national tuberculosis surveillance system

DATA SET

reference guide

Now with new and improved variables!

> Division of Tuberculosis Elimination Centers for Disease Control and Prevention Department of Health and Human Services 2015

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TB Reference Guide Introduction

- The TB Reference Guide (Guide) provides guidance on the use of the National Tuberculosis Surveillance System (NTSS) data, which contains detailed information on each case of tuberculosis reported to the Centers for Disease Control and Prevention (CDC) since 1993. This guide is an update of the first edition published in 2005. Since that time, the Division of Tuberculosis Elimination (DTBE) and its partners have begun using a new data collection form with new instructions and an expanded variable list. In addition, reporting areas have transitioned from using the Tuberculosis Information Management System (TIMS) to report via the National Electronic Disease Surveillance System (NEDSS)-based system (NBS), eRVCT (a CDC developed software), and commercial and state developed systems. Within the NBS environment there is no longer one correct way to submit data to CDC. To address these changes and provide a bridge from TIMS to NEDSS, we have added new sections to this guide.
- Although the primary intended users of the Guide are scientists conducting analytic surveillance data set projects, the Guide will be useful for anyone who wants to understand the technical details of the NTSS data. Below is a brief description of the Reference Guide sections used to prepare an analytic surveillance data set project.

1 1 5	
Section 1-	Provides a copy of the Revised (2009) Report of Verified Case of Tuberculosis
Data Dictionary	(RVCT) form and an associated data dictionary. The dictionary is presented as
	a table listing each item in the dataset in alphabetical order by variable name,
	with an accompanying definition.
Section 2-	Provides trending guidance information on data collection and reporting
Data Management	procedures for the revised RVCT form. Additionally, RVCT variable subset-
	ting criteria are included in this section. TB data checks and caveats regarding
	the NTSS data also provide crucial information regarding completeness of risk
	factor data and other important points that every researcher must consider.
Section 3-	Contains sample code that can be used to get started on an analytic project.
Getting Started with Data	This code includes all calculated variables (i.e., site of disease, duration of
	therapy, miliary disease) as well as other coding issues (i.e., creating a perma-
	nent SAS dataset).
Section 4-	Contains useful technical appendices. The Appendices contain three key
Appendices	resources (Assurance of Confidentiality, Expired/Revised RVCT Trending
	information, and Codes) that may be helpful during NTSS data analysis.

Commonly Used Acronyms

- AIDS Acquired Immunodeficiency Syndrome
- ASC -Analytic Steering Committee
- CDC Centers for Disease Control and Prevention
- CDS Common Data Store
- COTS Commercial off the Shelf
- DTBE Division of Tuberculosis Elimination
- eRVCT electronic Report of Verified Case of Tuberculosis
- FIPS Federal Information Processing Standards
- FU1 RVCT Follow Up Report-1
- FU2 RVCT Follow Up Report-2
- HIV Human Immunodeficiency Virus
- ISO International Standardizing Organization
- MDR Multidrug-resistant
- NBS NEDSS Base System
- NCHHSTP National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
- NEDSS National Electronic Disease Surveillance System
- NTGS National Tuberculosis Genotyping Service
- NTSS National Tuberculosis Surveillance System
- OMB Office of Management and Budget
- PHIN Public Health Information Network
- PHIN VADS PHIN Vocabulary Access and Distribution System
- RVCT Report of Verified Case of Tuberculosis
- SEOIB Surveillance, Epidemiology, and Outbreak Investigations Branch
- TB Tuberculosis
- TIMS Tuberculosis Information Management System
- XDR Extensively Multidrug-resistance

RVCT Data Access Introduction

This section is designed to assist you in understanding the procedures, the forms, and a number of data access issues prior to beginning an analysis project. The National TB Surveillance System (NTSS) data contains data reported to CDC using a standard case report form called the Report of Verified Case of Tuberculosis (RVCT). The NTSS data resides in a shared directory with restricted access and specifications for its use, and you will be granted access after you have obtained the appropriate approvals from the Analytic Steering Committee (ASC). The development and maintenance of the NTSS data is coordinated by the Surveillance Team, led by Roque Miramontes, (404) 639-6306, zxi3@cdc.gov; and access to the data is communicated to you via e-mail.

You will work with your supervisor to develop a proposal for an analysis project. This proposal will be submitted to the NTSS Analytic Steering Committee (ASC). If approved, you will participate in confidentiality training online. In this training you will be required to electronically sign a nondisclosure agreement, a request to access the NTSS data, a statement regarding safeguards for individuals and establishments against invasions of privacy, an agreement to abide by the policies and procedures to maintain confidentiality and data security, and the restrictions on the release of data from the NTSS.

The online training containing assurance justification, and guidelines and procedures, can be found at http://intranet.cdc.gov/nchhstp/dtbe/confidentiality/default.asp. You can also access this link through the DTBE intranet webpage. You can do this by: first logging in with your username and password to the CDC intranet homepage; once on the DTBE page, select "organization" found in "DTBE Resources" at the bottom of the page; next, scroll down to the Branches heading, select "Surveillance, Epidemiology, and Outbreak Investigations Branch" (SEOIB); lastly select launch Assurance of Confidentiality Training to begin. Copies of the forms found in the online training are also included in Appendix I of this document for your convenience.

The most recent NTSS data can be accessed in SAS format at \\cdc\project\NCHHSTP_dtbe_surv_ data\frozens\pc061114.sas7bdat. You will store project files and personally created SAS data sets in your project folder: \\cdc\project\NCHHSTP_dtbe_surv_data\[Project Name], which is created when data set access is granted.

Example:

The 2013 data set can be accessed at \\cdc\project\NCHHSTP_dtbe_surv_data\frozens\pc061114. sas7bdat. Prior year's datasets are stored at \\cdc\project\NCHHSTP_dtbe_surv_data\NTSS archive. Your study files should be maintained in the subfolder that was created for you when you received your confidentiality training. For example, \\cdc\project\NCHHSTP_dtbe_surv_data\TB Among Filipinos.

Starting with the 2013 dataset, selected genotyping variables are included with this dataset. If your approved ASC project involves the use of genotyping data prior to the 2013 dataset, there was a separate procedure to gain access to this data. If you have questions about linked genotyping and surveillance data, please contact the genotyping data steward, Steve Kammerer, (404) 639-2243, fzk3@cdc. gov.

Analytic Project Procedure Steps

Steps	Contact
 Proposal development Generate hypotheses Determine data needed RVCT only Other data sources (e.g., U.S. Census for population data) 	Project Supervisor
2. Obtain verbal approval from supervisor	Project Supervisor
 3. Submit Proposal Form via e-mail to the National TB Surveillance System (NTSS) Analytic Steering Committee (ASC) coordinator, Glenda Newell, gtn1@cdc.gov The proposal will include a brief project description with background, null hypothesis, intended analyses, and how analysis will address the null hypothesis 	ASC Coordinator
 4. Submit Analytic Plan Form via e-mail to the National TB Surveillance System (NTSS) Analytic Steering Committee (ASC) coordinator, Glenda Newell, gtn1@cdc.gov The form will include project background and methods of analysis. 	ASC Coordinator
If approval granted:	
 6. Review the Confidentiality Security Statement for the National Tuberculosis Surveillance System on-line at http://intranet.cdc.gov/nhhstp/dtbe/confidentiality/default.asp. Electronically sign and submit the Confidentiality Security Statement attachments found in the online training. These attachments are also located in the appendix of this Guide for your convenience. 	Self
 7. If necessary, receive training in SAS CDC University - Register through the HHS Learning Portal One-on-one with local SAS expert Analysis techniques / epidemiology One-on-one with local Epidemiology expert 	CDC Corporate University
8. Review TB Reference Guide for orientation to NTSS data.	Self
9. Contact the data steward, Bob Pratt (404) 639-8529, rbp5@cdc.gov, for assistance in re- questing access to NTSS data from Information Technology Services Office (ITSO).	Data Steward, ITSO
10. Obtain e-mail notice from ITSO that access to data has been granted.	ITSO
11. Perform analysis During analysis but before manuscript completion, schedule ASC presentation with Glenda Newell, (404) 639-8441, gtn1@cdc.gov	Project Supervisor
12. If necessary, request assistance with scientific writing and presentation development	Project Supervisor

Note: Contact Roque Miramontes, Surveillance Team Leader, SEOIB, at (404) 639-6306, zxi3@cdc. gov with suspected data errors. Please do not contact the reporting area or local jurisdiction directly.

Surveillance Steering Committee Proposal Form

Date submitted:

Short project title:

Principal investigator:

Co-Investigator:

Co-Authors:

Other Collaborators:

Project supervisor:

Proposed starting date:

Proposed time to finish data analysis:

Proposed time to finish manuscript draft:

Do you need SAS programming assistance?

Are you requesting statistical assistance?

Do you intend to make conclusions about any aspect of TB that are generalizable and extend beyond the population in NTSS?

If yes, please explain:

Do you intend to make conclusions about clinical aspects of TB management, including diagnosis, treatment, or outcomes?

If yes, please explain:

Do you require access to coded data elements that can be linked to identifiable information (e.g., state case number)?

If yes, please explain:

Brief project description: Please include 1) background; 2) null hypothesis/hypotheses; 3) intended analyses; and 4) how analysis will address null hypotheses.

Other expected outcomes:

Analytic Steering Committee Analytic Plan Form

- 1. Title:
- 2. Background (updated, if needed from Proposal):
- 3. Methods of Analysis:
 - a. Data sources (in addition to RVCT data; e.g., U.S. Census data, NHCS statistics)
 - b. Study population (selection criteria)
 - c. Key variables used in analysis, associated definitions if not RVCT data item
 - d. IT issues (analytic software being used, any support or planning issues)
 - e. Statistical/epi analytic approaches
- 4. Table Shells/Figures:
- 5. Study Limitations:

Section 1: Data Dictionary

Data Dictionary Introduction

To use the data maintained in the National Tuberculosis Surveillance System (NTSS), the researcher should understand how to interpret the information in the data set. The sections below introduce the revised RVCT data collection form and guidance on the variables collected. More detailed form completion instructions appear in the Report of Verified Case of Tuberculosis (RVCT) Instruction Manual. Atlanta, GA: Department of Health and Human Services, CDC June, 2009.

RVCT Form:

Data stored in the NTSS data are collected using a standard case reporting form called the Report of Verified Case of Tuberculosis (RVCT). This form lists demographic, clinical, risk factor, drug susceptibility, and treatment information for each person with a reported TB case. The current RVCT form can be found online by accessing the following link. Go to ftp://ftp.cdc.gov/pub/Software/TIMS/2009%20RVCT%20Documentation and click on Software Development Materials. Then click on 2009 RVCT Form [9-15-08] FINAL.pdf. This form replaces the previous RVCT which was used for data collection from 1993 through 2008. States that had not transitioned from TIMS by the end of 2008 used this form for 2009. The previous RVCT data can be accessed at ftp://ftp.cdc.gov/ pub/software/TIMS/documentation and click on Apx SUR II RVCT Forms with Field Names. Then, click on TIMS Archive and Documentation. Click on 2009 RVCT documentation for information on revised variables, messaging, vocabulary, training materials, etc.

The form has been revised (Rev 09/15/2008) for data collection, capturing data on new test options, testing dates, new anti-TB drugs and more. Most reporting areas began using this form in January, 2009. Prior to the revised RVCT, the form was expanded in 2003 to collect accurate race and ethnicity information in accordance with the OMB directive "Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity," available at http://www.whitehouse.gov/sites/de-fault/files/omb/assets/information_and_regulatory_affairs/re_app-a-update.pdf.

Variable Definitions:

This section consists of a table with the dataset variable name and a brief definition for each. Discontinued variables are indicated by an asterisk. More detailed coding information for calculated variables appear in Pre-calculated Variables and in Appendix 1 of this reference guide.

Section Enclosures:

- 1. RVCT Form
- 2. Variable Definitions

Variable Name	Var. Type	Code	RVCT Code Definitions
AGE	Numeric	3-Digit Number	Patient age at report date.
AGE3	Char	00-04	Patient age 0 - 4 years old at report date.
		05-14	Patient age 5 - 14 years old at report date.
		15-24	Patient age 15 - 24 years old at report date.
		25-44	Patient age 25 - 44 years old at report date.
		45-64	Patient age 45 - 64 years old at report date.
		65+	Patient age 65 or older at report date.
		UNK	Patient age unknown at report date.
ALCOHOL	Char	N	This patient has used NOT alcohol to excess within the past 12 months.
		Y	This patient has used alcohol to excess within the past 12 months
		UNK	Unknown whether this patient has used
AMIND	Char	Y	Indicates this patient considers himself or herself to be American Indian or Alaska Na- tive.
ANERGY	Char	Y	Discontinued - Was patient anergic?
		N	
		UNK	
ARRIVEDATE	Date	MMDDYYYY	The month, day and year the person first arrived in the US if s/he was born in another country. Even if this person is considered U.Sborn because at least one parent was a U.S. citizen, but was actually born in anoth- er country, record the date they first arrived in the U.S.
ASIAN	Char	Y	Indicates this patient considers him/herself to be Asian.
ASAINEXT	Char	Race Code	Indicates the Asian subcategory if the pa- tient considers him/herself to be Asian.
ASIANNME	Char	Race Code	Indicates the Asian subcategory if the pa- tient considers him/herself to be Asian.
BLACK	Char	Y	Indicates this patient considers him/herself to be black or African American.
CITY	Char	City Name	City name of the home address (permanent or temporary residence) for this patient.
CLIMITS	Char	N	Indicates patient lives outside the city limits.
		UNK	Unknown if this person lives within the city limits.
		Y	Indicates patient lives within the city limits.

Variable Name	Var. Type	Code	RVCT Code Definitions
ClusterName	Char	Specify	Two-letter state abbreviation followed by 4 digits consecutively assigned as new geno- type clusters are identified in a state (based on spoligotype and MIRU in a specific state).
ClusterName2	Char	Specify	Three-digit suffix added to Cluster Name for further discrimination of cluster using MIRU2 results.
CNEGDATE	Date	MMDDYYYY	If this patient did convert from a positive to a negative culture, the complete date that the specimen was collected for the first documented negative sputum culture. This date should be at least 1 week after the last positive was obtained, and there should be no positive cultures after this date.
CNTDATE	Date	MMDDYYYY	The month, day, and year that the health de- partment responsible for counting TB cases verified the case as TB and included it in the official case count.
CNTRYLIVCD1-3	Char	3 or 4-Letter Country Code	If the pediatric patient lived outside the U.S. for $> = 2$ mos, indicates the codes of the countries where the pediatric patient lived during this period.
CNTRYLIVNME1-3	Char	Country Name	If the pediatric patient lived outside the U.S. for $> = 2$ mos, indicates the names of the countries where the pediatric patient lived during this period.
CNTRYLN	Char	Country Name	Country of origin long name (spelled out) for this patient.
CONVERT	Char	N	This patient had an initial positive sputum culture that did NOT convert to a document- ed negative culture.
		Y	This patient had an initial positive sputum culture that converted to a documented negative culture.
		UNK	Patient had an initial positive sputum cul- ture but the results of all follow-up cultures are not known or it is not known whether follow-up cultures were done.

Variable Name	Var. Type	Code	RVCT Code Definitions
CONVREAS	Char	IMPROVE	No later specimens were found to be culture negative, because there was no f/u sputum despite induction (clinical improvt).
		NOTCOLL	No later specimens were found to be culture negative, because there no f/u sputum was collected.
		DIED	No later specimens were found to be culture negative, because the patient died.
		REFUSED	No later specimens were found to be culture negative, because the patient refused.
		ОТН	No later specimens were found to be culture negative, because of some other reason.
		UNK	No later specimens were found to be culture negative, because of an unknown reason.
		LOST	No later specimens were found to be culture negative, because the patient was lost to follow-up.
CONVSPEC	Char	Specify	If no later specimens were found to be culture negative, and the reason for not documenting sputum culture conversion is "other", specifies this other reason.
CORRICE	Char	Y	If this patient was a resident of a correc- tional facility, indicates the patient was under custody of Immigration and Customs Enforcement at the time of diagnosis.
		N	If this patient was a resident of a correction- al facility, indicates the patient was NOT under custody of Immigration and Customs Enforcement at the time of diagnosis.
CORRINST	Char	N	This patient was NOT an inmate of a correc- tional facility at the time of the TB diagnos- tic evaluation.
		Y	This patient was an inmate of a correctional facility at the time of the TB diagnostic evaluation.
		UNK	Unknown whether this patient was an in- mate of a correctional facility at the time of the TB diagnostic evaluation.

Variable Name	Var. Type	Code	RVCT Code Definitions
CORRTYPE	Char	FEDPRIS	This patient was a resident of a federal prison.
		STAPRIS	This patient was a resident of a state prison.
		LOCJAIL	This patient was a resident of a local jail.
		CORRFAC	This patient was a resident of a juvenile correctional facility.
		ОТН	This patient was a resident of an other correctional facility.
		UNK	Unknown whether this patient was a resident of a correctional facility.
СОТ	Char	Y	Yes, patient completed therapy within 1 year.
		Ν	No, patient didn't complete therapy within 1 year.
		UNK	It is unknown whether patient completed therapy within 1 year.
COTELIG	Char	Y	Patient is eligible to complete therapy within one year based on a complicated algorithm considering site of disease, ri- fampin resistance, age, whether moved out of country or died during therapy.
		Ν	Patient is not eligible to complete therapy within one year based on a complicated algorithm considering site of disease, ri- fampin resistance, age, whether moved out of country or died during therapy.
COUNTRY	Char	3-Digit Code	Discontinued - Country Code.
COUNTY	Char	County Name	County name associated with the home ad- dress (permanent or temporary residence) for this patient.
COUNTYFIPS	Char	County FIPS Code	County code associated with the home ad- dress (permanent or temporary residence) for this patient.
CPOSDATE	Date	MMDDYYYY	Discontinued - Date of the first positive sputum culture.

Variable Name	Var. Type	Code	RVCT Code Definitions
CTSCAN	Char	NOR	Initial CT Scan or other chest imaging study showed NO abnormalities consistent with TB.
		ABN	Initial CT Scan or other chest imaging study showed abnormality consistent with TB.
		NOT	Indicates initial CT Scan or other chest im- aging study was not done.
		UNK	Indicates unknown results of the initial CT Scan or other chest imaging study.
CTSCANCAV	Char	Y	If CT scan result is abnormal, there is evi- dence of 1 or more lung cavities.
		Ν	If CT scan result is abnormal, there is NO evidence of 1 or more lung cavities.
		UNK	If CT scan result is abnormal, unknown whether there is evidence of 1 or more lung cavities.
CTSCANMIL	Char	Y	If CT scan result is abnormal, there is evi- dence of miliary disease.
		N	If CT scan result is abnormal, there is NO evidence of miliary disease.
		UNK	If CT scan result is abnormal, unknown whether there is evidence of miliary disease.
CULTANA1	Char	2-Digit Ana- tomic Code	Anatomic code of first tissue or fluid cul- ture.
CULTANA2	Char	2-Digit Ana- tomic Code	Discontinued - Anatomic code of second tis- sue or fluid culture.
CULTANAT	Char	Anatomic # Code	Whether the culture result of tissue or fluid is positive or negative, the anatomic code for tissue or fluid.
CULTCOL	Date	MMDDYYYY	Indicates the date the first positive or nega- tive results of culture of tissue and other body fluids were collected. Any positive result supersedes a negative result in report- ing specimen collection dates.
CULTLAB	Char	PUB	If the results are positive, a public health reporting laboratory.
		СОМ	If the results are positive, a commercial reporting laboratory.
		OTH	If the results are positive, an other reporting laboratory.

