Form Approved
OMB No. 0920-0773
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"National Surveillance for Severe Adverse Events Among Persons on Treatment of Latent Tuberculosis Infection"

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Extension without change

January 18, 2018

ATTACHMENT – 8: Informed Consent Form

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Centers for Disease Control and Prevention (CDC)
Division of Tuberculosis Elimination

Informed Consent Form

Title: National Surveillance for Severe Adverse Events Associated with Treatment of Latent Tuberculosis Infection

Project Officer: Adam Langer, DVM, MPH, DACVPM

Introduction/Background/Purpose: You are being asked to volunteer to participate in a surveillance project by the Division of Tuberculosis Elimination, Centers for Disease Control and Prevention, Atlanta, Georgia. The purpose of this project is to find out why severe adverse events such as hospitalization or death occur after taking medicines for treatment of latent (not active) tuberculosis (TB) infection. We call this LTBI which means the person has been exposed to active TB and the TB germs have entered the body but these TB germs are not contagious and not making the person sick. You are being asked to participate because you have developed a severe adverse event or reaction that may have been related to the medicine you took for LTBI to prevent you from getting TB in the future. This project will also identify some risk factors that may help explain why these severe adverse events happen. This information may be helpful in developing guidelines to prevent these severe adverse events. Taking part in this project is voluntary. We are hoping that all of those who developed a severe adverse event from medicines used for treatment for LTBI will participate in this project. If you choose to participate in this project then the duration of time for your participation will be that for which it takes for you to answer our questions.

Procedures: Participation in this project involves talking to us about what happened that led to your admission to the hospital or healthcare facility after taking the medicine for treatment of LTBI. The estimated time for you to answer our questions is 45 minutes to one hour. If you answer "yes" to the question concerning whether or not you ever had a severe adverse event after taking a medicine for treatment of LTBI then participation will also include permission to CDC personnel to contact your physician. The medical release form will seek to obtain only your medical information related to the severe adverse event. Also, information concerning events that may have caused the severe reaction will be requested. CDC personnel will collect and analyze this information.

Although participation is voluntary, you are being asked to mark NO if you choose not to participate.

When we have people participating in this project, we hope that we can provide information that helps to identify what risks for severe adverse event there are with taking medicines for LTBI and what risk-modifiers there may be to help decrease the risk of severe adverse events related to taking LTBI medicines.

Risks: There are no physical risks involved in this project. There is the risk that you will be offended by the questions that you are asked. There is also a risk that your health information is accidentally released to the wrong people, or that more information than is requested is accidentally released.

Benefits: Taking part in this project may not immediately benefit you personally, but we may learn new things that may help either you or others in the future. Your participation in the project may help us learn more about the causes of severe adverse events related to taking a medicine for treatment of LTBI.

Confidentiality: All project information will be kept private to the extent allowed by law. Only the project personnel may review your medical records. The information we collect during the interview will be recorded in a CDC computer with a password protected secure server. This project has an Assurance of Confidentiality 308(d) protection for the data collected including date of birth, other demographic information, and highly sensitive information such as HIV infection status, correctional facility residence, and alcohol or drug use. This consent form including your name and additional information will be kept in a locked file at the local health department. Information collected by CDC will identify you only by an ID number and not by name. This information will be maintained or destroyed according to the CDC Records Control Schedule. This project will identify some risk factors that may help explain why these severe adverse events happen. This information may be helpful in developing guidelines to prevent these severe adverse events. The summary results of the project may be reported at meetings or in medical literature. These reports will not include any information that could identify you directly.

Compensation: There is no compensation for your participation in this project.

Costs: The only cost associated with this project is possibly the cost of your transportation in meeting us at a place that is convenient for you.

Contact Persons: You may contact the project officer at CDC, Adam Langer, at 404-639-1882. You may contact the personnel at your local health department; name _____ and phone number _____, at any time if you have questions concerning this project.

Voluntary Participation/Withdrawal: Participation in this project is voluntary, and you may withdraw at any time after you have given your permission. There are no expected risks involved with your withdrawal from this project. If you agree to participate and later wish to withdraw from this project you will need to contact Adam Langer, at 404-639-1882 or the personnel at your local health department; name _____ and phone number _____ to end your participation in this project.

Consent to Participate:

By checking the YES box you are agreeing to participate in this project.

By signing this consent, you are not waiving any of your legal rights.

I volunteer to participate in this project. [ ] YES [ ] NO

Signature: _____

Printed Name: _____

Date: _____