**National Surveillance for Severe Adverse Events (NSSAE) Data Collection Form**

Public reporting burden of this collection of information is estimated to average 4 hours 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 (P920-0773)

Information contained on this form which would permit identification of any individual has been collected with a guarantee that it will be held in strict confidence, will be used for surveillance purposes, and will not be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m).

***Part 2. To be completed by the nurse***

***\*The information requires input from the medical clerk by searching the records of the admitting hospital and other hospitals where the patient might have been evaluated in the past.***

**Able to speak English?** Yes \_\_\_\_\_ No\_\_\_\_\_\_

If No, what is the primary language?\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Preferred language (please answer even if patient speaks English):\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Language in which follow-up and monitoring visits were conducted\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Adverse event leading to hospitalization or death associated with LTBI treatment:**

Anaphylaxis \_\_\_\_ Metabolic acidosis \_\_\_\_ Other, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Liver injury \_\_\_\_ Severe dermatitis \_\_\_\_

**\*Admission to hospital:** Yes \_\_\_\_\_\_No \_\_\_\_\_ Unknown \_\_\_\_\_

 If Yes: Date:\_\_\_\_\_\_\_\_\_\_\_ Date discharged:\_\_\_\_\_\_\_\_\_\_\_

 Reason:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Severity of adverse event outcome: (Check all that apply)**

Still Sick \_\_\_\_\_ Full recovery \_\_\_\_\_ Pending \_\_\_\_\_

Recovery with residual effects \_\_\_\_\_

Evaluated for possible liver transplant but did not have transplant\_\_\_\_\_\_\_\_\_\_\_\_

Liver transplant \_\_\_\_\_ Unknown \_\_\_\_\_

Death: Yes \_\_\_ No \_\_\_\_\_ Date died: \_\_\_\_\_\_\_\_\_\_

**LTBI DIAGNOSIS AND TREATMENT**

**Reason(s) for tuberculin skin test (TST)/Interferon Gamma Release Assay (IGRA) for LTBI**

**Check all that apply:**

Contact to person with TB disease \_\_\_\_\_ Recently (past 2 years)? \_\_\_\_\_

Risk factors for TB

HIV infection: \_\_\_\_\_ HIV test date: \_\_\_\_\_\_\_\_\_\_

Diabetes \_\_\_\_\_ Renal failure \_\_\_\_\_ Organ transplant \_\_\_\_\_

Cancer or leukemia \_\_\_\_\_ Abnormal chest radiograph\_\_\_\_\_ Chronic steroid administration \_\_\_\_\_

Immunosuppressive therapy other than chronic steroid administration \_\_\_\_, Specify\_\_\_\_\_\_\_\_

Excessive alcohol use within the past year\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Illicit drug use within the past year\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Unknown\_\_\_\_\_\_\_\_\_\_\_

 Congregational setting: Jail \_\_\_ Prison \_\_\_ Homeless shelter \_\_\_

 Long-term care facility\_\_\_ Other, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Occupational risk of exposure \_\_\_\_\_

health care worker\_\_\_\_\_\_, correctional facility worker\_\_\_\_\_\_, migrant/seasonal worker\_\_\_\_\_\_\_\_\_\_

Routine/administrative work requirement \_\_\_\_\_

Foreign born\_\_\_\_\_

School admission requirement\_\_\_\_\_\_\_\_\_

Unknown \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**TST:** Date TST placed: \_\_\_\_\_\_\_ Date TST read: \_\_\_\_\_\_

 TST result: \_\_\_\_\_mm Positive\_\_\_ Negative \_\_\_

Converter (documented negative baseline TST)? Yes\_\_\_\_\_\_ No\_\_\_\_\_

**If IGRA performed, which test?**

QuantiFERON TB Gold test (QFT-G)\_\_\_\_\_\_\_

QuantiFERON-TB Gold-in-tube test (QFT-GIT)\_\_\_\_\_

 T-Spot TB test\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date of IGRA performed: \_\_\_\_\_\_\_\_\_\_**

**Test result\*:**

Result: Positive\_\_\_\_\_ Negative\_\_\_\_\_Indeterminate\_\_\_\_\_

 Quantitative results (list all available values):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Converter (documented negative baseline IGRA)? (Yes/No\_\_\_\_\_

\*Refer to the following guideline to interpret results: CDC. Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis Infection --- United States, 2010, MMWR, Recommendations and Reports, June 25, 2010 / 59(RR05);1-25 <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm?s_cid=rr5905a1_e>

**LTBI TREATMENT REGIMEN(S):** Please specify the medication(s) taken by the patient.

|  |  |  |  |
| --- | --- | --- | --- |
| **Medication** | **Daily or** **twice weekly** | **Initial regimen****dosage (mg)** | **Second regimen****dosage (mg)** |
| INH |  |  |  |
| RIF |  |  |  |
| PZA |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Initial TLTBI start date: \_\_\_\_\_\_\_\_\_\_ End date: \_\_\_\_\_\_\_\_\_\_**

**Second TLTBI start date: \_\_\_\_\_\_\_\_\_\_ End date: \_\_\_\_\_\_\_\_\_\_**

**Medication lot number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Medication manufacturer: \_\_\_\_\_\_\_\_\_\_\_\_\_**

**Patient’s weight: \_\_\_\_\_ lbs**