Variable Name	Var. Type	Code	RVCT Code Definitions
CULTOTHR C	Char	POS	Indicates a positive result of culture ex- amination of any tissue or fluid other than sputum.
		NEG	Indicates a negative result of culture ex- amination of any tissue or fluid other than sputum.
		NOT	Indicates culture examination of any tissue or fluid other than sputum was not done.
		UNK	Indicates an unknown culture examina- tion result of any tissue or fluid other than sputum.
CULTREP	Date	MMDDYYYY	For the first tissue or fluid culture reported to be positive, the month, day, and year the result was reported by the laboratory.
DateReceived	Date	MMDDYYYY	Date the genotyping laboratory received the isolate from the state laboratory.
DATESUBM	Date	MMDDYYYY	The month, day, and year the RVCT form (questions 1-32) was submitted to or completed by the reporting area.
DEATHDATE	Date	MMDDYYYY	If the patient was dead at the time of TB di- agnosis, the month, day, and year the patient died.
DIS_SITE	Char	BOTH	Both pulmonary and extrapulmonary site of disease.
		EXTRAPULM ONLY	Extrapulmonary site of disease only.
		PULM ONLY	Pulmonary site of disease only.
		UNK	Unknown site of disease.
DOT	Char	Ν	This patient did NOT receive directly observed therapy, it was totally self-admin-istered.
		Y	This patient received totally directly ob- served therapy.
		BOTH	This patient received both directly observed therapy and self-administered therapy.
		UNK	Unknown whether this patient received directly observed therapy.

Variable Name	Var. Type	Code	RVCT Code Definitions
DOTSITE	Char	ВОТН	Site of directly observed therapy is both at a clinic or other healthcare facility and in the field.
		CLINIC	Site of directly observed therapy is at a clinic or other healthcare facility.
		FIELD	Site of directly observed therapy is in the field.
		UNK	Site of directly observed therapy is un- known.
DOTWEEKS	Char	# Weeks of DOT	Number of weeks of DOT.
DURATION	Numeric	days	Duration of therapy in days (start date - end date).
ETHNIC	Char	HISP	Indicates this patient considers himself or herself to be of Hispanic origin.
		NONHISP	Indicates this patient considers himself or herself NOT to be of Hispanic origin.
		UNK	Unknown ethnicity.
EXTCLINIC	Char	Y	Indicates the reason therapy was extended >12 months was because of clinical indica- tions (other than adverse drug reactions).
EXTFAIL	Char	Y	Indicates the reason therapy was extended >12 months was because a sputum specimen tested positive 4 or more months after treatment program.
EXTNONAD	Char	Y	Indicates the reason therapy was extended >12 months was because there were barriers to the patient's adherence to anti-TB therapy.
EXTOTH	Char	Y	Indicates the reason therapy was extended >12 months was for some other reason.
EXTREACT	Char	Y	Indicates the reason therapy was extended >12 months was because the patient had a significant adverse drug reaction.
EXTRIF	Char	Y	Indicates the reason therapy was extended >12 months was because the patient was resistant to rifampin.
EXTSPEC	Char	Specify	Specifies the other reason for why therapy was extended >12 months.

Variable Name	Var. Type	Code	RVCT Code Definitions
FalsePositive	Char	Y	Indicates an isolate that is believed to be positive due to a laboratory or clerical error, rather than due to TB disease in the patient.
		Ν	Indicates an isolate that is NOT believed to be positive due to a laboratory or clerical error, rather than due to TB disease in the patient.
FIRSTLINE	Char	Y	Yes, patient has firstline drug resistance.
		Ν	No, patient does not have firstline drug resistance.
FSUSAM	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for amikacin (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for amikacin (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for amikacin (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for amikacin (if done).
FSUSANA	Char	Anatomic Code #	If final drug susceptibility testing was done with a non-sputum specimen type, indicates the anatomic code of the appropriate site.
FSUSCAP	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for capreomycin (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for capreomycin (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for capreomycin (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for capreomycin (if done).

Variable Name	Var. Type	Code	RVCT Code Definitions
FSUSCIP	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for ciprofloxacin (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for ciprofloxacin (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for ciprofloxacin (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for ciprofloxacin (if done).
FSUSCYC	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for cycloserine (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for cycloserine (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for cycloserine (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for cycloserine (if done).
FSUSDATE	Date	MMDDYYYY	If follow-up drug susceptibility was done, the complete collection date of the first iso- late on which follow-up drug susceptibility testing was performed.
FSUSEMB	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for ethambutol (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for ethambutol (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for ethambutol (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for ethambutol (if done).

Variable Name	Var. Type	Code	RVCT Code Definitions
FSUSETH	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for ethionamide (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for ethionamide (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for ethionamide (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for ethionamide (if done).
FSUSINH	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for isoniazid (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for isoniazid (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for isoniazid (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for isoniazid (if done).
FSUSKAN	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for kanamycin (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for kanamycin (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for kanamycin (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for kanamycin (if done).

Variable Name	Var. Type	Code	RVCT Code Definitions
FSUSLEVO	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for levofloxacin (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for levofloxacin (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for levofloxacin (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for levofloxacin (if done).
FSUSMOXI	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for moxifloxacin (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for moxifloxacin (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for moxifloxacin (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for moxifloxacin (if done).
FSUSOFL	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for ofloxacin (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for ofloxacin (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for ofloxacin (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for ofloxacin (if done).

Variable Name	Var. Type	Code	RVCT Code Definitions
FSUSOTH1	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for the last other drug (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for the first other drug (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for the first other drug (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for the first other drug (if done).
FSUSOTH2	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for the second other drug (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for the second other drug (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for the second other drug (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for the second other drug (if done).
FSUSPAS	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was performed for para-amino salicylic acid (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for para-amino salicylic acid (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for para-amino salicylic acid (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was performed for para-amino salicylic acid (if done).

Variable Name	Var. Type	Code	RVCT Code Definitions
FSUSPZA	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for pyrazinamide (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for pyrazinamide (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for pyrazinamide (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for pyrazinamide (if done).
FSUSQUIN	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for other quinolones (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for other quinolones (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for other quinolones (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for other quinolones (if done).
FSUSRIB	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for rifabutin (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for rifabutin (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for rifabutin (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for rifabutin (if done).

Variable Name	Var. Type	Code	RVCT Code Definitions
FSUSRIF	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for rifampin (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for rifampin (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for rifampin (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for rifampin (if done).
FSUSRPT	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for rifapentine (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for rifapentine (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for rifapentine (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for rifapentine (if done).
FSUSSM	Char	R	Resistant results of susceptibility testing on the last isolate for which testing was per- formed for streptomycin (if done).
		S	Susceptibility results of susceptibility test- ing on the last isolate for which testing was performed for streptomycin (if done).
		NOT	Susceptibility testing NOT done on the last isolate for which testing was performed for streptomycin (if done).
		UNK	Unknown results of susceptibility testing on the last isolate for which testing was per- formed for streptomycin (if done).
FSUSSPEC1	Char	Specify	If susceptibility testing was done for another drug, specifies the name of the first other drug.
FSUSSPEC2	Char	Specify	If susceptibility testing was done for another drug, specifies the name of the second other drug.

Variable Name	Var. Type	Code	RVCT Code Definitions
FSUSSPUT	Char	Y	Final drug susceptibility testing was done, indicates a sputum specimen type.
		N	Final drug susceptibility testing was done, indicates a NON sputum specimen type.
FSUSTEST	Char	N	This patient did NOT had follow-up drug susceptibility testing done.
		Y	This patient had follow-up drug susceptibil- ity testing done.
		UNK	Unknown whether this patient had follow- up drug susceptibility testing done.
GeneFamily	Char	Indo-Oceanic	One of seven phylogenetic lineages: Indo-
		East Asian	Oceanic, East Asian, East African Indian,
		East African	Euro-American, Mycobacterium Bovis, or
		Indian	Mycobacterium Africanum (assigned by
		Euro-American	CDC Iab).
		Mycobacterium	
		Bovis	
		Mycobacterium	
		Africanum	
GeneSubFamily	Char	Specify	Sublineages of Euro-American and Indo-
	<u> </u>	ļ	Oceanic (assigned by CDC lab).
GENONUMB	Char	Genotyping Ac-	If an isolate was submitted for genotyping,
		cession #	indicates the genotyping accession num-
			ber for the current 1B case assigned by the
GenoStatus	Char	Genotyped	Genotyping information is available for the
Genostatus		Genotyped	TB patient.
		Genotyped	TB patient with more than one genotype re-
		Unresolved	sult where a result has not been "selected".
		Missing	Genotyping information is not available for the TB patient.
GENOTYPE	Char	Y	The isolate was submitted for genotyping.
		Ν	The isolate was NOT submitted for geno-
GenotyneCreateDate	Date		Date a complete genotype result is available
Genotypeereatebate	Dute		in TB GIMS; assigned only when BOTH
			Spoligotype AND MIRU/MIRU2 have been
			reported.
GenotypeReportDate	Date	MMDDYYYY	Date a genotype result is first reported
			(i.e. has either spoligotype OR MIRU and
			MIRU2).

Variable Name	Var. Type	Code	RVCT Code Definitions
GenType	Char	Specify	National designation assigned to each unique combination of spoligotype and 24-locus-MIRU (MIRU) identified in the U.S.
GUARDCD1	Char	3 or 4-Letter Country Code	Indicates the code of the country where the first primary guardian was born.
GUARDCD2	Char	3 or 4-Letter Country Code	Indicates the code of the country where the second primary guardian was born.
GUARDNME1	Char	Country Name	Indicates the name of the country where the first primary guardian was born.
GUARDNME2	Char	Country Name	Indicates the name of the country where the second primary guardian was born.
HIVBASE	Char	MEDICAL DOCS	Discontinued - HIV status is based upon a medical documentation.
		PT HISTORY	Discontinued - HIV status is based upon patient history.
		UNK	Discontinued - Basis of HIV status is un- known.
HIVCDCNO	Numeric	7-Digit Number	Discontinued - Patient's CDC # if HIV sta- tus is positive.
HIVLOCNO	Char	City/County HIV/AIDS #	If HIV status is positive, the City/County HIV/AIDS patient number (if AIDS report- ed in 1993 or later).
HIVSTANO	Char	State HIV/ AIDS #	If HIV status is positive, the State HIV/ AIDS patient number (if AIDS reported in 1993 or later).
HIVSTAT	Char	NEG	Laboratory HIV test result is negative.
		POS	Laboratory HIV test result is positive.
		IND	Laboratory HIV test result is indeterminate.
		REFUSED	Refused to have HIV test done.
		NOTOFFRD	Laboratory HIV test not offered.
		TDUNK	Laboratory HIV test done, but result is unknown.
		UNK	HIV status is unknown.
HOMELESS	Char	Ν	This patient was NOT homeless at any time during the past 12 months prior to the TB diagnostic evaluation.
		Y	This patient was homeless at any time during the past 12 months prior to the TB diagnostic evaluation.
		UNK	Unknown whether this patient was homeless at any time during the past 12 months prior to the TB diagnostic evaluation.

Variable Name	Var. Type	Code	RVCT Code Definitions
IDU	Char	Ν	This patient has NOT injected illegal drugs
			within the past 12 months.
		Y	This patient has injected illegal drugs within
			the past 12 months.
		UNK	Unknown whether this patient has injected
			illegal drugs within the past 12 months.
IMMIGSTAT	Char	NA	Patient's immigration status at first entry
			into the U.S.: N/A.
		IMMVISA	Patient's immigration status at first entry
			into the U.S.: immigrant visa.
		STUVISA	Patient's immigration status at first entry
			into the U.S.: student visa.
		EMPLVISA	Patient's immigration status at first entry
			into the U.S.: employment visa.
		TOURVISA	Patient's immigration status at first entry
			into the U.S.: tourist visa.
		FAMVISA	Patient's immigration status at first entry
			into the U.S.: family visa.
		REFUGEE	Patient's immigration status at first entry
			into the U.S.: refugee.
		ASYLUM	Patient's immigration status at first entry
			into the U.S.: asylee/parolee.
		ОТН	Patient's immigration status at first entry
			into the U.S.: other.
		UNK	Patient's immigration status at first entry
			into the U.S. is unknown.
INITAM	Char	Ν	Amikacin is NOT part of the initial treat-
			ment regimen for the disease, and was NOT
			taken for at least 2 weeks.
		Y	Amikacin is part of the initial treatment
			regimen for the disease, and was taken for at
			least 2 weeks.
		UNK	Unknown if amikacin is part of the initial
			treatment regimen for the disease.
INITCAP	Char	N	Capreomycin is NOT part of the initial
			treatment regimen for the disease, and was
			NOT taken for at least 2 weeks.
		Y	Capreomycin is part of the initial treatment
			regimen for the disease, and was taken for at
			least 2 weeks.
		UNK	unknown if capreomycin is part of the initial
			treatment regimen for the disease.

Variable Name	Var. Type	Code	RVCT Code Definitions
INITCIP	Char	Ν	Ciprofloxacin is NOT part of the initial treatment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Ciprofloxacin is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if ciprofloxacin is part of the ini- tial treatment regimen for the disease.
INITCYC	Char	Ν	Cycloserine is NOT part of the initial treat- ment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Cycloserine is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if cycloserine is part of the initial treatment regimen for the disease.
INITDRG	Char	NO DRUGS	Initial treatment regimen includes no drugs.
		ONE DRUG	Initial drug regimen includes one and only one drug.
		IR	Initial treatment regimen includes isoniazid and rifampin only.
		IRZ	Initial treatment regimen includes isoniazid, rifampin, and pyrazinamide only.
		IRZE	Initial treatment regimen includes isoniazid, rifampin, pyrazinamide, and ethambutol only.
		OTHMULT	Initial treatment regimen includes two or more drugs that does not exactly match IR, IRZ, and IRZE.
		UNK	Initial treatment regimen is unknown.
INITEMB	Char	N	Ethambutol is NOT part of the initial treat- ment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Ethambutol is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if ethambutol is part of the initial treatment regimen for the disease.

Variable Name	Var. Type	Code	RVCT Code Definitions
INITETH	Char	N	Ethionamide is NOT part of the initial treat- ment regimen for the disease, and was taken for at least 2 weeks.
		Y	Ethionamide is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if ethionamide is part of the initial treatment regimen for the disease.
INITINH	Char	Ν	Isoniazid was NOT part of the initial treat- ment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Isoniazid is part of the initial treatment regi- men for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if isoniazid is known to be part of the initial treatment regimen for the disease.
INITKAN	Char	Ν	Kanamycin is NOT part of the initial treat- ment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Kanamycin is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if kanamycin is part of the initial treatment regimen for the disease.
INITLEVO	Char	N	Levofloxacin is NOT part of the initial treat- ment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Levofloxacin is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if levofloxacin is part of the initial treatment regimen for the disease.
INITMOXI	Char	N	Moxifloxacin is NOT part of the initial treatment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Moxifloxacin is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if moxifloxacin is part of the ini- tial treatment regimen for the disease.

Variable Name	Var. Type	Code	RVCT Code Definitions
INITOFL	Char	Ν	Ofloxacin is NOT part of the initial treat- ment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Ofloxacin is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if ofloxacin is part of the initial treatment regimen for the disease.
INITOTH1	Char	Ν	Another drug not listed is NOT part of the initial treatment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Another drug not listed is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if another drug not listed is part of the initial treatment regimen for the disease.
INITOTH2	Char	N	Another drug not listed is NOT part of the initial treatment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Another drug not listed is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if another drug not listed is part of the initial treatment regimen for the disease.
INITPAS	Char	Ν	Para-amino salicylic acid is NOT part of the initial treatment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Para-amino salicylic acid is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if para-amino salicylic acid is part of the initial treatment regimen for the disease.
INITPZA	Char	N	Pyrazinamide was NOT part of the initial treatment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Pyrazinamide is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if pyrazinamide is part of the ini- tial treatment regimen for the disease.

Variable Name	Var. Type	Code	RVCT Code Definitions
INITRIB	Char	Ν	Rifabutin is NOT part of the initial treat- ment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Rifabutin is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if rifabutin is part of the initial treatment regimen for the disease.
INITRIF	Char	Ν	Rifampin was NOT part of the initial treat- ment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Rifampin is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if rifampin is part of the initial treatment regimen for the disease.
INITRPT	Char	N	Rifapentine is NOT part of the initial treat- ment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Rifapentine is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if rifapentine is part of the initial treatment regimen for the disease.
INITSM	Char	Ν	Streptomycin is NOT part of the initial treatment regimen for the disease, and was NOT taken for at least 2 weeks.
		Y	Streptomycin is part of the initial treatment regimen for the disease, and was taken for at least 2 weeks.
		UNK	Unknown if streptomycin is part of the ini- tial treatment regimen for the disease.
INITSPEC1	Char	Specify	If another drug is part of the initial treat- ment regimen for the disease, indicates the specific name of the first other drug.
INITSPEC2	Char	Specify	If another drug is part of the initial treat- ment regimen for the disease, indicates the specific name of the second other drug.
INTFGCOL	Date	MMDDYYYY	For positive or negative IGRA results, the month, day, and year the blood sample was collected.

Variable Name	Var. Type	Code	RVCT Code Definitions
INTFGSPEC	Char	Specify	For pos or neg IGRA results, indicates the specific type of IGRA blood test performed (e.g. QuantiFERON- TB Gold Test [QFT-G]).
INTFGTEST	Char	POS	Indicates positive results of the Interferon Gamma Release Assay (IGRA) used to de- tect TB infection.
		NEG	Indicates negative results of the Interferon Gamma Release Assay (IGRA) used to de- tect TB infection.
		NOT	Indicates the Interferon Gamma Release As- say (IGRA) was NOT done.
		UNK	Indicates unknown results of the Interferon Gamma Release Assay (IGRA) used to de- tect TB infection.
		IND	Indicates indeterminate results of the Inter- feron Gamma Release Assay (IGRA) used to detect TB infection.
IsolateType	Char	Specify	Type of culture that is being shipped to the genotyping lab (i.e. LJ slant or MGIT broth).
ISUSAM	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for amikacin (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for amikacin (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for amikacin (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for amikacin (if done).
ISUSANA	Char	Anatomic Code #	If the initial drug susceptibility testing was done with a non-sputum specimen type, indicates the anatomic code of the appropri- ate site.

Variable Name	Var. Type	Code	RVCT Code Definitions
ISUSCAP	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for capreomycin (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for capreomycin (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for capreomycin (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for capreomycin (if done).
ISUSCIP	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for ciprofloxacin (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for ciprofloxacin (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for ciprofloxacin (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for ciprofloxacin (if done).
ISUSCYC	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for cycloserine (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for cycloserine (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for cycloserine (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for cycloserine (if done).
ISUSDATE	Date	MMDDYYYY	If drug susceptibility was done, the com- plete collection date of the first isolate on which susceptibility was performed.

