will be asked to keep a diary to monitor any potential symptoms that they may experience.
- Participation in this study is entirely voluntary and individuals can choose to stop study activities and remove themselves from the study at any time.

- Trained CAIH research staff, the majority of whom are Navajo or other Indigenous professionals, are responsible for conducting all study activities. CAIH is not responsible for clinical care of participants. While in this, study participants continue to receive medical care from their primary care providers (e.g., I.H.S.)

How are people recruited and what is "informed consent"?

- People who are interested in joining the study may contact a participating CAIH site or email: johnshopkinscaih@gmail.com
- The informed consent process is very important. All participants must understand what the study involves, the risks and benefits, and that participation is voluntary.
- The informed consent document is written in English. Bilingual study staff can provide some study information in Navajo or Apache. However, individuals who do not read and speak English will be excluded from the study as we cannot be sure that consent is understood and voluntary.
- As part of the consent process, all potential participants will take a short quiz to determine whether they understand the study. If participants do not pass this quiz or our staff believes for some other reason that they do not fully understand the voluntary and experimental aspects of the trial, they will be excluded from the study.

Why would tribal communities participate in this study?

- COVID-19 has had a major impact on tribal communities. Many people have been sick and many lives have been lost. **A safe and effective vaccine could help to end this pandemic.**
- Native people continue to experience the burden of COVID-19 at disproportionate rates while **remaining the least represented in studies of interventions that can prevent or treat COVID-19**.
    - At one point the tribal communities in the southwest had the highest COVID-19 infection rate in the United States, and has higher rates of severe disease and death from COVID-19.
    - Native Americans currently make up less than 1% of COVID-19 vaccine trial participants.
- COVID vaccines will be licensed and recommended in the coming year. It is important to know if the vaccines will be efficacious in tribal communities or if one of the vaccines may be preferable. By joining in this study, tribes will have data to make informed decisions about COVID-19 vaccines.

Who approved this study?

- Our Center operates with recognition and respect for tribal sovereignty and the inherent right of Tribal Nations to decide what research occurs on tribal lands and how best to oversee research activities. All of our research involves at least two layers of approval, which is a common standard in research with American Indian communities: 1) Community approval; and 2) Individual Participant consent.
- For Navajo Nation, the Navajo Nation Human Research Review Board (NNHRRB) is the entity that is responsible for determining what human subjects research is allowed. The decision to submit this protocol to the NNHRRB was made following input and guidance from community members, elders, healthcare providers and members of the leadership team at Navajo Nation COVID-19 Health Command Operations Center. The NNHRRB reviewed and approved this proposal in August. Reports on the trial have been presented and approved by the Health Education and

Human Services Committee and at Agency Council and Health Board Meetings of the participating areas.
- For White Mountain Apache, the decision to submit this protocol to the National I.H.S. IRB was made following input and guidance from community members, elders, Tribal leaders, healthcare providers and members of the leadership team at the Whiteriver Service Unit. The Tribal Council passed a resolution of support for this trial.
- The National I.H.S. IRB and the Johns Hopkins School of Public Health Institutional Review Board (IRB) have also approved this study.

What are the benefits of joining this study?

- Volunteers in this study will help to figure out what will work to prevent COVID-19 disease.
- It will be months before an approved vaccine may become available to anyone. Because of this timeline, if the vaccine used in this trial is effective, people in the trial may have already received something of benefit before other Americans.

What are the risks of joining the study?

In this study, there are risks related to the investigational vaccine and risks related to study procedures.

- Vaccines often have side effects, which are typically temporary—like sore arm, low fever, muscle aches and pains. In the studies done to date, this vaccine causes similar side effects as other vaccines. As with any vaccine given by injection, people may have an allergic reaction. The allergic reaction could be minor (rashes) or more severe (swelling of the face or lips and/or shortness of breath). A severe allergic shock (anaphylactic shock) could occur requiring emergency medical assistance.
- The collection of the nasal swab and blood sample may cause temporary discomfort.

If you get the vaccine through this trial, can you potentially get family members sick? Is there a quarantine period when you receive the vaccine?

- The vaccine cannot give you COVID-19 disease and there is no quarantine period required. This vaccine is created using a synthetic or lab-made portion of the code for the virus protein and not the actual virus. This means that this vaccine cannot cause COVID-19 infection.

Is there compensation offered to join a research study? Is this fair?

- Volunteers are paid for their time and inconvenience to be in the study. Over the course of the 2-year study, payments will total $710 plus $5/week for every week that the electronic diary is completed.
- This amount is similar to what volunteers in other parts of the country are receiving for participating in this trial.
- When the IRBs review protocols, they ensure that the amount of compensation is neither too little nor too much so as to be considered coercive.

Is research akin to exploitation of participants?

No, this study is voluntary. Study staff are trained in research ethics and during the informed consent process, staff **ensure that participants understand what the study involves, the risks and benefits, and that it is voluntary.**

- Right now, Native Americans have few opportunities to participate in COVID-19 vaccine trials because most are being done in urban areas, but many people have expressed an interest in being part of these studies. This trial will **enroll approximately 44,000 people throughout the U.S. and around the world**, with **a few hundred people enrolled across Johns Hopkins Center for American Indian Health sites in the Southwest**.
- Native people have endured egregious acts of violence by researchers in the past and remain vulnerable to exploitation. To prevent this, tribal **Research Review Boards carefully review all research proposals that are brought forward to ensure that they offer potential benefit to the population and are ethical.** The Boards reviewed and approved this study, just as they do for all research activities carried out in partnership with the Johns Hopkins Center for American Indian Health.

What are the demographics of other enrollees in this trial?

- The Pfizer/BioNTech COVID-19 vaccine trial has enrolled over 40,000 participants from 5 countries and 39 U.S. states. Overall, .7% of enrollees are Native American, 4% are Asian, 10% are Black, 28% are Hispanic/Latinx, and 71% are non-Hispanic whites.

Does the Center ask for input on proposed research studies from tribal elders and traditional healers?

- The Center seeks from input from community members and key stakeholders, including from elders and traditional healers. Studies are discussed at Agency Council meetings, which include many elders. Separate from these meetings, we reach out to traditional healers for discussion.

How does a vaccine provide immunity?

- When a person is infected with a pathogen or germ—like a virus or a bacteria—their body mounts an immune response to fight it. This immune response involves white blood cells and proteins called antibodies, which are germ fighters.
- After the person recovers, the body's immune system may remember that germ and be prepared to respond quickly with the right antibodies if the person is infected again.
- Vaccines mimic this process. They provide specific instructions to our immune systems—helping our bodies know what to look for in the future. This prompts our bodies to make the right kinds of germ-fighting antibodies that would be needed to fight that germ if the person were to get infected in the future.
- How long the body is able to keep that memory of the germ can vary. Sometimes one dose of a vaccine is enough, sometimes more doses are needed over time to prevent infection over time.

People interested in volunteering or learning more about the study can email: johnshopkinscaih@gmail.com.