

BLOOD COLLECTION CONSENT/ASSENT FORM

Undetermined agent and risk factors for chikungunya or dengue virus infections among community service volunteers in the Dominican Republic, 2014

Public reporting burden of this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74 Atlanta, Georgia 30333; ATTN: PRA (0920-1011)

Undetermined agent and risk factors for chikungunya or dengue virus infections among community service volunteers in the Dominican Republic, 2014

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Other CDC Branches:

CDC NCEZID, Division of Vector-Borne Infectious Disease, Arboviral Disease Branch

CDC NCEZID, Division of Vector-Borne Infectious Disease, Dengue Branch

Texas Department of State Health Services

Laboratory Testing:

All participants will have one serum specimen collected (3-4 cc target) to detect evidence of recent CHIKV and DENV infection. All samples will be tested by RT-PCR (dengue and chikungunya), IgM ELISA (dengue and chikungunya) and IgG ELISA (chikungunya and dengue); all IgM-positive specimens will be confirmed by plaque reduction neutralization test (PRNT). Serum specimens will be sent to the CDC Dengue Branch in San Juan, Puerto Rico, where they will be batched and tested. During the intervening period, all specimens will be stored under appropriate conditions. Chikungunya PRNTs will be performed at CDC Arboviral Diseases Branch in Fort Collins, Colorado.

Human Subjects

Non-research determination — this investigation constitutes a public health response requiring timely intervention to prevent additional cases.

Risks and benefits: Risks are minimal and primarily include pain or bruising during collection of the serum specimen. All efforts will be made to maintain the security of questionnaires, but there is a slight risk that information collected will be available to non-investigator personnel. Benefits of participation include direct benefit to participants in terms of potential knowledge of the cause of any symptomatic illnesses while in the DR and understanding of effective behavioral or other interventions that enable travelers to prevent infection with CHIKV or DENV. For any patients not yet aware that they had been infected with CHIKV or DENV or for those who had not yet received care for their illness, being directed to an appropriate healthcare resource might occur and could be of benefit.

Informed consent: As stated above, participation in this investigation and responses to survey questions are completely voluntary. Written consent will be obtained from participants ≥ 18 years of age and parental permission for minors <18 years of age. Written assent will also be obtained from minors <18 years of age.

Paper copies of data collection instruments will be stored in a locked, secured filing cabinet at the CDC offices; only investigators directly involved in the investigation will have access to illness logs, surveillance information, and investigation data. Information about sensitive topics such as sexual behavior or drug use will not be collected. Investigators will maintain the participant name and unique identifier so that diagnostic test results can be reported to investigation participants. Any reports related to the findings of this investigation will not include personal identifying information.



CONSENT/PARENTAL PERMISSION FORM

Undetermined risk factors for chikungunya or dengue virus infections among community service volunteers in the Dominican Republic, 2014

The US Centers for Disease Control and Prevention is working with your service organization and the Texas Department of Health to investigate possible chikungunya virus infections among volunteers and staff. Chikungunya is a disease characterized by fever and joint pains. The virus that causes this disease is transmitted by the same mosquito that transmits another virus called dengue virus. Dengue virus has been present in the Dominican Republic for many years. Chikungunya virus was only recently introduced into the Dominican Republic. We are trying to find out if and how many people may have been infected among the volunteers and staff deployed to the Dominican Republic this summer. In addition, we are trying to get information about the daily practices of people who got infected. With this information, we will try to figure out risk factors for infection. We will also try to identify people who got infected but may not have known that they were infected. Finally, we will try to determine if it was a dengue virus or chikungunya virus infection that caused the symptoms among those that became ill.

We would like to ask that you/your child fill out a questionnaire that we have developed to try to answer the questions in the above paragraph. We expect that it will take about 20 minutes to complete. We would also like to take approximately 1 ½ tablespoons of blood, which we will use to test whether you have/your child has been recently infected with the viruses that cause chikungunya and dengue. If any of the blood sample is left over, we would like to store it for future chikungunya and dengue testing. We will NOT perform any genetic or HIV testing on it or test for other diseases.

We will give you the results of your/your child's test, but they will not be available in time to be useful in making any decisions about your health care. If the test shows that you/your child had a recent chikungunya or dengue virus infection, we will also inform the health department in the state where you live.

In addition to the questionnaire, we are aware that your service organization collects health information on a weekly health log for each participant as well as clinical information when a participant becomes ill. This information may be helpful to us in determining when people became ill as well as the extent of their illness; therefore we would like to obtain this information for volunteers whose illnesses are compatible with chikungunya or dengue. We would also like to obtain information regarding previous yellow fever and Japanese encephalitis vaccination as this information might affect test results.

All the information you/your child give(s) us will be kept private to the extent possible, and only the investigators working on the investigation will be able to see it. There is a small risk though that personnel not involved with the investigation could see your information. Reports of the investigation will be summaries, and no information will be shared with others that can identify you personally.

Answering the questions is completely voluntary, and you/your child can stop answering any time you/your child want(s), or you/they can decide not to answer any particular question. The same applies to the blood specimens.

Do you have any questions? If not, please read the statements below and if you agree, sign and date the form where indicated. If you do not agree to any of the following statements, please draw a line through the statement you do not agree with and initial next to the line.

- I agree to answer questions and to have my or my child's blood drawn
- I agree to allow my or my child's blood to be stored for future chikungunya and dengue testing
- I agree to allow the service organization to furnish my or my child's weekly health log and related health information to investigators
- I agree to allow the service organization to furnish my or my child's vaccination data to investigators
- I agree to be contacted in the future

Participant Name: _____

Date: _____

Parent/Guardian Name: _____

Signature: _____



ASSENT FOR MINORS <18 YEARS OF AGE

Undetermined risk factors for chikungunya or dengue virus infections among community service volunteers in the Dominican Republic, 2014

We are working with the U.S. Centers for Disease Control and Prevention to try to determine if there were volunteers or staff that experienced an illness called 'chikungunya' in the Dominican Republic. This disease causes fever and body pain, and is transmitted by the same mosquitoes that transmit dengue virus. This virus was only recently introduced into the Dominican Republic and illnesses from this virus have been reported there. We are trying to find out if and how many people may have been infected among the volunteers and staff deployed to the Dominican Republic this summer. In addition, we are trying to get information about the daily practices of people who got sick to try and figure out risk factors for infection, possibly identify people that have been infected but may not have known that they were infected, and also find out whether it was dengue or chikungunya infection that made them ill.

To do that, we would like to ask you some questions about things that you were doing over the past few weeks. We would also like to take approximately 1 ½ tablespoons of blood, which we will use to test for evidence of having been recently infected with the viruses that cause chikungunya and dengue. This would mean that we would put a small needle in your arm and take some of your blood. It might pinch a little at first, but should not be too painful. This is to test for chikungunya and dengue. Your parent/guardian has given their permission for you to answer these questions and give some blood.

I agree to answer the questionnaire and have my blood drawn.

Name: _____

Date: _____

Signature: _____