Variable Name	Var. Type	Code	RVCT Code Definitions
ISUSEMB	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for ethambutol (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for ethambutol (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for ethambutol (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for ethambutol (if done).
ISUSETH	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for ethionamide (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for ethionamide (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for ethionamide (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for ethionamide (if done).
ISUSINH	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for isoniazid (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for isoniazid (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for isoniazid (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for isoniazid (if done).
Variable Name	Var. Type	Code	RVCT Code Definitions
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ISUSKAN	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for kanamycin (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for kanamycin (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for kanamycin (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for kanamycin (if done).
ISUSLEVO	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for levofloxacin (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for levofloxacin (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for levofloxacin (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for levofloxacin (if done).
ISUSMOXI	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for moxifloxacin (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for moxifloxacin (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for moxifloxacin (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for moxifloxacin (if done).

Variable Name	Var. Type	Code	RVCT Code Definitions
ISUSOFL	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for ofloxacin (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for ofloxacin (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for ofloxacin (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for ofloxacin (if done).
ISUSOTH1	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for the first other drug (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for the first other drug (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for the first other drug (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for the first other drug (if done).
ISUSOTH2	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for the second other drug (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for the second other drug (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for the second other drug (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for the second other drug (if done).

Variable Name	Var. Type	Code	RVCT Code Definitions
ISUSPAS	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was performed for para-amino salicylic acid (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for para-amino salicylic acid (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for para-amino salicylic acid (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was performed for para-amino salicylic acid (if done).
ISUSPZA	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for pyrazinamide (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for pyrazinamide (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for pyrazinamide (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for pyrazinamide (if done).
ISUSQUIN	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for other quinolones (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for other quinolones (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for other quinolones (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for other quinolones (if done).

Variable Name	Var. Type	Code	RVCT Code Definitions
ISUSRIB	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for rifabutin (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for rifabutin (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for rifabutin (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for rifabutin (if done).
ISUSRIF	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for rifampin (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for rifampin (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for rifampin (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for rifampin (if done).
ISUSRPT	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for rifapentine (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for rifapentine (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for rifapentine (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for rifapentine (if done).

Variable Name	Var. Type	Code	RVCT Code Definitions
ISUSSM	Char	R	Resistant results of susceptibility testing on the first isolate for which testing was per- formed for streptomycin (if done).
		S	Susceptibility results of susceptibility test- ing on the first isolate for which testing was performed for streptomycin (if done).
		NOT	Susceptibility testing NOT done on the first isolate for which testing was performed for streptomycin (if done).
		UNK	Unknown results of susceptibility testing on the first isolate for which testing was per- formed for streptomycin (if done).
ISUSSPEC1	Char	Specify	If susceptibility testing was done for another drug, specifies the name of the first other drug.
ISUSSPEC2	Char	Specify	If susceptibility testing was done for another drug, specifies the name of the second other drug.
ISUSSPUT	Char	Y	If initial drug susceptibility testing was done, indicates a sputum specimen.
		Ν	If initial drug susceptibility testing was done, indicates a NON sputum specimen.
ISUSTEST	Char	Ν	This patient has NO isolates upon which drug susceptibility testing was performed.
		Y	This patient has isolates upon which drug susceptibility testing was performed.
		UNK	Unknown if this patient has any isolate upon which drug susceptibility testing was per- formed.
LKCASE1NO	Char	Case #	Indicates the ID number of the first linked case.
LKCASE1ST	Char	2-Letter State Code	Indicates the 2-letter postal code of the state reporting this first linked case.
LKCASE1YR	Char	YYYY	Indicates the year the first linked case is reported (YYYY).
LKCASE2NO	Char	Case #	Indicates the ID number of the second linked case.
LKCASE2ST	Char	2-Letter State Code	Indicates the 2-letter postal code of the state reporting this second linked case.
LKCASE2YR	Date	YYYY	Indicates the year the second linked case is reported (YYYY).

Variable Name	Var. Type	Code	RVCT Code Definitions
LKREAS1	Char	1	Reason for linking this first case to the cur- rent case: a recurrence or a previous diagno- sis of TB.
		2	Reason for linking this first case to the cur- rent case: epidemiologically linked case, source case, or contact with another case.
		3	Reason for linking this first case to the current case: case transferred from another area.
LKREAS2	Char	1	Reason for linking this second case to the current case: a recurrence or a previous diagnosis of TB.
		2	Reason for linking this second case to the current case: epidemiologically linked case, source case, or contact with another case.
		3	Reason for linking this first second to the current case: case transferred from another area.
LOCALID	Char	Alphanumeric	Unique patient identifier assigned at the lo- cal level.
LONGTERM	Char	N	This patient was NOT a resident of a long- term care facility at the time of the TB diagnostic evaluation.
		Y	This patient was a resident of a long-term care facility at the time of the TB diagnostic evaluation.
		UNK	Unknown whether this patient was a resident of a long-term care facility at the time of the TB diagnostic evaluation.
LONGTYPE	Char	NURSING	This patient was a resident of a nursing home long-term care facility.
		HOSPITAL	This patient was a resident of a hospital- based long-term care facility.
		RESID	This patient was a resident of a residential long-term care facility.
		MENTAL	This patient was a resident of a mental health long-term care facility.
		ALCDRUG	This patient was a resident of an alcohol/ drug treatment long-term care facility.
		ОТН	This patient was a resident of an other long- term care facility.
		UNK	Unknown whether this patient was a resident of a long-term care facility.

Variable Name	Var. Type	Code	RVCT Code Definitions
MAJSITE	Char	2-Letter Code	Major Site of Disease.
MDR	Char	Y	Patient has a multi-drug resistant case of TB based on initial susceptibility testing.
		Ν	Patient does not have a multi-drug resistant case of TB based on initial susceptibility testing.
		UNK	Uncertain whether patient has a multi-drug resistant case of TB due to insufficient ini- tial susceptibility testing.
MICRANA1	Char	2-Digit Ana- tomic Code	Anatomic code of first tissue or fluid exam.
MICRANA2	Char	2-Digit Ana- tomic Code	Discontinued - Anatomic code of second tis- sue or fluid exam.
MICRANAT	Char	Anatomic # Code	Whether the result of tissue or fluid exam is positive or negative, the anatomic code for tissue or fluid.
MICRCOL	Date	MMDDYYYY	Indicates the date the first positive or nega- tive results of an examination for a smear or, pathology, or cytology of tissue and/or other body fluids were collected. Any positive result supersedes a negative result in report- ing specimen collection dates.
MICREXAM	Char	POS	Indicates positive results of microscopic examination of any tissue or fluid other than sputum.
		NEG	Indicates negative results of microscopic examination of any tissue or fluid other than sputum.
		NOT	Indicates microscopic examination of any tissue or fluid other than sputum was not done.
		UNK	Indicates unknown results of microscopic examination of any tissue or fluid other than sputum.
MICRPATH	Char	Y	Indicates the type of exam that corresponds with pos or neg results was for pathology/ cytology.
MICRSMR	Char	Y	Indicates the type of exam that corresponds with pos or neg results was a smear.
MILIARY	Char	Y	Yes, there is evidence of miliary disease.
		N	No, there is not evidence of miliary disease
		UNK	It is unknown whether there is evidence of miliary disease

Variable Name	Var. Type	Code	RVCT Code Definitions
MIRU	Char	Specify	Result of 12-loci mycobacterial interspersed repetitive units (MIRU) typing. Generates a 12-character string.
MIRU2	Char	Specify	Result of additional 12-loci MIRU (for a total of 24-loci). MIRU2 was only routinely performed after March 2009. It can be requested on pre-2009 isolates.
MOVCITYNME1-2	Char	City Name	If the patient moved in-state, but out-of- jurisdiction, specifies first/second city to which the patient moved to.
MOVCNTYNME1-2	Char	County Name	If the patient moved in-state, but out-of-ju- risdiction, specifies first/second county long name to which the patient moved to.
MOVCTRYCD1-2	Char	Country 3 or 4-Letter Code	If the patient moved out of the U.S., speci- fies the first/second country alpha code the patient moved to.
MOVCTRYNME1-2	Char	Country Name	If the patient moved out of the U.S., speci- fies the first/second country long name the patient moved to.
MOVED	Char	Y	The patient moved outside the local report- ing jurisdiction during TB therapy.
		N	The patient did NOT move outside the local reporting jurisdiction during TB therapy.
MOVINST	Char	Y	If the patient moved during TB therapy, indicates the patient moved within the state, but out of the local health department jurisdiction (e.g., moved to another city or county).
MOVOUTST	Char	Y	If the patient moved during TB therapy, indicates the patient moved out of the state.
MOVOUTUS	Char	Y	If the patient moved during TB therapy, indicates the patient moved from the U.S. to another country.
MOVREF	Char	Y	If the patient moved out of the U.S., a refer- ral was made to a TB program or physician outside of the U.S.
		Ν	If the patient moved out of the U.S., a referral was NOT made to a TB program or physician outside of the U.S.
MOVSTATECD1-2	Char	State code	If the patient moved out of state, specifies the first/second state or reporting area the patient moved to.

Variable Name	Var. Type	Code	RVCT Code Definitions
NAAANA	Char	Anatomic # Code	If the specimen is not sputum, the anatomic code that represents the appropriate specimen.
NAACOL	Date	MMDDYYYY	Indicates the date the first positive or nega- tive results of NAA testing were collected. Any positive result supersedes a negative re- sult in reporting specimen collection dates.
NAALAB	Char	PUB	For positive NAA test results, a public health reporting laboratory.
		СОМ	For positive NAA test results, a commercial reporting laboratory.
		ОТН	For positive NAA test results, an other reporting laboratory.
NAAREP	Date	MMDDYYYY	For the first NAA test result reported posi- tive, the month, day, and year the result was reported by the laboratory.
NAASPUT	Char	Y	Indicates a sputum specimen on which NAA testing was done.
		Ν	Indicates NOT a sputum specimen on which NAA testing was done.
NAATEST	Char	POS	Indicates the positive result for any NAA test that has been approved by the FDA and CLIA. Any positive result supersedes all other test results.
		NEG	Indicates a negative result for any NAA test that has been approved by the FDA and CLIA.
		NOT	Indicates an NAA test was not done.
		UNK	Indicates an unknown result for any NAA test that has been approved by the FDA and CLIA.
		IND	Indicates an indeterminate result for any NAA test that has been approved by the FDA and CLIA.
NAHAW	Char	Y	Indicates this patient considers himself or herself to be Native Hawaiian or other Pa- cific Islander.
NAHAWEXT	Char	Race Code	Indicates the Native Hawaiian or Other Pacific Islander subcategory if the patient considers him/herself to be NAHAW.
NAHAWNME	Char	Race Code	Indicates the Native Hawaiian or Other Pacific Islander subcategory if the patient considers him/herself to be NAHAW.

Variable Name	Var. Type	Code	RVCT Code Definitions
NATION	Char	3 or 4-Letter Country Code	The country in which this patient held citizenship during the early years of life, whether or not the person was U.S. born. The three-letter abbreviation of the coun- try of origin is entered. This field has been expanded to include USBORN persons who were not born in the U.S., but have parents of U.S. citizenship.
NONCNTREAS	Char	US	The verified TB case was NOT counted by the jurisdiction because it was counted by another U.S. area.
		OOC	The verified TB case was NOT counted by the jurisdiction because TB treatment was initiated in another country.
		REC	The verified TB case was NOT counted by the jurisdiction because it was a recurrent case within 12 months after completion of therapy.
NONIDU	Char	N	This patient has NOT used noninjecting drugs within the past 12 months.
		Y	This patient has used noninjecting drugs within the past 12 months.
		UNK	Unknown whether this patient has used non- injecting drugs within the past 12 months.
NONSPEC	Char	Specify	If the current case is NOT counted, specifies the country where it was counted.
OCCUCORR	Char	Y	Discontinued - Occupation: Correctional Employee.
OCCUHCW	Char	Y	Discontinued - Occupation: Health Care Worker.
OCCUMIGR	Char	Y	Discontinued - Occupation: Migratory Agri- cultural Worker.
OCCUOTH	Char	Y	Discontinued - Occupation: Other.
OCCUUNEM	Char	Y	Discontinued - Occupation: Unemployed.
OCCUUNK	Char	Υ	Discontinued - Occupation: Unknown.
OCCUPATN	Char	CORR HCW	Discontinued - Calculated variable for oc- cupation based on all responses that apply
		MIGR	within the past 24 months.
		MULT	4
			4
			4
		UNK	

Variable Name	Var. Type	Code	RVCT Code Definitions
OLDCOTELIG	Char	Y	Patient is eligible to complete therapy within one year based on a complicated al- gorithm considering site of disease, rifampin resistance, age, whether died during therapy.
		Ν	Patient is not eligible to complete therapy within one year based on a complicated al- gorithm considering site of disease, rifampin resistance, age, and/or whether died during therapy.
ORIGIN	Char	FBORN	Born outside the U.S. or in a U.Saffiliated jurisdiction.
		USBORN	Born in the U.S., born abroad of a U.S. citi- zen or born in a U.Saffiliated jurisdiction.
		UNK	Unknown origin of birth.
OUTUS	Char	Y	If the person is younger that 15 years of age, this person lived outside of the U.S. for an uninterrupted period of more than 2 months.
		Ν	If the person is younger that 15 years of age, this person did NOT live outside of the U.S. for an uninterrupted period of more than 2 months.
		UNK	If the person is younger that 15 years of age, unknown whether this person lived outside of the U.S. for an uninterrupted period of more than 2 months.
РСКТуре	Char	Specify	National designation assigned to each unique combination of spoligotype and 12-locus-MIRU (MIRU) identified in the U.S.
PREVMULT	Char	Y	Discontinued - Indicates patient had mul- tiple previous episodes of TB.
PREVTB	Char	Ν	Indicates this patient has NOT had a previous diagnosis of TB.
		UNK	Unknown whether this patient has had a previous diagnosis of TB.
		Y	Indicates this patient has had a previous diagnosis of TB, defined as having had veri- fiable disease in the past, been discharged or lost to supervision for more than 12 consecutive months, and then had verifiable disease again.

Variable Name	Var. Type	Code	RVCT Code Definitions
PREVYR	Char	YYYY	If there was a previous case of TB, provides the year in which this patient's previous episode of TB was diagnosed. If this patient had more than one previous episode, the most recent year is listed.
PRIMARYOCC	Char	HCW	Patient's occupation within the 12 months before TB evaluation: health care worker.
		CORR	Patient's occupation within the 12 months before TB evaluation: correctional facility employee.
		MIGR	Patient's occupation within the 12 months before TB evaluation: migrant/seasonal worker.
		ОТН	Patient's occupation within the 12 months before TB evaluation: other occupation.
		UNEMP	Patient's occupation within the 12 months before TB evaluation: unemployed.
		RETIRED	Patient's occupation within the 12 months before TB evaluation: retired.
		NOTSEEK	Patient's occupation within the 12 months before TB evaluation: not seeking employment.
		UNK	Patient's occupation within the 12 months before the diagnostic TB evaluation is un-known.
PROVCORR	Char	Y	Indicates nursing homes, assisted living facilities, or all types of correctional facili- ties had primary responsibility for clinical outpatient decision making.
PROVHD	Char	Y	Indicates a TB program or a health clinic of a health department had primary responsi- bility for clinical outpatient decision mak- ing.
PROVIHS	Char	Y	Indicates Indian Health Services (IHS), a tribal health department, or a tribal corpora- tion had primary responsibility for clinical outpatient decision making.
PROVINPAT	Char	Y	Indicates a patient did not receive outpatient TB care; only inpatient care was provided in a hospital.
PROVOTH	Char	Y	Indicates some other provider had primary responsibility for clinical outpatient decision making.

Variable Name	Var. Type	Code	RVCT Code Definitions
PROVPRIV	Char	Y	Indicates a private physician or health care provider, HMO, or private managed health care provider had primary responsibility for clinical outpatient decision making.
PROVTYPE	Char	BOTH HEALTH	Calculated variable for type of health care provider.
		DEPT	-
		PRIV / OTH	
		UNK	
PROVUNK	Char	Y	Indicates the provider who has primary re- sponsibility for clinical outpatient decision making is not known.
RACECALC	Char	AMIND	American Indian or Alaska Native.
		ASIAN	Asian.
		BLACK	Black or African American.
		MULT	Multiple Race.
		NAHAW	Native Hawaiian or Other Pacific Islander.
		WHITE	White.
		UNK	Unknown race.
RACEHISP	Char	AMIND	American Indian or Alaska Native, non Hispanic.
		ASIAN	Asian, non Hispanic.
		BLACK	Black or African American, non Hispanic.
		HISP	Hispanic.
		MULT	Multiple race, non Hispanic.
		NAHAW	Native Hawaiian or Other Pacific Islander, non Hispanic.
		WHITE	White, non Hispanic.
		UNK	Unknown race or unknown ethnicity.

Variable Name	Var. Type	Code	RVCT Code Definitions
REASONEVAL	Char	TBSYMP	Indicates the single primary reason patient evaluated: TB symptoms.
		ABXRAY	Indicates the single primary reason patient evaluated: Abnormal chest x-ray.
		CONTACT	Indicates the single primary reason patient evaluated: contact investigation.
		TARGET	Indicates the single primary reason patient evaluated: targeted testing.
		HCW	Indicates the single primary reason patient evaluated: health care worker.
		EMPTEST	Indicates the single primary reason patient evaluated: employment/admin testing.
		IMMEXAM	Indicates the single primary reason patient evaluated: immigration medical exam.
		INCIDENT	Indicates the single primary reason patient evaluated: incident lab result.
		UNK	Indicates the single primary reason patient evaluated is unknown.
RISKDIAB	Char	Y	This patient has a diagnosis of diabetes mel- litus (Type I or Type II) either before or at the time of TB diagnosis.
RISKIMMUNO	Char	Y	This patient had immunosuppression due to either a medical condition or medication, or immunosuppressive therapy.
RISKINFECT	Char	Y	This patient is a contact of an infectious TB patient within 2 years or less.
RISKLTBI	Char	Y	This patient had a previous diagnosis of latent TB infection (LTBI) and did not com- plete treatment for LTBI.
RISKMDR	Char	Y	This patient is a contact of a patient with multi-drug resistant (MDR) TB, within 2 years or less, regardless of whether the pa- tient with MDR TB was infectious.
RISKMISSED	Char	Y	This patient is a contact of a known TB patient, but was not evaluated or diagnosed with LTBI or TB at that time.
RISKNONE	Char	Y	This patient has no TB risk factors that could be identified.
RISKORGAN	Char	Y	This patient has received a solid organ transplant (e.g. kidney, heart).
RISKOTH	Char	Y	This patient had a risk factor other than those listed.

