

**GENERAL PATIENT INFORMATION SHEET FOR A RESEARCH STUDY
(TRANSLATED ENGLISH)**

Title:	Peru Respiratory and Enteric infection Survey of IncidENCE over Time (PRESIENTE)
Protocol number:	mRNA-IDOB-P906
Approving institutions:	Asociación Benéfica PRISMA, Peru and Ministry of Health DIRESA Callao, Peru
Collaborator & funder:	ModernaTX, Inc., USA
Principal investigators:	Dr. Sumona Datta and Dr. Carlton Evans

Introduction

We are giving you this form as you are invited to participate in a research study. This form describes why we are doing the research study and the activities we will be carrying out.

It is your choice if you want to participate in this research study. If you change your mind, you are free to leave the study at any time. If you let us know that you no longer wish to participate, we will stop contacting you. Taking part in this research study is entirely voluntary, and whether you participate or not will not change the care you get in your health center.

Before choosing if you want to be a part of this research study, please read this form carefully, or have it read to you so that you understand how the research study works. We urge you to discuss any questions you have about this research study with our team members. You can also talk to your family and friends about it before you make your decision. You can choose to join this research study today, or you have up to 1 week to make your decision.

If you decide to participate, you must complete the last page of this form. If so, 2 copies of the form must be signed and dated. One copy will be for you and your records, and the other will be kept by the research study team.

Participants

We are inviting you and approximately a thousand other people in Callao to take part in this research study. We wish to invite you to participate in this research study because your home was selected by random chance. We will also invite other members of your household who regularly sleep in the same household as you for 4 or more times a week, and who will undergo the same process for obtaining consent as you.

You cannot join the research study if you expect to move away from this address before mid 2026 (which is when the study will most likely end). Furthermore, if you are an adult unable to read or an adult assigned a legal guardian because you are legally considered to not have capacity to make decisions you will not be able to participate in this study.

Objectives

During this study, we are trying to better understand the health of households in this community, like yours. When people get sick with a stuffy nose, headache, coughing, sneezing, stomach pain, diarrhea, vomiting, or fever, we will try to understand why they have become sick. This includes searching for the type of germ that may have caused the illness and trying to understand how these germs spread in families.

We are studying your symptoms so that we can learn better ways to prevent illnesses for example with vaccines or treatments.

What will happen if you choose to join this research study

- In your home, we will check your height, weight, and ask about your health 4 times a year (including today). This will take less than 1 hour of your time each time. We may check your vaccination record in the health center and in the Ministry of Health system if you are unable to provide the information we require.
- We will ask you daily throughout all the study how you are, to check if you are sick. Most of the time we will ask you these questions through your phone by WhatsApp or a text message. This will take you less than 1 minute to answer.
- Usually 3 times per week, or if you do not reply to our phone questions, we will visit your home to ask you the same questions to check if you are sick.

Whenever you tell us that you are sick, and sometimes just by chance:

- We will ask you daily on your phone more questions about how you feel, and if you needed any healthcare. These questions will take less than 5 minutes to answer.
- Usually, we will ask to visit you at your home whilst you are sick.
- Each time you tell us you have become sick, usually the next day we will visit you to collect some samples, once each time you get sick. If you have symptoms of a flu-like illness, we will request swabs from your throat and nose. And if you have a stomach illness, we will ask for a sample of your saliva and for you to collect a sample of your stool.

Possible risk and discomfort

Nothing in this research study involves risks to your health. However, if you do feel you were harmed because of your participation in this research study please contact the study coordinators using the contact details you will find in the section headed "Questions" who will investigate and if appropriate remedy your claim.

To participate in this study we require you to answer questions and provide the samples we have outlined above, therefore the possible discomfort or inconveniences include:

- If you do not respond to our daily questions regularly, or if you decline to give us any samples requested, you will no longer be allowed to continue with this research study, and we will stop contacting you.
- Asking some private questions that you can decide whether or not to answer. Please note that we will never ask you any sensitive questions via text messages or WhatsApp.
- The time taken to reply to our questions and be present at visits, which will only be carried out by research personnel with an identification card from the Asociación Benéfica PRISMA.
- Some people do not like having swabs from their throat and nose taken.

Possible benefits

If you give us samples from your nose and throat when you are ill, then we carry out a free test for COVID and flu and give you the written results of both. We will do this right away in your home if we can. Except for offering these, we cannot provide results for any other tests including from stool samples. We can never provide medical advice and cannot give any treatment because this is not permitted as part of our role in this observational research study.

Every part of this research study is free, and we will never ask you for money nor any of your bank details.

No one can be paid for participating in this research study. However, we would like to reimburse you for participating in this research study. Depending on logistics these include:

For the participant:

- We will give you a food parcel gift worth 20 Soles now and 4-times a year. We will do this to make up for the time that you are at home answering our questions.
- We will pay your travel costs if we advise you to go to your health center.

For the home:

- We will pay for cell phone credit for at least one person in your home for as long as you are participating in this research study.

Your privacy

We will protect your name, address and DNI information, so that it is only known by our research study team at Asociación Benéfica PRISMA. We will destroy our register of your address and DNI when our research study ends. We will keep our copy of this form for up to 20 years.

The samples that we have collected from you will be assigned a code. Your answers and samples will be analyzed after your name, address and national identity number have been removed to preserve your privacy.

Storage of your answers and samples

Some of your answers to our questions and some parts of your samples may be sent with none of your identifiable information to 4 places. 1. Universidad Peruana Cayetano Heredia, Peru. 2. Johns Hopkins University, USA. 3. Imperial College London University, UK. And 4. The company ModernaTX, Inc., USA. Your answers and your samples will also be stored for up to 20 years and may be shared with other research institutions in the future. Your answers and your samples will only be used for research to try to prevent disease. They will never be paid for and will never be sold to anyone.

The results of this study will be published in an online journal for anyone to read for free. This type of research publication shares the research findings to try to help prevent disease. This research publication will not show who you are and will not show anything private.

Questions

Please ask our team anything you want, now or in the future. If you have more questions or a complaint, you can call our phone xxxxxx or xxx xxxx to speak with our team. To save your costs, we'll call you back if you want.

The ethics experts at DIRESA Callao (tel. xxx xxxx or xxx xxxx) and Asociación Benéfica PRISMA (tel. xxx xxxx extension xxx) who are formed of people independent of the researchers, whose purpose is to protect the dignity, well-being, rights and safety of participants in biomedical research, have reviewed and approved this research study, and you can call them at any time. For the duration of the study, they will continue to monitor this research.

The title of this project and the protocol number are at the top of every page, in case you want to call anyone about this project.