Variable Name	Var. Type	Code	RVCT Code Definitions
RISKRENAL	Char	Y	This patient had end-stage renal disease
			or chronic renal failure at the time of TB
			diagnosis.
RISKSPEC	Char	Specify	If other TB risk factors were identified,
			specifies comments regarding these factors.
RISKTNF	Char	Y	This patient had recently received, or was
			receiving, TNF-alpha antagonist therapy at
			the time of TB diagnosis.
RPTDATE	Char	YYYYMM	The month and year that a health depart-
			ment (county or state) first became aware
			that this patient might have TB.
RPTDATE	Date	MMDDYYYY	The month, day, and year that a health
			department (county or state) first became
			aware that this patient might have IB.
RPTMONTH	Char	MM	Month portion of Month-Year Reported.
RPTYEAR	Char	YYYY	Year portion of Month-Year Reported.
RXDATE CHRX-	Date	MMDDYYYY	The month, day, and year of this patient
DATE			began therapy for TB or suspected TB.
			CHRXDATE is the character representation
			of the start therapy date.
SEX	Char	M	Patient's sex at birth is male.
		F	Patient's sex at birth is female.
		UNK	Patient's sex at birth is unknown.
ShippedDate	Date	MMDDYYYY	Date the isolate was shipped from state
			laboratory to the genotyping laboratory.
SITEANAT1	Char	Site of Disease	If the site is other than those listed, specifies
		2-Letter Code	the anatomic code(s) of this site.
SITEANAT2	Char	Site of Disease	If the site is other than those listed, specifies
		2-Letter Code	the anatomic code(s) of this site.
SITEANAT3	Char	Site of Disease	If the site is other than those listed, specifies
		2-Letter Code	the anatomic code(s) of this site.
SITEBONE	Char	Y	Indicates the site of TB disease is in the
			bone and/or joint.
SITEGENIT	Char	Y	Indicates the site of TB disease is genitouri-
			nary.
SITELARYN	Char	Y	Indicates the site of TB disease is laryngeal.
SITELYMAXIL	Char	Y	Indicates the site of TB disease is lymphat-
			ıc: axıllary.
SITELYMCERV	Char	Y	Indicates the site of TB disease is lymphat-
			ıc: cervical.
SITELYMINTRA	Char	Y	Indicates the site of TB disease is lymphat-
			ic: intrathoracic.

Variable Name	Var. Type	Code	RVCT Code Definitions
SITELYMOTH	Char	Y	Indicates the site of TB disease is lymphat- ic: other location than those listed.
SITELYMUNK	Char	Y	Indicates the site of TB disease is lymphat- ic: unknown location.
SITEMENIN	Char	Y	Indicates the site of TB disease is menin- geal.
SITEMILI	Char	Y	Discontinued - Indicates the site of disease is miliary.
SITENOTSTA	Char	Y	Indicates the site of TB disease is not stated in the patient's medical records and/or labo- ratory reports.
SITEOTH	Char	Y	Indicates the site of TB disease is a site other than those listed.
SITEPERIT	Char	Y	Indicates the site of TB disease is peritoneal.
SITEPLR	Char	Y	Indicates the site of TB disease is pleural.
SITEPULM	Char	Y	Indicates the site of TB disease is pulmo- nary.
SPCULT	Char	POS	Indicates a positive result of culture exami- nation.
		NEG	Indicates a negative result of culture exami- nation.
		NOT	Indicates culture examination was not done.
		UNK	Indicates unknown result of culture exami- nation.
SPCULTCOL	Char	MMDDYYYY	Month, day, and year the first sputum cul- ture with a positive or negative result was collected. Any positive result supersedes a negative result in reporting specimen collec- tion dates.
SPCULTLAB	Char	PUB	If the sputum culture results are positive, a public health reporting laboratory.
		СОМ	If the sputum culture results are positive, a commercial reporting laboratory.
		ОТН	If the sputum culture results are positive, an other reporting laboratory.
SPCULTREP	Char	MMDDYYYY	For the first sputum culture reported posi- tive, the month, day, and year the laboratory reported the results.
SpecimenCollection- Date	Date	MMDDYYYY	Date that the clinical specimen (which sub- sequently produced the submitted isolate) was collected from the patient.

Variable Name	Var. Type	Code	RVCT Code Definitions
Spoligotype	Char	Specify	Result of the PCR based genotyping method based on spacer oligonucleotide typing. Generates a 15-character string.
SPSMEAR	Char	POS	Indicates a positive result of microscopic examination of sputum smear (spontaneous or induced).
		NEG	Indicates a negative result of microscopic examination of sputum smear (spontaneous or induced).
		NOT	Indicates test of microscopic examination of sputum smear (spontaneous or induced) was not done.
		UNK	Indicates unknown result of microscopic examination of sputum smear (spontaneous or induced).
SPSMRCOL	Date	MMDDYYYY	Month, day, and year the first sputum speci- men with a positive or negative result was collected. Any positive result supersedes a negative result in reporting specimen collec- tion dates.
STAT	Numeric	1	Patients with positive culture and initial susceptibility to INH and RIF.
		2	Patients with positive culture and initial resistance to INH and susceptible to RIF.
		3	Patients with positive culture and initial resistance to RIF.
		4	All other patients including culture negative and culture unknown.
STATE	Char	2-Letter State Code	Reporting jurisdiction of the TB case.
STATUS	Char	ALIVE	Indicates this patient was alive at the time of diagnosis.
		DEAD	Indicates this patient was dead at the time of diagnosis. Patient is classified dead at diagnosis if deceased at the time the investi- gation of possible TB was initiated.
		UNK	Unknown.

Variable Name	Var. Type	Code	RVCT Code Definitions
STOPDIED	Char	DISEASE	If the patient was alive at diagnosis, but died before start or completion of treatment, cause of death related to TB disease.
		THERAPY	If the patient was alive at diagnosis, but died before start or completion of treatment, cause of death related to TB therapy.
		UNRELATED	If the patient was alive at diagnosis, but died before start or completion of treatment, cause of death unrelated to TB disease.
		UNK	If the patient was alive at diagnosis, but died before start or completion of treatment, unknown cause of death.
STOPREAS	Char	ADVERSE	Primary reason therapy was ended and not resumed b/c of an adverse treatment event.
		COMPLETED	Primary reason therapy was ended and not resumed b/c therapy was completed.
		DIED	Primary reason therapy was ended and not resumed b/c the patient died.
		LOST	Primary reason therapy was ended and not resumed b/c patient lost to follow-up.
		MOVED	Discontinued - Primary reason therapy was ended and not resumed b/c patient moved.
		NOT TB	Primary reason therapy was ended and not resumed b/c it was not TB.
		ОТН	Primary reason therapy was ended and not resumed b/c of some other reason.
		REFUSED	Primary reason therapy was ended and not resumed b/c patient was uncooperative or refused.
		UNK	The primary reason was unknown why therapy was ended and not resumed.
STOPTHER CHSP- DATE	Date	MMDDYYYY	The date this patient stopped taking therapy for TB or suspected TB. CHSPDATE is the character representation of the date therapy stopped.
SubLabName	Char	Specify	The name of the lab shipping the isolate for genotyping.

Variable Name	Var. Type	Code	RVCT Code Definitions
TBCAUSE	Char	Y	If the patient was dead at the time of TB
			diagnosis, that TB was a cause of this death.
		N	If the patient was dead at the time of TB
			diagnosis, that TB was NOT a cause of this
			death.
		UNK	If the patient was dead at the time of TB di-
			agnosis, unknown whether TB was a cause
			of this death.
TBTEST	Char	POS	Indicates positive result of the Mantoux
			tuberculin skin test performed during the
		NEG	Indicates negative result of the Mantoux
			diagnostic evaluation
		NOT	Indicates Mantoux tuberculin skin test
			was NOT performed during the diagnostic
			evaluation
		UNK	Indicates unknown result of the Mantoux
			tuberculin skin test performed during the
			diagnostic evaluation.
TBTESTDATE	Date	MMDDYYYY	For positive or negative TST results, the
			month, day, and year the TST was placed.
TBTESTMM	Char	MM of Indura-	For pos or neg TST results, the tuberculin
		tion	reaction in millimeters (mm) of induration.
THERREAS	Char	COMPLETED	Primary reason therapy was ended and not
			resumed b/c therapy was completed.
		LOST	Primary reason therapy was ended and not
			resumed b/c patient lost to follow-up.
		REFUSED	Primary reason therapy was ended and not
			resumed b/c patient was uncooperative or
			Deine men and the men and a dead and a set
		NOTIB	Primary reason therapy was ended and not resumed b/c it was not TB
			Drimary reason therapy was anded and not
			resumed b/c the patient died
		ОТН	Primary reason therapy was ended and not
			resumed b/c of some other reason.
		UNK	The primary reason was unknown why
			therapy was ended and not resumed.
		ADVERSE	Primary reason therapy was ended and not
			resumed b/c of an adverse treatment event.
UNKRACE	Char	Y	Other race.

Variable Name	Var. Type	Code	RVCT Code Definitions
USBORN	Char	N	Indicates the person was NOT born in the U.S. and neither parent was a U.S. citizen.
		UNK	Unknown whether the person was born in the U.S.
		Y	Indicates the person was U.Sborn (or born abroad to a parent who was a U.S. citizen). To be U.Sborn the person must either 1) be born in 1 of the 50 states or the District of Columbia , or 2) be born outside the U.S. to at least one parent who was a U.S. citizen.
USDATE	Char	YYYYMM	Indicates the person was U.Sborn (or born abroad to a parent who was a U.S. citizen). To be U.Sborn the person must either 1) be born in 1 of the 50 states or the District of Columbia , or 2) be born outside the U.S. to at least one parent who was a U.S. citizen.
USMONTH	Char	MM	Month portion of Month-Year Arrived in U.S.
USYEAR	Char	YYYY	Year portion of Month-Year Arrived in U.S.
VERCOUNT	Char	Y	Indicates the current case is officially counted as a TB case.
VERCRIT	Char	1	Verified by positive culture.
		1A	Verified by positive NAA result.
		2	Verified by positive smear in the absence of a positive or negative culture.
		3	Verified by clinical case definition.
		4	Verified by provider diagnosis.
VERSION	Char	V1	TIMS
		V2	NEDSS
WHITE	Char	Y	Indicates this patient considers himself or herself to be white.
XDR	Char	Y	Patient has an extensively drug resistant case of TB based on initial susceptibility testing.
		N	Patient does not have an extensively resis- tant case of TB based on initial susceptibil- ity testing.
		UNK	Uncertain whether patient has an extensive- ly drug resistant case of TB due to insuffi- cient initial susceptibility testing.

Variable Name	Var. Type	Code	RVCT Code Definitions
XRAY	Char	NOR	Indicates initial chest radiograph showed no
			abnormalities consistent with TB.
		ABN	Indicates any initial chest radiograph show-
		NOT	Indicates chest radiograph was not taken
		1101	during diagnostic evaluation.
		UNK	Indicates unknown results of the chest ra- diograph taken during diagnostic evaluation.
XRAYCAV	Char	Y	If initial chest x-ray result is abnormal, there is evidence of 1 or more lung cavities.
		N	If initial chest x-ray result is abnormal, there is NO evidence of 1 or more lung cavities.
		UNK	If initial chest x-ray result is abnormal, it is unknown whether there is evidence of 1 or more lung cavities.
XRAYCOND	Char	STABLE	Discontinued - Indicates patient condition
		WORSEN	observed on chest x-ray.
		IMPROVE	
		UNK	
XRAYMIL	Char	Y	If initial chest x-ray result is abnormal, there is evidence of miliary disease.
		N	If initial chest x-ray result is abnormal, there is NO evidence of miliary disease.
		UNK	If initial chest x-ray result is abnormal, it is unknown whether there is evidence of mili- ary disease.
YEAR	Char	YYYY	Year portion of Month-Year Counted.
YEARGRP	Char	< 1	Number of years that a foreign born patient lived in the U.S. prior to a diagnosis of TB is less than 1.
		1-4	Number of years that a foreign born patient lived in the U.S. prior to a diagnosis of TB is 1 to 4.
		5-9	Number of years that a foreign born patient lived in the U.S. prior to a diagnosis of TB is 5 to 9.
		10+	Number of years that a foreign born patient lived in the U.S. prior to a diagnosis of TB is 10 or more.
YRSIN_US	Numeric	3-Digit Number	Years in U.S. calculated from entry in the country to report date.
YRSINUS2	Numeric	3-Digit Number	Years in U.S. (using partial dates).

Variable Name	Var. Type	Code	RVCT Code Definitions
ZIPCODE	Char	Zip Code	5-digit zip code of the home address (per- manent or temporary residence) for this patient.
ZIPSUFFIX	Char	Zip Code Suffix	4-digit zip code suffix of the home address (permanent or temporary residence) for this patient.

Section 2: Data Management

Data Management Introduction

The NTSS data contains individual patient information for all counted and verified cases. Beginning with the revised RVCT, formally introduced in 2009, the TB data set will include information on many new data items. Several previously existing data items will not be in the new record. New variables to allow for trending across the expired and revised RVCT forms have been created.

The NTSS data has been modified from the active, or unadjusted, data set to include external data and to reflect the resolution of known issues that impact data integrity. Updates to individual records to adjust for case data unaffected by earlier software upgrades are made. Data for each U.S. territory and Puerto Rico are included if all records have been reported for the current year. Information on variables, such as missing city and county data that have not been received at CDC but are known through contact with the reporting area are included. Only counted and verified cases for 1993 through the most recently completed calendar year are included.

There are caveats and interpretations for the use of the NTSS data that must be considered. The absence of certain TIMS validations in the early years of the NTSS data has left some records with erroneous results for some variables. Owing to the expansion of the RVCT form in 1993 and the learning curve necessary to fully implement it, most risk factor data are missing from the early years of data collection, specifically through about 1995. We anticipate a delay on achieving high levels of completeness for several new data items due to a learning curve for the revised RVCT variables. Also, HIV data are still incomplete. HIV test results include persons with positive, negative, or indeterminate HIV test. In California, the number of patients testing negative, indeterminate, refusing testing, not offered testing, test performed but status unknown, unknown, or missing HIV data was not reported to CDC. California did not report AIDS test results from 2005-2010. In 2011, California started reporting HIV data through the RVCT. Rhode Island did not report HIV test results for years 1993-1997. Vermont's HIV test results are not available from 2007 onward.

Not all variables measure outcomes that apply to all records. Without creating a subset of the appropriate group of patients, one may overestimate the amount of missing data. A table for the subsetting criteria for all impacted variables is included in this section.

Our ongoing data management process has identified inconsistent results that have been referred to each reporting area for review. A list of data checks is provided that identifies issues that may still be unresolved, and therefore suggests that the data may warrant a closer look.

Section Enclosures:

- 1) RVCT Variable Subsetting Criteria
- 2) Data Checks
- 3) Caveats for TB Data Set Use

RVCT Variable Subset Criteria

Not all data items are defined for all records. To restrict your data to the appropriate subgroup of records, the subset criteria must be used for the variables described below.

The table below shows common SAS numeric and alpha code interpretations that may be useful for the susbetting criteria in this section.

SAS Numeric Code	SAS alpha Code	Interpretation
>=	ge	Greater than or equal to
<=	le	Less than or equal to
^=	ne	Not equal to
=	eq	Equal to
>	gt	Greater than
<	lt	less than

RVCT Form Pages 1 -3

RVCT Form Name	Variable	Subsetting Criteria Code
7. Previous Diagnosis of Tuberculosis	PREVYR	If PREVTB = 'Y';
	ASIANEXT	If ASIAN = 'Y';
11 Paga	ASIANNME	
	NAHAWEXT	If NAHAW = 'Y';
	NAHAWNME	
	USDATE	If NATION NOT IN
13. Month-Year Arrived in U.S.		(' ', 'USA'); ORIGIN = 'FBORN';
15 Status at TD Diagnosis	DEATHDATE	If STATUS='DEAD';
13. Status at TB Diagnosis	TBCAUSE	
	SITEANAT1	If SITEOTH = 'Y';
16. Site of TB Disease	SITEANAT2	
	SITEANAT3	
17 Sputum Smear	SPSMRCOL	If SPSMEAR IN
		('POS','NEG');

	SPCULTCOL	If SPCULT IN
18. Sputum Culture	SPCULTREP	('POS','NEG');
	SPCULTLAB	
	MICRCOL	If MICREXAM IN
19. Smear/Pathology/Cytology of Tissue and Other	MICRANAT	('POS','NEG');
Body Fluids	MICRSMR]
	MICRPATH	
	CULTCOL	If CULTOTHR IN
20 Culture of Tiggue and Other Dody Elvide	CULTREP	('POS','NEG');
20. Culture of fissue and Other Body Fluids	CULTLAB]
	CULTANAT	
	NAACOL	If NAATEST IN
		('POS','NEG');
	NAAREP	
21. Nucleic Acid Amplification Test Results	NAASPUT	If NAATEST IN
		('POS','NEG') and
		NAASPUT ne 'Y';
	NAAANA	
22A. Initial Chest Radiograph	XRAYCAV	If XRAY = 'ABN';
	XRAYMIL	
22B. Initial Chest CT Scan or Other Chest Imaging	CTSCANCAN	If CTSCAN='ABN';
Study	CTSCANMIL	
23 Tuberculin Skin Test a Diagnosist	TBTESTMM	If TBTEST IN
	TBTESTDATE	('POS', 'NEG');
24. Interferon Gamma Release Assay for Mycobac-	INTFGCOL	If INTFGTEST IN
terium Tuberculosis at Diagnosis	INTFGSPEC	('POS', 'NEG');
26 HIV Status	HIVSTANO	If HIVSTAT = 'POS';
	HIVLOCNO	
28. Resident of Correctional Facility at Time of	CORRTYPE	If CORRINST = 'Y';
Diagnosis	CORRICE	
29. Resident of Long-Term Care Facility at Time	LONGTYPE	If LONGTERM =
of Diagnosis		'Y';
37 Initial Drug Regimen	INITSPEC1	If INITOTH1 = 'Y';
1 5 / . minum Drug regimen	INITSPEC2	If INITOTH2 - V'

Example:

"Year of Previous Diagnosis of TB" variable is valid only for patients with a previous episode of TB.

Examine the responses for PREVYR (Year of Previous Diagnosis) PROC FREQ; TABLE PREVYR; Where PREVTB = 'Y'; Follow-Up Report - 1 Form

The following variables are from the Follow Up Report - 1 form. All variables completed on this form are for culture-positive patients (if VERCRIT = (1)).

RVCT Form Name	Variable	Subsetting Criteria			
All variables if VERCRIT = '1';					
38. Genotyping Accession Number	GENONUMB	IF GENOTYPE='Y';			
	ISUSDATE	If ISUSTEST = 'Y';			
	ISUSSPUT				
	ISUSANA	IF ISUSTEST='Y' AND ISUSSPUT NE 'Y';			
	ISUSINH				
39. Initial Drug Susceptibility Test-	ISUSRIF				
ing	ISUSPZA				
	ISUSEMB				
	ISUSSM				
	ISUSETH				
	ISUSKAN				
	ISUSCYC				
	ISUSCAP				
	ISUSPAS	$\begin{bmatrix} 1 \\ 1 \\ 1 \\ 1 \\ 1 \\ 1 \\ 1 \\ 1 \\ 1 \\ 1 $			
	ISUSAM	$\begin{bmatrix} 11 & 15 \\ 0 & 51 $			
	ISUSRIB				
	ISUSCIP				
	ISUSOFL				
40 Initial Drug Susceptibility Re-	ISUSRPT				
sults	ISUSLEVO				
	ISUSMOXI				
	ISUSQUIN	-			
	ISUSOTH1				
	ISUSOTH2				
	ISUSSPEC1	If $ISUSTEST = 'Y'$ and $ISUSOTH1 =$			
		'Y';			
	ISUSSPEC2	If $ISUSTEST = 'Y'$ and			
		ISUSOTH2 = 'Y';			

Example:

"Was Initial Susceptibility Testing Done?" valid only for patients with a positive culture. Examine the responses for ISUSTEST PROC FREQ; TABLE ISUSINH; Where VERCRIT = '1'and ISUSTEST= Y';

Follow-Up Report - 2 Form

The following variables are from the Follow Up Report - 2 form. All variables completed on this form are "Alive at Diagnosis" patients (if STATUS = 'ALIVE').

RVCT Form Name	Variable	Subsetting Criteria			
All variables if STATUS = 'ALIVE';					
	CONVERT	If SPCULT = 'POS';			
41 Sputum Culture	CNEGDATE	If SPCULT = 'POS' and CONVERT = 'Y';			
Conversion	CONVREAS	If SPCULT='POS' and CONVERT='N';			
	CONVSPEC	If SPCULT='POS' and CONVERT='N' and CONVREAS='OTH';			
	MOVINST	If MOVED='Y';			
	MOVOUTST				
	MOVOUTUS				
	MOVREF				
42. Moved	MOVSTATECD1-2	If MOVED='Y' and MOVOUTST='Y';			
	MOVCITYNME1-2	If MOVED='Y' and MOVINST='Y';			
	MOVCNTYNME1-2				
	MOVCTRYCD1-2	If MOVED='Y' and MOVOUTUS='Y';			
	MOVCNTYNME1-2				
43. Date Therapy Stopped	STOPTHER	If RXDATE ^= .			
	DOT	If INITDRG NOT IN ('NO DRUGS',			
47. Directly Observed		'UNK');			
Therapy	DOTWEEKS	If INITDRG NOT IN ('NO DRUGS',			
		'UNK') and DOT ^= 'N';			
48. Final Drug Sus-	FSUSTEST	If ISUSTEST = 'Y';			
ceptibility Testing	FSUSDATE	If ISUSTEST = 'Y' and FSUSTEST = 'Y';			

	FSUSINH	
	FSUSRIF	
	FSUSPZA	
	FSUSEMB	
	FSUSSM	
	FSUSETH	
	FSUSKAN	
	FSUSCYC	
	FSUSCAP	
	FSUSPAS	
40 Einel Conservatibil	FSUSAM	If $ISUSTEST = Y$ and $FSUSTEST = Y';$
ity Results	FSUSRIB	
	FSUSCIP	
	FSUSOFL	
	FSUSRPT	
	FSUSLEVO	
	FSUSMOXI	
	FSUSQUIN	
	FSUSOTH1	
	FSUSOTH2	
	FSUSSPEC1	If ISUSTEST = 'Y' and FSUSTEST = 'Y'
		and FSUSOTH1 = 'Y';
	FSUSSPEC2	If ISUSTEST = 'Y' and FSUSTEST = 'Y' and FSUSOTH2 = 'Y';

Example:

"Reason Therapy Stopped" variable is valid only for patients alive at diagnosis and on one or more anti-TB drugs. Examine the responses for STOPREAS (Reason Therapy Stopped) PROC FREQ; TABLE STOPREAS; Where STATUS = 'ALIVE' and INITDRG NOT IN ('NO DRUGS', 'UNK');

Data Checks

The following are data quality checks performed against the NTSS data to identify inconsistencies in the data. Each reporting area has evaluated at least some of the items referenced here. No action is required, however, for analyses that look at the data in fine detail, some of the items listed below may be worth reviewing to see if the data should be excluded from your analysis.

The following checks of the data suggest that the results warrant a closer look:

Inconsistent Data Line Listing Report

The Inconsistent Data Line Listing Report will contain specific query results for items that may need a second look. The data provided is not absolutely incorrect however it is not consistent with normal expected data.

Inconsistent	Inconsistent	Content	Content_	Content_	Content	Content_	Content_
Data Cd	Doto Cd Doso	Variable 1	Variable_	Variable_	Variable 2	Variable_	Variable_
Data_Cu	Data_Cu_Desc	variable_1	Desc_1	Value_1	variable_2	Desc_2	Value_2
ID0801	Q08 Age at Report (DEM115- Date of Birth and INV111- Date Report- ed) is greater than or equal to 100 years old.	CALC (INV111 - DEM115)	Age at Report	114			
ID0802	Q08 Age at Report (DEM115- Date of Birth and INV111- Date Re- ported) is less than 18 years and greater than or equal to 75 years old AND Q28 a resident of a federal prison (TB129- Resident of Correctional Facility at Time of Diag- nosis.	CALC (INV111- DEM115)	Age at Report	5	TB129	28 - Resident of Cor- rectional Facility	PHC46 ~ Feder- al Prison

Inconsis- tent_Data_ Cd	Inconsistent_Data_Cd_Desc	PSEUDOcode
ID0701	Q07 Previous Diagnosis of TB Disease YEAR (TB103) is prior to 1930	PREVYEAR < 1930
ID0801	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is greater than or equal to 100 years old.	AGE >= 100
ID0802	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is less than 18 years or greater than or equal to 75 years old AND Q28 a resident of a federal prison (TB129-Resident of Correctional Facility at Time of Diagnosis).	(AGE < 18 or >= 75) AND in FEDERAL PRISON
ID0803	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is less than 18 years or greater than or equal to 75 years old AND Q28 a resident of a state prison (TB129-Resident of Correctional Facility at Time of Diagnosis).	(AGE < 18 or >= 75) AND in STATE PRIS- ON
ID0804	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is less than 18 years or greater than or equal to 75 years old AND Q28 a resident of a local jail (TB129-Resident of Correctional Facility at Time of Diagnosis).	(AGE < 18 or >= 75) AND in LOCAL JAIL
ID0805	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is less than 10 years or greater than or equal to 25 years old AND Q28 a resident of a juvenile facility (TB129-Resident of Correctional Facility at Time of Diagnosis).	(AGE < 10 or >= 25) AND in JUVENILE FACILITY
ID0806	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is less than 18 years or greater than or equal to 75 years old AND Q28 a resident of other correc- tional facility (TB129-Resident of Correctional Facility at Time of Diagnosis).	(AGE < 18 or >=75) AND in OTHER COR- RECTIONAL FACIL- ITY
ID0807	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is less than or equal to 30 years old AND Q29 a resident of a nursing home (TB131-Resident of Long Term Care Facility at Time of Diagnosis).	(AGE <= 30) AND in NURSING HOME
ID0808	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is less than or equal to 5 years old AND Q29 a resident of a mental health residential facility (TB131-Resident of Long Term Care Facility at Time of Diagnosis).	(AGE <= 5) AND in MENTAL HEALTH FACILITY

Data Checks for the Inconsistent Data Report

ID0809	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is less than or equal to 13 years or greater than or equal to 75 years old AND Q29 a resident of an alcohol or drug treatment facility(TB131-Resident of Long Term Care Facility at Time of Diagnosis).	(AGE <= 13 or >= 75) AND in ALCOHOL OR DRUG TREATMENT FACILITY
ID0810	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is less than or equal to 13 years old AND Q31 an injecting drug user (TB148-Injecting Drug User within Past Year).	(AGE <= 13) AND an INJECTING DRUG USER
ID0811	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is less than or equal to 13 years old AND Q32 a non-injecting drug user (TB149-Non-Injecting Drug User within Past Year).	(AGE <= 13) AND an NON-INJECTING DRUG USER
ID0812	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is less than or equal to 13 years old AND Q33 an alcohol abuser (TB150-Excess Alcohol Use within Past Year).	(AGE <= 13) AND an ALCOHOL ABUSER
ID0813	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is less than or equal to 13 years old AND Q30 a healthcare worker (TB206-Primary Occupation within the Past Year).	(AGE <= 13) AND a HEALTHCARE WORKER
ID0814	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is less than 18 years old or greater than 70 years old AND Q30 a correctional employee (TB206- Primary Occupation within the Past Year).	(AGE < 18 or > 70) AND a CORREC- TIONAL EMPLOYEE
ID0815	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is less than or equal to 13 years old or greater than 75 years old AND Q30 a migratory farm (TB206-Primary Occupation within the Past Year).	(AGE <= 13 or > 75) AND a MIGRATORY FARM WORKER
ID0816	Q08 Age at Report (DEM115-Date of Birth and INV111- Date Reported) is less than or equal to 13 years old or greater than or equal to 90 years old AND Q30 other occupation (TB206-Primary Occupation within the Past Year).	(AGE <= 13 or >= 90) AND a OTHER OC- CUPATION
ID1101	Q11 Race – Asian (DEM152) is not selected when Q12 Country of Birth (DEM126) is PHILLIPPINES	Race Category <> Asian AND NATION = PHILLIPPINES
ID1102	Q11 Race – AMIND (DEM152) is selected when Q12 Country of Birth (DEM126) is INDIA	Race Category = AMIND AND NATION = INDIA
ID1103	Q11 Race – All Race categories (DEM152) are selected	Race Category + AMIND, ASIAN, BLACK, NAHAW and WHITE

ID1301	Q13 Month-Year Arrived in US (DEM2005) is prior to 1920	YEAR(DateArrived) < 1920
ID3601	Length of Therapy (TB176-Q43 Date Therapy Stopped AND TB147-Q36 Date Therapy Started) is less than 120 days AND Stop Reason = COMPLETED	(STOPTHERDate – RXDate) < 120 days AND stopreas = COM- PLETED
ID3602	Length of Therapy (TB176-Q43 Date Therapy Stopped AND TB147-Q36 Date Therapy Started) is more than 1095 days	(STOPTHERDate – RXDate) > 1095 days
ID3603	Q36 Date Therapy Started (TB147) is more than 60 days after or more than 14 days prior to Q39 Date of first iso- late for susceptibility testing (TB157)	(ISUSDate – RXDate) > 60) OR (ISUSDate – RXDate) < -14)
ID3701	Q37 Initial Drug Regimen consists of 7 or more drugs	INITDRUGRegimen- COUNT >= 7
ID3901	Q39 Initial Susceptibility Testing Date (TB157) is more than 730 days from Q48 Final Susceptibility Testing Date (TB183)	(FSUSDATE – ISUS- DATE) > 730 days
ID4001	Q40 Initial ISONIAZID Susceptibility Result (TB158) = RESISTANT AND Q49 Final ISONIAZID Susceptibility Result (TB184) = SUSCEPTIBLE	ISUSINH = RESIS- TANT AND FSUSINH = SUSCEPTIBLE
ID4002	Q40 Initial RIFAMPIN Susceptibility Result (TB159) = RESISTANT AND Q49 Final RIFAMPIN Susceptibility Result (TB185) = SUSCEPTIBLE	ISUSRIF = RESIS- TANT AND FSUSRIF = SUSCEPTIBLE
ID4003	Q40 Initial PYRAZINAMIDE Susceptibility Result (TB160) = RESISTANT AND Q49 Final PYRAZIN- AMIDE Susceptibility Result (TB186) = SUSCEPTIBLE	ISUSPZA = RESIS- TANT AND FSUSPZA = SUSCEPTIBLE
ID4004	Q40 Initial ETHAMBUTOL Susceptibility Result (TB161) = RESISTANT AND Q49 Final ETHAMBU- TOL Susceptibility Result (TB187) = SUSCEPTIBLE	ISUSEMB = RESIS- TANT AND FSUSEMB = SUSCEPTIBLE
ID4101	Q41 Sputum Culture Conversion duration (TB147-Q36 Date Therapy Started AND TB175-Q41 Sputum culture conversion First Negative Date) with Q40 RIF resistance (TB159) is less than 15 days or more than 300 days.	ISUSRIF = Resistant AND ((CONVERT- NEGDate – RXDate) <15) OR (CONVERT- NEGDate – RXDate) >300))
ID4102	Q41 Sputum Culture Conversion duration (TB147-Q36 Date Therapy Started AND TB175-Q41 Sputum culture conversion First Negative Date) with Q40 non-RIF resis- tance (TB159) is less than 15 days or more than 120 days.	ISUSRIF \diamond Resistant AND ((CONVERT- NEGDate – RXDate) <15) OR (CONVERT- NEGDate – RXDate) >120))
ID4103	Q41 Sputum Culture Conversion Reason Not Document- ed (TB277) = DIED with Q44 Reason Therapy Stopped (TB177) <> DIED	CONVRSNNOTDOC = DIED AND STO- PREAS <> DIED

ID4201	Q42 Moved (TB280) = OUT OF COUNTRY AND Q44 Reason Therapy Stopped TB177) $>$ COMPLETED, DIED or OTHER	MOVED = OUT OF COUNTRY AND STOPREAS NOT IN (COMPLETED, DIED, OTHER)
ID4501	Q45 Reason Therapy Extended > 12 months (TB291) = RIFAMPIN RESISTANCE AND ISUSRIF (TB159) RESISTANT	TXREASONEXT = RIFAMPIN RESIS- TANCE AND ISUSRIF <> RESISTANT

Caveats for TB Data Set Use

Nation Coding

For data analysis from 1993 through early 2001: when specifying "Russia" for Nation, select "Soviet Union" as well because this will ensure that all cases are selected. Also, when specifying "Czech Republic" for Nation, select "Czechoslovakia" as well. Caution: Reporting just Russian/ Czech Republic cases may not give you every Russian/Czech Republic record; however, reporting Russian/Soviet Union and Czech Republic/Czechoslovakia records may give you too many.

Completeness

When the RVCT was modified in 1993 and again in 2009, the new variables that were introduced did not have a history of data collection. As a result, it took at least a couple of years of data collection after the new variables were introduced before many were relatively complete. This was especially true for risk factor data in 1993, new diagnostic tests, and other variables such as: reasons evaluated for TB, additional TB risk factors, reason therapy extended beyond 12 months, and immigration status at first entry into the U.S. This last variable may continue to be incomplete as it is not a variable that some TB programs feel comfortable collecting. Regardless, pay close attention to variables that have high levels of missing and unknown responses and plan your analysis accordingly.

- New York City risk factor data for 1993 is almost all unknown.
- California HIV data previously consisted of HIV positive status data available through 2004 until 2011 when all California HIV data became available.
- Vermont HIV data is unavailable beginning in 2007.

Race

- Prior to 2003, the RACE variable was coded as ASIAN with a specification of ASIAN RACE (i.e. Vietnamese, Polynesian, Thai)
- In 2003, the RACE variable coding was changed to 1) ASIAN or 2) NAHAW (Native Hawaiian or Pacific Islander).
- To trend across this 2003 RACE variable change, ASIAN RACE was examined. If this variable was unknown or missing, then the NATION variable was examined.
 - If NATION did not match an Asian or Native Hawaiian/Pacific Islander country, then the new-2003 RACE variable was coded as UNKNOWN.

Pre-2003 RACE	Pre-2003 ASIAN Specify	Pre-2003 NATION	New 2003 RACE
ASIAN	Asian Race (i.e., Japanese)	N/A	ASIAN
	NAHAW Race (i.e., Tonga)	N/A	NAHAW
	Unknown/Missing	ASIAN Country	ASIAN
		NAHAW Country	NAHAW
		Neither ASIAN nor	UNK
		NAHAW Country	

Section 3: Getting Started with the Data
Getting Started with the Data

The objective of this section is to provide useful code to save you time as well as to standardize how the TB surveillance data are analyzed, where possible. The sample code section consists of SAS code arranged into 3 subsections:

- Pre-calculated Variables
- Subsetting
- Other Coding Issues

Pre-calculated Variables

• The pre-calculated variables subsection documents how these variables, which are already included in the TB Data Set, have been created. This is provided on a for-your-information basis only.

Subsetting

• This section provides concise information which identifies the correct subset of patients for which a variable is defined.

Other Coding Issues

• The coding issues subsection provides assistance in using RVCT follow-up data, creating a permanent SAS dataset, and using the TB Data Set format library.

Pre-calculated Variables

Case Verification Criteria ("Vercrit") Calculation

The calculation of case verification is hierarchical. A record that satisfies the criteria for more than one Case Verification value will be assigned the value that appears first in the hierarchy. For example, a record that meets the criteria for both Positive Culture (vercrit = '1') and Clinical Case Definition (vercrit = '3') will be assigned a value of Positive Culture (vercrit = '1').

NOT A VERIFIED CASE (vercrit = '0')

Appears twice in the hierarchy because there are two sets of criteria that will result in a Case Verification value of Not a Verified Case (vercrit = 0). They are:

Reason Therapy Stopped or Never Started is Not TB (stopreas = 'NOTTB')
 Suspect Case (vercrit = '5') is changed by the user to Not a Verified Case (vercrit = '0')

Suspect Case is the default Case Verification value assigned to all records created in the Surveillance module.

0 - Not a Verified Case The record is assigned a 0-*Not a Verified Case* verification value (vercrit = '0') if:

Reason Therapy Stopped or Never Started is Not TB (stopreas = 'NOTTB').

POSITIVE CULTURE (vercrit = '1')

The record is assigned a 1-Positive Culture verification value (vercrit = '1') if:

Sputum Culture is Positive (spcult = 'POS') - OR -Culture of Tissue and Other Body Fluids is Positive (cultothr = 'POS').

POSITIVE NAA (vercrit = '1A')

The record is assigned a 1A-Positive NAA verification value (vercrit = '1A') if:

Nucleic Acid Amplification Test Result is Positive (naatest = 'POS').

POSITIVE SMEAR/TISSUE (vercrit = '2')

The record is assigned a 2-Positive Smear/Tissue verification value (vercrit = '2') if:

Sputum Smear is Positive (spsmear = 'pos') - OR – Smear/Pathology/Cytology of Tissue and Other Body Fluids is Positive (micrexam = 'POS')

- AND -

Sputum Culture is either Not Done (spcult = 'NOT') or Unknown (spcult = 'UNK') - AND -Culture of Tissue and Other Body Fluids is either Not Done (cultothr = 'NOT') or Unknown (cultothr = 'UNK').

- AND-

Nucleic Acid Amplification Test Result is either Not Done (naatest = 'NOT'), Unknown (naatest = 'UNK') or Indeterminate (naatest = 'IND').

CLINICAL CASE DEFINITION (vercrit = '3')

The record is assigned a 3-Clinical Case Definition verification value (vercrit = 3) if all of the following are true:

Site of TB Disease is NOT Missing or is not Site Not Stated (sitenotsta = 'Y'). - AND -

Sputum Culture is either Negative, Not Done, or Unknown (spcult in ['NEG', 'NOT', or 'UNK'])

- AND –

Culture of Tissue and Other Body Fluids is either Negative, Not Done, or Unknown (cultothr in ['NEG', 'NOT', or 'UNK']).

- AND -

Nucleic Acid Amplification Test Result is either Negative, Not Done, Unknown, or Indeterminate (neatest in ['NEG', 'NOT', 'UNK', or 'IND'])

- AND -

When Site of TB Disease is either Pulmonary (sitepulm='Y'), Pleural

(siteplr = 'Y'), or Lymphatic: Intrathoracic (sitelymintra = 'Y') with no extrapulmonary site included then either

Initial Chest Radiograph is Abnormal (xray = 'ABN')

- OR –

Initial Chest CT Scan or Other Chest Imaging Study is Abnormal

(ctscan = 'ABN').

- AND -

Tuberculin (Mantoux) Skin Test at Diagnosis is Positive (tbtest = 'POS') - OR –

Interferon Gamma Release Assay for Mycobacterium tuberculosis at Diagnosis is Positive (intfgtest = 'POS').

- AND -

Initial Drug Regimen has at least two drugs marked Yes (initXXX = 'Y').

SUSPECT (vercrit = '5')

All new records are considered 5-Suspect (vercrit = 5) until they meet the criteria for another Case Verification value or are overwritten by the user.

OVERWRITE SUSPECT OPTIONS (vercrit = '4' or vercrit = '0')

If criteria to satisfy any of the previous case verifications are not met, the user has the option to overwrite the assigned case verification default value 5-Suspect (vercrit = 5) by selecting either:

4 Verified by Provider Diagnosis (Overwrites Suspect)
The user elects to overwrite case verification default value 5-Suspect (vercrit = '5') with 4-Verified by Provider Diagnosis (vercrit = '4').
0 Not a Verified Case (Overwrites Suspect)
The user elects to overwrite the 5-Suspect (vercrit = '5') case verification default with 0-Not a Verified Case (vercrit = '0').

If Case Verification has a value of (5 - Suspect' (vercrit = (5))) and the user changes the value to (0 - Not a Verified Case' (vercrit = (0))) or (4 - Verified by Provider' (vercrit = (4))), then (5 - Suspect' (vercrit = (5)))) will not be included in the rule calculation and the user entered value should be maintained for Case Verification.

Initial Drug Regimen

Initial Drug Regimen (initdrg) is calculated using the responses to individual drugs listed in Initial Drug Regimen. The codes are assigned as follows:

'NO DRUGS'

The record is assigned a No Drugs Initial Drug Regimen value (initdrg = 'NO DRUGS') if: No drugs are marked Yes (initXXX ^= 'Y')

- AND –

At least one drug = No (initXXX = 'N').

'ONE DRUG'

The record is assigned a One Drug Initial Drug Regimen value (initdrg = 'ONE DRUG') if: One and only one drug = Yes (initXXX = 'Y').

'IRZE'

The record is assigned a INH, RIF, PZA and EMB Initial Drug Regimen value (initdrg = 'IRZE') if all of the following are true:

Isoniazid is marked Yes (initinh = 'Y') - AND – Rifampin is marked Yes (initrif = 'Y') - AND – Pyrazinamide is marked Yes (initpza = 'Y') - AND – Ethambutol is marked Yes (initemb = 'Y') - AND – No other drugs are marked Yes (initXXX ^= 'Y')

'IRZ'

The record is assigned a INH, RIF and PZA Initial Drug Regimen value (initdrg = 'IRZ') if all of the following are true:

Isoniazid is marked Yes (initinh = 'Y') - AND – Rifampin is marked Yes (inirif = 'Y') - AND – Pyrazinamide is marked Yes (initpza = 'Y') - AND -No other drugs are marked Yes (initXXX ^= 'Y').

'IR'

The record is assigned a 4-INH and RIF Initial Drug Regimen value (initdrg = 'IR') if all of the following are true:

Isoniazid is marked Yes (initinh = 'Y') - AND – Rifampin is marked Yes (initrif = 'Y') - AND – No other drugs are marked Yes (initXXX ^= 'Y').

'OTHMULT'

The record is assigned an Any Other Multiple Drug Combination Initial Drug Regimen value (initdrg = 'OTHMULT') if:

Two or more drugs are marked Yes (initXXX = 'Y') in any combination that does not exactly match the combinations used for the following Initial Drug Regimen values: 2-INH, RIF, PZA and EMB 3-INH, RIF and PZA 4-INH and RIF

'UNK'

The record is assigned an Unknown Initial Drug Regimen value (initdrg = 'UNK') if:

All the drugs are either marked Unknown (initXXX = 'UNK') -or- are missing (' ').

The following pre-calculated variables are provided below in SAS Code.

```
YRSIN_US: Years in U.S.
```

Extract month & year for years in U.S. calculation

```
IF ORIGIN = 'FBORN';
    IF REPORTDATE NE . AND ARRIVEUSDATE NE . THEN DO;
IF ARRIVEUSDATE > REPORTDATE THEN YRSIN US = .;
ELSE YRSIN US = INT((REPORTDATE - ARRIVEUSDATE)
/ 365);
END;
ELSE IF REPORTDATE NE . AND ARRIVEUSDATE = . AND
USMONTH NE ' ' AND USYEAR NE ' ' THEN DO;
IF MDY(USMONTH,1,USYEAR) > REPORTDATE THEN
YRSIN US = ::
ELSE YRSIN US = INT((REPORTDATE - MDY(USMONTH,1,
USYEAR)) / 365);
END:
ELSE IF REPORTDATE = . AND ARRIVEUSDATE NE . AND
RPTMONTH NE ' ' AND RPTYEAR NE ' ' THEN DO;
IF ARRIVEUSDATE > MDY(RPTMONTH,1,RPTYEAR) THEN
YRSIN US = ::
ELSE YRSIN US = INT((MDY(RPTMONTH,1,RPTYEAR) - ARRIVEUSDATE) / 365);
END:
ELSE IF REPORTDATE = . AND ARRIVEUSDATE = . AND
RPTMONTH NE ' ' AND RPTYEAR NE ' ' AND USMONTH NE ' '
AND USYEAR NE ' ' THEN DO;
IF MDY(USMONTH,1,USYEAR) > MDY(RPTMONTH,1,
RPTYEAR) THEN YRSIN US = .;
ELSE YRSIN US = INT((MDY(RPTMONTH,1,RPTYEAR) -
MDY(USMONTH,1,USYEAR)) / 365);
END;
ELSE YRSIN US = ::
```

ORIGIN: Origin of Birth

U.S.-born includes those born in the U.S. states and territories IF USBORN = 'Y' OR (USBORN = 'N' AND NATION IN ('ASM', 'FSM', 'GUM', 'MHL', 'MIUM', 'MNP', 'PRI', 'PLW', 'UMI', 'PUUM', 'VIR')) THEN ORIGIN = 'USBORN' ; ELSE IF USBORN = 'N' AND NOT (NATION IN ('ASM', 'FSM', 'GUM', 'MHL', 'MIUM', 'MNP', 'PRI', 'PLW', 'UMI', 'PUUM', 'VIR', ' ')) THEN ORIGIN = 'FBORN' ; ELSE IF USBORN = 'UNK' OR USBORN = ' 'AND NATION = ' ' THEN ORIGIN = 'UNK' ;

DIS_SITE: Site of Disease

```
IF SITEPULM = 'Y' AND SITEPLR = ' ' AND SITELYMCERV = ' ' AND
SITELYMINTRA = ' ' AND SITELYMAXIL = ' ' AND
SITELYMOTH = ' ' AND SITELYMUNK = ' '
AND SITELARYN = ' ' AND SITEBONE = ' ' AND SITEGENIT = ' ' AND SITEMENIN
= ' ' AND SITEPERIT = ' '
AND SITEOTH = ' ' AND ((VERSION*='V1' AND
MILIARY IN ('N', 'UNK')) OR VERSION='V2')
THEN DIS SITE = 'PULM ONLY';
ELSE IF SITEPULM = ' ' AND (SITEPLR = 'Y' OR SITELYMCERV = 'Y'
OR SITELYMINTRA = 'Y' OR SITELYMAXIL = 'Y' OR
SITELYMOTH = 'Y' OR SITELYMUNK = 'Y' OR
SITELARYN = 'Y' OR SITEBONE = 'Y' OR SITEGENIT = 'Y' OR
SITEMENIN = 'Y' OR SITEPERIT = 'Y' OR SITEOTH = 'Y') AND
((VERSION='V1' AND MILIARY IN ('N', 'UNK')) OR VERSION='V2')
THEN DIS SITE = 'EXTRAPULM ONLY';
ELSE IF (SITEPULM = 'Y' AND (SITEPLR = 'Y' OR
SITELYMCERV = 'Y' OR SITELYMINTRA = Y' OR
SITELYMAXIL = 'Y' OR SITELYMOTH = 'Y' OR
SITELYMUNK = 'Y' OR SITELARYN = 'Y' OR
SITEBONE = 'Y' OR SITEGENIT = 'Y' OR SITEMENIN = 'Y' OR
SITEPERIT = 'Y' OR SITEOTH = 'Y')) OR (VERSION='V1' AND
MILIARY = Y'
THEN DIS SITE = 'BOTH';
ELSE IF (SITEPULM = ' ' AND SITEPLR = ' ' AND SITELYMCERV = ' '
AND SITELYMINTRA = ' ' AND SITELYMAXIL = ' ' AND
SITELYMOTH = ' 'AND SITELYMUNK = ' 'AND
SITELARYN = ' 'AND SITEBONE = ' 'AND SITEGENIT = ' '
AND SITEMENIN = ' 'AND SITEPERIT = ' 'AND SITEOTH = ' ') OR SITENOTSTA =
'Y' AND ((VERSION='V1' AND MILIARY = 'UNK') OR VERSION='V2')
THEN DIS SITE = 'UNK';
```

*VERSION is a variable which indicates the version of the RVCT form. V1=The version in place under TIMS, V2=the revised RVCT released in 2009.

Pulmonary Involvement:

IF DIS_SITE IN ('PULM ONLY', 'BOTH')

RACEHISP: Combination of Race and Ethnicity

Calculation to be used in official CDC statistics beginning 2003 for race/ethnicity. Hispanic category (ETHNIC = 'HISP') includes persons of any race.

```
IF ETHNIC = 'HISP' THEN RACEHISP = 'HISP';
ELSE IF ETHNIC = ' OR ETHNIC = 'UNK' THEN RACEHISP = 'UNK';
ELSE IF (WHITE = 'Y') + (BLACK = 'Y') + (AMIND = 'Y') +
(ASIAN = 'Y') + (NAHAW = 'Y') + (UNKRACE='Y') > 1
THEN RACEHISP= 'MULT';
ELSE IF AMIND = 'Y' THEN RACEHISP = 'AMIND';
ELSE IF ASIAN = 'Y' THEN RACEHISP = 'ASIAN';
ELSE IF BLACK = 'Y' THEN RACEHISP = 'BLACK';
ELSE IF NAHAW = 'Y' THEN RACEHISP = 'NAHAW';
ELSE IF WHITE = 'Y' THEN RACEHISP = 'WHITE';
ELSE IF UNKRACE = 'Y' THEN RACEHISP = 'UNK';
ELSE IF UNKRACE = ' AND AMIND = ' 'AND ASIAN = ' 'AND
BLACK = ' AND NAHAW = ' 'AND WHITE = ''
THEN RACEHISP = 'UNK';
```

RACECALC: Race (Including multiracial and unknown)

```
IF UNKRACE = ` ` AND AMIND = ` ` AND ASIAN = ` ` AND
BLACK = ` ` AND NAHAW = ` ` AND WHITE = ` `
THEN RACECALC = ` `;
ELSE IF (WHITE = `Y`) + (BLACK = `Y`) + (AMIND = `Y`) +
(ASIAN = `Y`) + (NAHAW = `Y`) + (UNKRACE=`Y`)> 1
THEN RACECALC = `MULT`;
ELSE IF AMIND = `Y` THEN RACECALC = `AMIND`;
ELSE IF ASIAN = `Y` THEN RACECALC = `ASIAN`;
ELSE IF BLACK = `Y` THEN RACECALC = `BLACK`;
ELSE IF NAHAW = `Y` THEN RACECALC = `NAHAW`;
ELSE IF WHITE = `Y` THEN RACECALC = `WHITE`;
ELSE IF UNKRACE = `Y` THEN RACECALC = `UNK`;
ELSE IF UNKRACE = ` ` AND AMIND = ` ` AND ASIAN = ` ` AND
BLACK = ` ` AND NAHAW = ` ` AND WHITE = ``
THEN RACECALC = `UNK`;
```

AGE3: Broad Age Groups

IF 0 <= AGE <= 4 THEN AGE3 = '00-04'; ELSE IF 5 <= AGE <= 14 THEN AGE3 = '05-14'; ELSE IF 15 <= AGE <= 24 THEN AGE3 = '15-24'; ELSE IF 25 <= AGE <= 44 THEN AGE3 = '25-44'; ELSE IF 45 <= AGE <= 64 THEN AGE3 = '45-64'; ELSE IF AGE >= 65 THEN AGE3 = '65+'; ELSE IF AGE = . or AGE = .N THEN AGE3 = 'UNK';

MDR: Initial Multidrug Resistance

Multidrug resistance is defined as being resistant to at least isoniazid and rifampin.

IF VERCRIT='1'AND ISUSTEST= 'Y'; IF ISUSINH IN ('R', 'S') AND ISUSRIF IN ('R', 'S') THEN DO; IF (ISUSINH='R'AND ISUSRIF='R') THEN MDR= 'Y'; ELSE MDR= 'N'; END; ELSE MDR = 'UNK';

XDR: Initial Extensive Drug Resistance

Extensive drug-resistance is defined as being resistant to at least isoniazid and rifampin and resistant to at least one second-line injectible drug and resistant to a flouroquinolone.

```
IF VERCRIT = '1' AND ISUSTEST = 'Y';

IF ISUSINH IN ('R', 'S') AND ISUSRIF IN ('R', 'S') AND (ISUSAM IN

('R', 'S') OR ISUSKAN IN ('R', 'S') OR ISUSCAP IN ('R', 'S'))

AND (ISUSOFL IN ('R', 'S') OR ISUSCIP IN ('R', 'S') OR

ISUSMOXI IN ('R', 'S') OR ISUSLEVO IN ('R', 'S') OR

ISUSQUIN IN ('R', 'S'))

THEN DO;

IF ISUSINH = 'R' AND ISUSRIF = 'R' AND

(ISUSAM = 'R' OR ISUSKAN = 'R' OR ISUSCAP = 'R') AND

(ISUSOFL = 'R' OR ISUSCIP = 'R' OR ISUSLEVO = 'R' OR

ISUSMOXI = 'R' OR ISUSQUIN = 'R')

THEN XDR= 'Y';

ELSE XDR= 'N';

END;

ELSE XDR= 'UNK';
```

FIRSTLINE: First-line Drug Resistance

(isoniazid, rifampin, pyrazinamide, ethambutol, streptomycin) Note: In 2003, streptomycin was removed from consideration as a first-line drug.

```
IF ISUSINH = 'R' THEN INH='I';
IF ISUSRIF = 'R' THEN RIF='R';
IF ISUSPZA = 'R' THEN PZA='Z';
IF ISUSEMB = 'R' THEN EMB='E';
PATTERN=CATS (INH, RIF, PZA, EMB);
IF PATTERN NE ' 'THEN FIRSTLINE='Y';
```

ELSE FIRSTLINE='N';

DURATION: Duration of Therapy

Variable (in days), handling missing day conditions in date fields

```
IF CHRXDATE NE ' ' AND CHSPDATE NE ' '
THEN DO;
STARTMO=SUBSTR(CHRXDATE,1,2);
STARTDAY=SUBSTR(CHRXDATE,3,2);
STARTYR=SUBSTR(CHRXDATE,5,4);
IF STARTDAY = ' ' THEN STARTDAY = '15';
START=MDY(STARTMO,STARTDAY,STARTYR);
ENDMO=SUBSTR(CHSPDATE,1,2);
ENDDAY=SUBSTR(CHSPDATE,3,2);
ENDYR=SUBSTR(CHSPDATE,5,4);
IF ENDDAY = ' ' THEN ENDDAY = '15';
END=MDY(ENDMO,ENDDAY,ENDYR);
DURATION=END-START;
END;
```

Percent COT: Percent Completion of Therapy within 1 Year

There are three steps to calculating Percent COT, they include the following: 1.) Identify patients that Completed Therapy within 1 Year (allows partial dates)

```
FLAG = 0;
IF SUBSTR(CHRXDATE,3,2) = ' ' AND
SUBSTR(CHRXDATE,5,4) NE ' '
THEN DO;
RXMONTH = SUBSTR(CHRXDATE,1,2); RXDAY = 15;
RXYEAR = SUBSTR(CHRXDATE, 5, 4);
RXDATE=MDY(RXMONTH,RXDAY,RXYEAR);
FLAG=1; END;
IF SUBSTR(CHSPDATE,3,2) = ' ' AND
SUBSTR(CHSPDATE, 5, 4) NE ' '
THEN DO;
STOPMO = SUBSTR(CHSPDATE, 1, 2); STOPDAY = 15;
STOPYEAR = SUBSTR(CHSPDATE, 5, 4);
STOPTHER=MDY(STOPMO, STOPDAY, STOPYEAR);
IF FLAG=1 THEN FLAG=2; ELSE FLAG=1; END;
IF STOPTHER = . OR RXDATE = . THEN FLAG=3;
IF FLAG < 3 THEN DO;
DURATION = STOPTHER - RXDATE;
IF STOPREAS = 'COMPLETED' THEN DO;
IF ((FLAG = 0 AND DURATION > 0 AND DURATION <= 366) OR
(FLAG = 1 AND DURATION > 0 AND DURATION <= 351) OR
(FLAG = 2 \text{ AND DURATION} > 0 \text{ AND DURATION} <= 336))
THEN COT = 'Y';
IF STOPREAS = 'COMPLETED' THEN DO;
IF ((FLAG = 0 AND (DURATION <= 0 OR DURATION > 366)) OR
(FLAG = 1 AND (DURATION <= 0 OR DURATION > 351)) OR
(FLAG = 2 AND (DURATION <= 0 OR DURATION > 336))
THEN COT = 'N'; END;
ELSE IF FLAG='3' AND STOPREAS='COMPLETED' THEN COT='UNK';
END;
```

2.) Resistance Status of Patient

STAT=4; IF VERCRIT = '1' AND ISUSTEST = 'Y' THEN DO; IF ISUSINH = 'S' AND ISUSRIF = 'S' THEN STAT = 1; ELSE IF ISUSINH = 'R' AND ISUSRIF = 'S' THEN STAT = 2; ELSE IF ISUSRIF = 'R' THEN STAT = 3; END; 3. Eligibility for Completing Therapy within 1 Year

IF STATUS = 'ALIVE' AND INITDRG NOT IN ('NO DRUGS', 'UNK') AND (STOPREAS NE 'DIED' OR (STOPREAS='DIED' AND (DURATION GT 366 OR DURATION LT 0))) AND STAT IN (1,2,4) AND (AGE GE 15 OR ((AGE GE 0 AND AGE LT 15) AND MILIARY NE 'Y' AND (CULTOTHR NE 'POS' OR (CULTOTHR='POS' AND CULTANA1 NE '06' AND CULTANA2 NE '06')))) AND SITEMENIN NE 'Y' AND SITEBONE NE 'Y' AND (SITEOTH NE 'Y' OR (SITEOTH = 'Y' AND SITEANAT1 NOT IN ('BA', 'SC', 'CR') AND SITEANAT2 NOT IN ('BA', 'SC', 'CR') AND SITEANAT3 NOT IN ('BA', 'SC', 'CR'))) AND (MOVED NE 'Y' OR (MOVED = 'Y' AND MOVOUTUS NE 'Y') OR (MOVED = 'Y' AND MOVOUTUS='Y' AND ((STOPREAS NOT IN ('COMPLETED', 'DIED') AND (DURATION GT 366 OR DURATION LT 0)) OR (STOPREAS IN ('COMPLETED', 'DIED') AND DURATION LT 0)))) THEN COTELIG ='Y': ELSE COTELIG ='N';

Example: Calculate Percentage COT within 1 Year

PROC FREQ; TABLE COT; WHERE COTELIG = 'Y';

MILIARY: Evidence of Miliary Disease

Prior to the revised RVCT, miliary was a disease site variable.

IF VERSION = 'V1' AND (MAJSITE = 'MI' OR SITEMILI = 'Y') THEN MILIARY = 'Y'; ELSE IF VERSION = 'V1' THEN MILIARY = 'N'; IF VERSION = 'V2' AND (XRAY = 'ABN' AND XRAYMIL = 'Y') OR (CTSCAN = 'ABN' AND CTSCANMIL = 'Y') THEN MILIARY = 'Y'; ELSE IF (XRAY = 'NOR' OR (XRAY = 'ABN' AND XRAYMIL = 'N')) OR (CTSCAN = 'NOR' OR (CTSCAN = 'ABN' AND CTSCANMIL = 'N')) THEN MILIARY = 'N'; ELSE MILIARY = 'UNK'; END;

Subsetting

Culture-Positive Cases Only

IF VERCRIT='1';

U.S. Cases Only (in order to not include territories)

IF STATE NOT IN ('AS', 'MP', 'FM', 'GU', 'PR', 'PW', 'MH', 'VI');

To remove any non-TB cases

IF VERCRIT GE '1' AND VERCRIT LE '4'; IF STOPREAS = 'NOTTB' THEN DELETE; IF VERCOUNT = 'Y';

Other Coding Issues

FU1 (Follow-up 1) RVCT Data

Example:

PROC FREQ; TABLE ISUSTEST; WHERE VERCRIT='1'; /* FU1 data are entered for culture-positive patients */ RUN;

FU2 (Follow-up 2) RVCT Data

Example:

PROC FREQ; TABLE PROVTYPE; WHERE STATUS='ALIVE'; /* FU2 data are entered for patients alive at diagnosis */ RUN;

Creating a Permanent SAS Dataset

LIBNAME OUT '\\cdc\project\NCHHSTP_DTBE_SURV_DATA; LIBNAME IN '\\cdc\project\NCHHSTP_DTBE_SURV_DATA ';

DATA OUT.MYDATASETNAME; SET IN.TBDATASETNAME; *** your other SAS statements ***; RUN;

\\cdc\project\NCHHSTP_DTBE_SURV_DATA- path name for location to write new permanent dataset (replace "PROJECT FOLDER" with your project name)

MYDATASETNAME - replace this with the name you want for your SAS dataset e.g., MDRSTUDY

TBDATASETNAME - replace this with the name of the TB Data Set

Section 4: Appendices

Appendices: Introduction

Several appendices have been reproduced in this Guide for your convenience. The appendices have been renumbered 1-3. All of the appendices included in the Guide were chosen to provide clarity through variable definitions and expanded code lists.

Appendix 1 – Confidentiality

This appendix contains information regarding: why DTBE performs surveillance, who can use surveillance data, what surveillance data can be used for, how surveillance data is protected and confidentiality forms that must be filled out before access to the data is granted.

Appendix 2 - Policy on Access to Genotyping Data for Research Purposes

This appendix contains information regarding: how to request and be granted access to TB Genotyping data from the TB GIMS dataset.

Appendix 3 - Expired/Revised Variable Labels and Trending

This appendix contains information regarding Expired versus Revised RVCT information. The Expired/Revised RVCT Variables section contains information on Expired RVCT variables and the new corresponding variables in the Revised RVCT. The Expired/Revised RVCT Trending section provides information on how Expired RVCT variable codes have been trended to match with newly created RVCT variable codes.

Appendix 4 – Codes

This section contains five code listings including: Anatomic, Site of Disease, State, Country, and Asian and Native Hawaiian/Pacific Islanders Race Codes.

Appendix 1: Assurance of Confidentiality

Request for Extension of and Amendments to Assurance of Confidentiality for the National Tuberculosis Surveillance System

Surveillance, Epidemiology, and Outbreak Investigations Branch Division of Tuberculosis Elimination or its successor organizational unit National Center for Hepatitis, HIV, STD, and TB Prevention or its successor organizational unit

> Original Assurance Issued: January 1991 Assurance Amended: May 1995 Assurance Extended: December 2004 Extension and Amendments Requested: October 2009 Extension and Amendments Application Finalized: January 2011

This document is an extended, updated, and amended Assurance of Confidentiality for the National Tuberculosis Surveillance System (NTSS).

A. Purpose of the Project

To assist in accomplishing the Centers for Disease Control and Prevention (CDC) goal of eliminating tuberculosis (TB) in the United States, the Division of Tuberculosis Elimination (DTBE) (all references to DTBE refer to DTBE or its successor organization) has collected TB incidence data since 1953. The Surveillance, Epidemiology, and Outbreak Investigations Branch (SEOIB) (all references to SEOIB refer to SEOIB or its successor organization), DTBE maintains the National TB Surveillance System (NTSS). In January 1991, the National Center for HIV, STD, and TB Prevention (NCHSTP) (in March 2007, NCHSTP became the National Center for Hepatitis, HIV, STD, and TB Prevention; all references to NCHHSTP refer to NCHHSTP or its successor organization) received an Assurance of Confidentiality from the Director of CDC for "Surveillance Activities and Investigations of Outbreaks of Tuberculosis Associated with Human Immunodeficiency Virus Infection." In May 1995, the Assurance was amended to include surveillance information regarding the characteristics of certain individuals diagnosed with HIV and multidrug-resistant TB (MDR TB). In 2004, the Assurance of Confidentiality was extended for surveillance activities only, apart from investigations of TB outbreaks; the system was renamed the NTSS. Several years of collecting data during outbreak investigations of TB demonstrated that these data do not require an Assurance of Confidentiality. All potentially identifying information collected during an outbreak investigation is destroyed after the investigation is complete.

TB is a reportable disease in every state. The NTSS has been conducted and maintained by the CDC, U.S. Public Health Service through the cooperation of the states since 1953. CDC currently conducts and maintains the system pursuant to the provisions of Section 308(d) of the Public Health Service Act [42 U.S.C. 242m(d)] and Section 306 of the Public Health Service Act [42 U.S.C. 242k].

NTSS was critical in the early detection of TB resurgence in 1992 and it continues to provide the information needed to inform our progress toward TB elimination goals. In 2009, DTBE expanded NTSS to collect new information to reflect the changing field of TB epidemiology, new drug treatments, and enhanced laboratory capacity for diagnostic tests. These data will provide the critical information needed to guide resource allocation and program improvement efforts. In 2009, NTSS received reports of 11,545 TB cases with a rate of 3.8 cases per 100,000 population, a

decrease of 10.5% from the rate of 4.2 per 100,000 reported for 2008. NTSS data enable DTBE to quickly detect this change and further analyze the new information.

The mission of DTBE is to provide leadership in preventing, controlling, and eventually eliminating TB from the United States in collaboration with partners at the community, state, and international levels. To accomplish this mission, DTBE key activities include supporting a nationwide framework for monitoring TB morbidity. NTSS has demonstrated its ability to play a key role in providing direction for TB control efforts and assisting in program planning and evaluation for decades. Maintenance of this system is critical to current national TB elimination efforts. The system is needed to continue to monitor TB trends and detect potential TB outbreaks, identify high-risk populations for TB, gauge program performance and assist in program planning, evaluation, and resource allocation.

The NTSS collects data on individual TB cases in the United States. Data are reported to NTSS from 60 areas including the 50 states, the District of Columbia, New York City, and the 8 U.S.-affiliated island nations using the Report of Verified Case of TB (RVCT). The RVCT consists of three data collection forms (CDC form 72.9 series): (1) Initial Case Report (CDC 72.9A), (2) the Initial Drug Susceptibility Report (Follow Up Report 1, CDC 72.9B), and (3) the Case Completion Report (Follow Up Report 2, CDC 72.9C). An RVCT is completed for each reported TB case and contains demographic, clinical, and laboratory information, including sensitive data (e.g., HIV-infection status, alcohol and drug use, residence in correctional facilities, occupational status, homelessness) and potentially personally identifiable information (e.g., date of birth, county, zip code).

Name and address of TB cases are retained by the reporting area completing the RVCT; CDC receives a state case number, and a city/county case number. State and city/county case numbers cannot be linked back to individual cases by anyone working at CDC. The state case number is the official state identification number for the case and is used to facilitate communication between CDC and a reporting area about a record when data issues are identified. Because data elements such as date of birth, county, and zip code information are collected on all reported TB cases, there is a possibility that persons may be indirectly identified, especially in areas of low TB incidence. In 2009, DTBE expanded the RVCT to include 11 new variables and 25 revised variables. Information is now collected on newer diagnostic tests, dates that these test results were recorded, co-morbid conditions, immigration status, and cause of death. Also in 2009, DTBE incorporated the data collection system into web-based reporting systems developed by either states or CDC.

DTBE modified the system several times to better monitor and respond to changes in TB morbidity. In 1985, the system changed from collecting aggregate data to collecting individual case reports using the RVCT. DTBE implemented further modifications in 1993 when the RVCT was expanded in response to the TB epidemic of the late 1980s and early 1990s, and incorporated into CDC software for electronic reporting of TB case reports to CDC. In 2009, the system transitioned to data collection vis the Public Health Information Network (PHIN)/National Electronic Disease Surveillance System (NEDSS).

Various (PHIN)-based messaging software systems are currently being used by local and state TB programs for RVCT data entry and electronic transmission of TB case reports to CDC. There is no significant difference from the current Security Statement in the way data are received at NCHHSTP or how the data are safeguarded. However, SEOIB, DTBE revised the Security Statement to include guidelines for remote access to NTSS data and the two amendments for the TB Genotyping Information Management System (TB GIMS) and the National Surveillance for Severe Adverse Events As-

sociated with Latent TB Infection (NSSAE). To assist reporting areas, SEOIB, DTBE also performs periodic data quality checks and provides reports for areas to use in the investigation of incomplete, inconsistent, and outlying data.

DTBE publishes annual reports summarizing national TB statistics and TB genotyping data also periodically conducts special analyses for publication in peer-reviewed scientific journals to further describe and interpret national TB data. Special analyses describe key trends, identify high risk groups, and assist in developing new elimination strategies. The annual reports are disseminated to state and large city TB control officers, pulmonary and infectious disease experts, and others concerned with TB control. The system also responds to special data requests to assist other government agencies and organizations in their TB control and prevention activities, but neither identifiable, indirectly identifiable, nor line-listed data are shared to respond to these requests.

All research projects that utilize NTSS data or national genotyping data linked to surveillance data through the TB GIMS require review and approval of the DTBE's Analytic Steering Committee (ASC). ASC promotes and coordinates collaborations between epidemiologists, statisticians, data programmers, and Surveillance Team staff. The primary goal of the ASC is to ensure the excellence and prompt publication of analyses of NTSS data.

To better define the magnitude of TB among persons who are HIV positive, it is necessary for CDC to collect surveillance information regarding the characteristics of these high-risk persons with active TB disease. Collecting data on HIV-infection status enables CDC to assist in determining the extent to which HIV infection is contributing to increased TB morbidity. These data are important in developing, implementing, and evaluating strategies for providing TB treatment to persons infected with both HIV and TB.

Surveillance data collected by the NTSS assist federal, state, and local public health officials and policy makers in program planning, evaluation, and resource allocation. Specific examples include use by the Institute of Medicine (IOM) Committee on the Elimination of TB in the United States in its evaluation of the status of TB control in the United States. Data from the national system, including special data requests, are used throughout the Committee's report, entitled "Ending Neglect: The Elimination of Tuberculosis in the United States." The U.S. General Accounting Office report (GAO-01-82) focusing on MDR TB, "Trends in Tuberculosis in the United States," is also based on data from NTSS, both published and in response to special requests. The collection of information on TB morbidity also helps determine resources required for federal elimination efforts, including support of state and local TB programs. These data are also used in DTBE materials for training and education of health care providers, the general public, and the media. TB surveillance data also fill a critical role in routine public health activities by enabling federal, state, and local public health officials to detect, respond to, and monitor outbreaks of TB disease.

TB surveillance activities are systematic and ongoing. Data collected in the RVCT are maintained in the NTSS and provide the sole source of valid, comprehensive, complete national TB statistics collected in a timely and standardized manner. SEOIB, DTBE has always treated the data collected by NTSS as highly sensitive and confidential information. State and local TB control programs have entrusted CDC with potentially identifiable sensitive patient information, under the protection granted by the Assurance of Confidentiality. The collection of these data is authorized by the Office of Management and Budget (OMB) under CDC's broad authority to conduct disease surveillance nationally and more specifically using the RVCT (OMB No. 0920-0026). SEOIB, DTBE recognizes the need to continue to protect the confidential and personal information collected through its activities. We are requesting an extension of the authorization to give an Assurance of Confidentiality for the collection of valid and timely data on TB in the United States. The current Assurance of Confidentiality expired in December 2009 and an extension was requested in a timely manner in October 2009.

In addition to the extension, we request two amendments to the Assurance of Confidentiality to cover two surveillance systems described below:

a) The Tuberculosis Genotype Information Management System (TB GIMS)

TB genotyping is a laboratory-based approach to analyze the genetic material of Mycobacterium tuberculosis isolates from individuals with TB disease. Specific sections of the genome (the total genetic content) form distinct genetic patterns that help distinguish different strains of Mycobacterium tuberculosis. In the United States, TB genotyping is performed through the National TB Genotyping Service (NTGS), which genotypes TB isolates for all state and local TB programs. In order to facilitate data management and access to genotyping information, CDC created the TB Genotyping Information Management System (TB GIMS), a secure online database, separate from NTSS, which allows state and local TB programs to access, manage and review genotyping data. TB GIMS serves as the national database for genotyping data in the United States. Access to TB GIMS for state and local users is determined by TB controllers or their designees and is only granted after a rigorous identity verification process. State and local users can only view data for their assigned jurisdiction; however, a data sharing agreement among all states grants users the ability to determine in which states patients with specific genotypes are located. Access to TB GIMS for CDC users is determined by the SEOIB Chief or his/her designee and is limited to CDC user with a clear need for access to TB GIMS for routine public health activities. No patient identifiers are used with TB GIMS.

Through TB GIMS, programs can link genotype results to patient surveillance records from NTSS. Linking genotype results to patient data allows programs to use genotyping to assist with the following activities: 1) distinguishing between relapsed disease and reinfection with a new strain, 2) detection of false-positive TB cultures, 3) confirming known epidemiologic links among patients, 4) identifying unknown epidemiologic links among patients, 5) detecting outbreaks, 6) defining the scope of an outbreak, and 7) monitoring outbreaks over time.

TB GIMS users can, depending on their access level, view line lists of patient information, aggregate reports summarizing demographic and risk factor information, maps of the distribution of genotypes and alert levels indicating when a genotype cluster is an unusual geospatial concentration and may represent an outbreak.

b) National Surveillance for Severe Adverse Events Associated with Latent TB Infection (NSSAE)

NSSAE received OMB approval on April 2008 for the standardized data collection form (OMB No. 0920-05AJ) to collect data on severe adverse events (hospitalization or death) associated with treatment for latent TB infection (LTBI). NSSAE's database is separate from NTSS but needs 308(d) protection because the data collection form includes date of birth, other demographic information, and highly sensitive information such as HIV infection status, correctional facility residence, and alcohol or drug use and may have the potential to indirectly identify TB cases. DTBE collects data on patients who had severe adverse events from healthcare providers and health departments (local/

state/territorial) from any of the 60 NTSS reporting areas. The purpose of NSSAE is to quantify the frequency of severe adverse events associated with LTBI treatment and characterize the clinical features of affected patients. NSSAE data will assist public health officials, policy makers, and health-care providers in preventing severe adverse events associated with treatment of LTBI. The data serve as a basis in supporting periodic evaluation of guidelines for treatment of LTBI and revision of these guidelines as needed.

Severe adverse events to TB treatment are rare but recognized as a catastrophic medical phenomenon. We need to know who is affected, how often this occurs, and whether there are personal risk factors that contribute to severity of adverse reactions. Without this information, we will not be able to recognize which anti-tuberculosis drug (s) are more likely to cause severe adverse reactions and how to change the antibiotic combinations used to treat persons with LTBI. Proper antibiotic regimens are crucial in the elimination of TB in the United States.

B. Justification of Need

1. Extent to which the Assurance of Confidentiality is important to the protection of the individual or institution

Maintaining a valid, comprehensive, and current national TB database requires collecting potentially identifiable information on HIV-infection status, demographic data (e.g., alcohol and drug use, residence in a correctional facility, homelessness), clinical information, and laboratory data for persons with active TB. Because of the sensitive nature of some of these data, the potential exists for legal action against or social discrimination against individuals if personal identifying information were disclosed. Due to public fears about infectious diseases, such as HIV/AIDS and TB, there have been reports of discrimination (e.g., in employment, education, health care) against persons with TB or infected with HIV. Patients may provide inaccurate or invalid information or may even delay or avoid seeking medical care in response to inquiries of a sensitive nature if confidentiality protection is not assured.

Furthermore, many physicians, health care agencies, and institutions are reluctant to release sensitive information on patients (e.g., HIV-infection status, self-reported behavioral risk factors, and adverse events) unless such information can be reported under an Assurance of Confidentiality. It is important that individuals, physicians, health care agencies, and institutions be assured that sensitive patient information, such as TB and HIV information, can be reported to CDC under an Assurance of Confidentiality.

2. Extent to which the individual or establishment will not furnish or permit access to data being requested unless an Assurance of Confidentiality is given

Under the CDC TB Cooperative Agreement, state and local health departments are required to report TB cases to CDC using the RVCT. Although reporting of severe adverse events associated with treatment for LTBI is not mandatory, the treatment decreases the chance of progression to TB disease. Some health care providers are reluctant or refuse to provide sensitive patient information to health departments due to confidentiality concerns, unless an Assurance of Confidentiality can be obtained by CDC. Some advocacy groups have historically been opposed to mandatory reporting of HIV-infection status because of concerns about confidentiality and the potential for discrimination in housing, employment, insurance, and access to medical care. However, these groups have not been

opposed to providing personal information about HIV-infected persons or reporting of HIV-infection status to federal health agencies if the reports are protected by an Assurance of Confidentiality.

In addition, even though SEOIB, DTBE does not collect personal identifiers, CDC is subject to federal disclosure laws, including the Freedom of Information Act (FOIA). It may also be possible to indirectly identify persons, especially if they live in areas where only a few TB cases reside. Since December 2004, when the Assurance of Confidentiality for NTSS was extended, there have been requests made to the Surveillance Team to provide data that may potentially identify patients. These requests came from the public and from researchers within CDC, and DTBE used the authority of the Assurance of Confidentiality to deny the requests. DTBE also used the Assurance of Confidentiality would promote confidence and cooperation by those parties reluctant to participate and would enhance accuracy and completeness of TB surveillance reporting to state and local health departments, and thereby to CDC.

Information that would permit identification of any individual on whom a record is maintained by CDC is collected with a guarantee to the agency, institution, physician, or individual providing the information that it will be held in strict confidence, will be used only for purposes stated in the assurance, and will not otherwise be disclosed or released without the consent of the individuals in accordance with Sections 306 and 308(d) of the Public Health Service Act (42 U.S.C. 242k and 242m). Data or information retained by the state or local health officials will be protected in accordance with state law.

3. The extent to which the information cannot be obtained with the same degree of reliability from sources that do not require an Assurance

The data collected by NTSS and TB GIMS provide the sole source of comprehensive, complete national TB statistics collected in a timely and standardized manner. NSSAE is also the sole source of comprehensive data on severe adverse events associated with treatment for LTBI. The usefulness of TB data, including sensitive data, such as HIV-infection status, reported to CDC could be limited if there is substantial bias in reporting to the states by physicians, hospitals, laboratories, or other health care providers. Some individuals, physicians, health care agencies, or institutions may have concerns that their provision of sensitive information, such as HIV-infection status or alcohol and drug use, could lead to potential litigation or disclosure of such information through subpoena. To increase the completeness of HIV-infection status and other sensitive information reporting for TB patients and the accuracy of those reports, it is vital that the data from these sources be collected under an Assurance of Confidentiality.

4. The extent to which the information is essential to the success of the particular statistical or epidemiological project and is not duplicative of other information gathering activities of the Department

NTSS and TB GIMS

The U.S. Public Health Service (USPHS) has been made responsible by an Act of Congress for national disease surveillance. Within USPHS, CDC has been delegated that responsibility. NTSS and TB GIMS, coordinated by CDC, are currently the only population-based sources of information on the incidence, trends, and demographic characteristics of persons with active TB. If these data are

not collected, reliable and consistent information will not be available on the extent and distribution of the TB problem in the United States. Federal health officials will not be able to efficiently detect and respond to outbreaks or changes in morbidity patterns. Effective assessment of federal, state, and local TB prevention and control efforts, based on timely and standardized data, will not be possible.

Complete and reliable NTSS data also play a critical role in increasing the usefulness of TB genotyping data. Genotyping results generated by NTGS do not consistently contain any information about the patient, beyond the state and laboratory that submitted the isolate for genotyping. It is only through linking genotyping data to NTSS data that genotyping can be consistently used to augment TB control activities. Programs have found this particularly valuable for identifying potential TB outbreaks. For example, one program identified a multi-state MDR outbreak by identifying where patients with a specific genotype were located and contacting those states to ask for assistance in identifying epidemiologic links among the patients.

NSSAE

In compliance with the recommendations of the Institute of Medicine (IOM), Ending Neglect: The Elimination of Tuberculosis in the United States towards reaching the Healthy People (HP) 2010 objective, CDC is detecting and treating latent TB infection (LTBI) through targeted testing and administration of LTBI treatment to prevent TB transmission.

Persons with LTBI are at highest risk for progression from latent infection to TB disease. However, with the increased number of persons with LTBI who will be treated with the recommended regimen of antibiotics, we anticipate that severe adverse events will occur more frequently. NSSAE provide data on how and why these events occur which are essential in modifying treatment regimens.

The goal of TB elimination in the United States cannot be achieved without NTSS, TB GIMS, and NSSAE. Information reported through these systems is not available from any other source. CDC's ability to effectively monitor TB trends in the United States and to devise innovative strategies to control TB will be severely hampered if information obtained from the national TB surveillance system cannot be accurately collected.

5. Extent to which the giving of the Assurance of Confidentiality might restrain CDC from carrying out its responsibilities

Providing an Assurance of Confidentiality for NTSS, TB GIMS, and NSSAE will not restrict CDC from carrying out its responsibilities.

The Assurance of Confidentiality, while protecting the privacy rights of persons with TB disease, will enable CDC to collect data, including sensitive data (e.g., HIV-infection status) to report statistics for monitoring TB trends. Information, without any personal identifiers, is released in aggregate form to (1) the scientific and medical communities, (2) the public and media to provide public health information about TB, (3) the public via a public use dataset, and (4) the public and scientific communities through our annual surveillance reports and publications in peer-reviewed journals.

CDC employees and contractors in SEOIB, selected CDC employees and contractors of DTBE and onsite DTBE guest researchers, fellows, visiting scientists, and graduate students who are granted access by the SEOIB Chief or his/her designee to have access to NTSS, TB GIMS, and NSSAE and

related data will receive training on confidentiality and data security and will be required to sign 308(d) confidentiality pledges.

NCHHSTP intends to share indirectly identifiable TB surveillance data with other CDC components, and will follow the procedures outlined in Attachment 3, "Release of National TB Surveillance System (NTSS), and/or Tuberculosis Genotyping Information System (TB GIMS), and/or National Surveillance of Severe Adverse Events Associated with Treatment for Latent TB Infection (NSSAE) Data." To fully comply with 308(d) requirements, NCHHSTP will also obtain a special pledge for those other components that is included in the Security Statement (Attachment 6.)

6. Extent to which the giving of the Assurance of Confidentiality outweigh the disadvantages of doing so

No disadvantages to CDC of providing an Assurance of Confidentiality for NTSS, TB GIMS, and NSSAE are foreseen. The Assurance of Confidentiality will increase the accuracy and completeness of reporting, thus enhancing the scientific validity of data. The ability to protect the privacy of persons reported through NTSS, TB GIMS, and NSSAE to CDC is essential to maintain the credibility CDC has established with the public health community, health care agencies, and institutions to assure continued cooperation with surveillance programs in the future.

Assurance of Confidentiality for the National Tuberculosis Surveillance System

Surveillance, Epidemiology, and Outbreak Investigations Branch Division of Tuberculosis Elimination, National Center for Hepatitis, HIV, STD, and TB Prevention, Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC), an agency of the United States Department of Health and Human Services, conducts the national tuberculosis (TB) surveillance system (NTSS). Report of Verified Case of Tuberculosis (RVCT) forms are submitted to CDC from TB control programs from designated reporting areas (i.e., the 50 states, the District of Columbia, New York City, and associated jurisdictions in the Pacific and Caribbean). The surveillance information requested by CDC consists of detailed reports of persons with TB, including sensitive information (e.g., HIV-infection status, alcohol and drug use, residence in a correctional facility). The goal of TB surveillance is to monitor trends of TB disease morbidity, to focus resources by identifying high-risk populations, and to assist state and local health TB control programs in controlling and eventually eliminating TB in the United States.

Information maintained by CDC is identified by computer-generated codes, patient date of birth, and a state/city assigned patient identification number. Information reported to CDC will be used for statistical summaries and research by CDC scientists and cooperating state and local health officials to understand and control the spread of TB. Information will also be linked to TB genotyping results through the TB Genotyping Information Management System (TB GIMS).¹ This information will improve the application of genotyping data at the national, state, and local levels and assist federal, state, and local public health officials with routine public health activities such as outbreak detection and response.

Information collected by National Surveillance for Severe Adverse Events Associated with Treatment for Latent TB Infection (NSSAE) will serve as a basis in supporting periodic evaluation of guidelines for treatment of LTBI and revision of these guidelines as needed. When necessary for confirming surveillance information or in the interest of public health and disease prevention, CDC may confirm information contained in case reports or may notify other medical personnel or health officials of such information; in each instance, only the minimum information necessary will be disclosed.

Information that would lead to direct or indirect identification of any individual on whom a record is maintained by CDC is collected under Section 306 of the Public Health Service Act (42 U.S.C. 242k) with a guarantee to the agency, institution, physician, or individual providing the information that it will be held in strict confidence, will be used only for purposes stated in this assurance of confidentiality, and will not otherwise be disclosed or released without consent of the individual, in accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)). This protection lasts forever, even after death. Data or information retained by the state or local health officials will be protected in accordance with state law.

No CDC TB surveillance information that could be used to identify any individual whether directly or indirectly, on whom a record is maintained, will be made available to anyone for non-public

^{1.} Information about TB GIMS can be found at: http://www.cdc.gov/tb/programs/genotyping/tb-gims/default.htm.

health purposes. In particular, such information will not be disclosed to the public; to family members; to parties involved in civil, criminal, or administrative litigation; for commercial purposes; or to agencies of the federal, state or local government. Data will be released to other components of CDC or to agencies of the federal, state, or local government for public health purposes in accordance with the policies for data release established in the CDC/ATSDR Policy on Releasing and Sharing Data.²

Information in these surveillance systems will be kept confidential. Only authorized CDC employees, their authorized contractors, guest researchers, fellows, visiting scientists, and graduate students, who participate in activities jointly approved by CDC and the sponsoring academic institution, and the like, will have access to the information. Authorized individuals are required to handle the information in accordance with procedures outlined in the Confidentiality Security Statement for NTSS, and/ or TB GIMS, and/or NSSAE and the CDC Staff Manual on Confidentiality. The exception to this is authorized state and local users of TB GIMS, who can view line listed data and aggregate reports based on NTSS information linked to genotyping data. State and local users can only view data for their jurisdiction and authorization to access the system is only granted by the TB Controller or his/ her designee. State and local users of TB GIMS are required to handle the information contained in TB GIMS in accordance with their own local procedures for data confidentiality; the TB Controller or his/her designee for the jurisdiction is responsible for ensuring that state and local users abide by local procedures for data confidentiality.

Remote access to the National Tuberculosis Surveillance System (NTSS), and/or TB GIMS, and/or NSSAE data using CDC IT On The Go (CITGO) meets federal requirements for data protected under the Public Health Service Act Section 308(d) Assurance of Confidentiality [42 U.S.C. 242 m(d)].

Conditions under which Assurance of Confidentiality provisions for remote access to NTSS, and/or TB GIMS, and/or NSSAE data for CDC users would be met include:

• Using a CDC computer for CITGO access, rather than a home personal computer or home laptop; this ensures adequate virus protection, encryption, and physical controls in case of intrusion, loss, or theft of the computer or computer passwords.

• Restricted access to the local area network (LAN) workspace where NTSS, and/or TB GIMS, and/or NSSAE data are stored through password protection authorized by the Data Steward or his/her designee after required annual Assurance of Confidentiality training for users; access is granted to user by Information Technology Services Office (ITSO)

As with any access to the NTSS, and/or TB GIMS, and/or NSSAE data, users are required not to remove electronic files from the designated LAN workspace accessed through CITGO, and not to produce "back-up" copies of the data or related databases to store in locations other than the designated LAN workspace accessed through CITGO.

CDC users of TB GIMS may access TB GIMS remotely through CITGO, as described above. Access to TB GIMS for state and local users is through the Secure Access Management System (SAMS), which meets federal requirements for data protected under the Public Health Service Act Section 308(d) Assurance of Confidentiality [42 U.S.C. 242 m(d)]. Since state and local users only have access to data for their jurisdiction, they are covered by their own jurisdictions' laws and regulations regarding management of confidential surveillance data.

2. CDC/ATSDR Policy on Releasing and Sharing Data. Manual Guide: General Administration, CDC-102, Date of issue, 4/13/03. Website http://basis1.cdc.gov/BASIS/masompb/POLICIES/POLI-CIES/DDD/385.

Confidentiality Security Statement for the National Tuberculosis Surveillance System, and/ or Tuberculosis Genotyping Information System (TB GIMS), and/or National Surveillance of Severe Adverse Events Associated with Treatment for Latent TB Infection (NSSAE)

Surveillance, Epidemiology, and Outbreak Investigations Branch (SEOIB) Division of Tuberculosis Elimination (DTBE) National Center for Hepatitis, HIV, STD, and TB Prevention (NCHHSTP)

The SEOIB, DTBE, NCHHSTP (all references to SEOIB, DTBE and NCHHSTP refer to current or successor organizational unit) has applied for an extension of 308(d) Assurance of Confidentiality protection for data collected through surveillance activities entitled "Request for Extension of and Amendments to Assurance of Confidentiality for the National Tuberculosis Surveillance System. Because of this Assurance of Confidentiality, documents and files which contain patient-level information on persons reported as tuberculosis (TB) cases are considered confidential materials and must be safeguarded to the greatest extent possible. The confidentiality of TB surveillance program data collected at the local and state levels are protected under state/Territorial law, rule, or regulation. Although patient and physician names, addresses, phone numbers, and other directly identifying information (e.g., Social Security number), are not reported to CDC by health departments, data on individual TB cases collected through the Report of Verified Case of Tuberculosis (RVCT) form and National Surveillance for Severe Adverse Events Associated with Treatment for Latent TB Infection (NSSAE) data collection form include date of birth, other demographic information, and highly sensitive information such as HIV infection status, correctional facility residence, and alcohol or drug use and may have the potential to indirectly identify TB cases. Therefore, these TB surveillance data have 308(d) protection, and the security requirement is rated as high.

It is the professional, ethical, and legal responsibility of each CDC employee and contractor, and onsite DTBE guest researcher, fellow, visiting scientist, and graduate student who is granted access to data from NTSS to protect the confidentiality of all persons reported as TB cases. This document describes the procedures and practices that DTBE will use to protect the confidentiality of the data collected as part of NTSS.

Portions of the data management, database technical support, and data analysis and programming work which support NTSS are performed under contract. Therefore, we have included reference to contractors in the Assurance of Confidentiality Statement and this Confidentiality Security Statement. The Procurement and Grants Office has included appropriate 308(d) clauses in the contracts and has obtained the required 308(d) confidentiality pledges from all contractor employees associated with the national TB surveillance system. All contractor staff undergoes limited background investigations prior to performing any work at CDC.

CDC employees, contractors, and non-employees (e.g. guest researchers, visiting fellows, students) and designated DTBE staff who have been authorized to have access to the NTSS, and/or TB GIMS, and/or NSSAE data are required to maintain and protect at all times the confidentiality of records that may come into their presence and under their control.

In particular, they may not discuss, reveal, present, or confirm to external parties information on, or characteristics of, individual cases, or small numbers of cases, in any manner that could directly or indirectly identify any individual on whom a record is maintained by NTSS. The only exception would be for DTBE employees and contractors who may contact state health departments with ques-

tions and clarifications on individual cases using the unique case number.

All CDC staff with access to NTSS, and/or TB GIMS, and/or NSSAE data will be required to take a training session online at which the confidentiality procedures for these surveillance systems will be explained in greater detail. Agreements/pledges will be signed online by each person who is authorized to access NTSS, and/or TB GIMS, and/or NSSAE records. Thereafter, online confidentiality training shall be conducted annually and participation in such training shall be mandatory for all persons granted access to surveillance system records and files; CDC staff, their contractors and guest researchers, visiting fellows, and students shall be required to sign online confidentiality agreements on an annual basis. Access to surveillance data will be withheld if these requirements are not fulfilled.

The Data Steward for NTSS, TB GIMS, and NSSAE will be Chief, SEOIB or his/her designee. The Technical Steward will be the Chief, Data Management and Statistics Branch (DMSB) (all references to DMSB refer to DMSB or its successor organizational unit) or his/her designee. It shall be the responsibility of the Data and Technical Stewards or their designees to provide for online training and obtaining signed online authorizations from employees, contractors, and guest researchers, visiting fellows, students who are granted access to surveillance records.

Attachment 1 is the Nondisclosure Agreement (CDC 0.979) that DTBE, NCHHSTP staff members with access to NTSS, and/or TB GIMS, and/or NSSAE data will sign. The signed documents will be retained by the Data Steward (SEOIB, DTBE) or his/her designee in an electronic database. Attachment 2 is the "Protocol to Maintain Data Security and Confidentiality" which includes the "Request for access to RVCT data" and the "Agreement to abide by policies and procedures to maintain confidentiality and data security and restrictions on release of data from NTSS, and/or TB GIMS, and/or NSSAE" both of which must be signed online by all CDC staff, their contractors and nonemployees, e.g. guest researchers, visiting fellows, students, etc., who are granted access to records, files and databases containing information from NTSS, and/or TB GIMS, and/or NSSAE. The signed documents will be retained by the Data Steward (SEOIB, DTBE) or his/her designee in an electronic database. Attachment 3 is the Policy for Release of NTSS, and/or TB GIMS, and/or NSSAE Data. Attachment 4 is the Contractor's Pledge of Confidentiality entitled "Safeguards for individuals and establishments against invasions of privacy." Contracts needed to support NTSS, and/or TB GIMS, and/or NSSAE contain 308(d) clauses, and all contractor employees with access to the data are required to sign this contractor pledge. Attachment 5 is the Pledge for Non-Employees (guest researchers, visiting fellows, students, etc.). Attachment 6 is a statement for "Safeguards for Individuals and Establishments" for other CDC, non-DTBE or its successor organizational unit employees to sign. Signed online documents will be retained by the Data Steward (SEOIB, DTBE) or his/her designee in an electronic database.

Restrictions on Use of Information and Safeguarding Measures:

• Information collected in the course of conducting NTSS, and/or TB GIMS, and/or NSSAE will be used only for epidemiologic, statistical, or TB control purposes and shall not otherwise be divulged or made known in any manner that could result in the direct or indirect identification of any individual on whom a record is maintained.

• Records or data containing names or other personally identifying information (such as addresses,

telephone numbers, and social security numbers) for individual patients will not be received by CDC on any records for NTSS, TB GIMS, and NSSAE. Any data that would allow CDC to link, and therefore identify individual patients through the RVCT and NSSAE form at the local, State, or Territorial level will be removed before transmittal to CDC.

• Data collection forms will contain only state assigned patient identification numbers or other stateassigned codes. Data collection prior to 2009 may contain soundex codes generated from patient surnames in addition to state-assigned codes. However, because these are 308(d) protected data, they will be transmitted to CDC in a secure and confidential manner. Hard copies of data collection forms may only be transmitted to CDC staff if identifying information has been stripped and records placed in sealed envelopes marked "confidential." Following data entry and verification, as soon as feasible, such hard copies will be shredded or destroyed. All CDC reporting software data transmissions are automatically encrypted by the software that generates the transfer files after automatically deleting patient identifiers. Electronic data are transmitted via Secure Data Network (SDN), as encrypted email attachments, or via Compact Disk (CDC) or Digital Video Disk (DVD) using couriers that can track shipments and require authorized signatures for delivery.

• CDC staff, their contractors and other authorized agents are responsible for protecting all confidential records containing information that could potentially identify, directly or indirectly, any person on whom a record is maintained, from eye observation, from theft, or from accidental loss or misplacement due to carelessness. All reasonable precautions will be taken to protect confidential surveillance data.

• All contractor personnel will receive project-specific training in confidentiality procedures, in addition to the training and background investigations they must receive/undergo prior to being hired by the contractor.

• If a local/state/territorial health department inadvertently fails to remove personal identifiers of individual patients, or health care providers before forwarding hard copy forms to CDC, or incorrectly enters such identifying data into comments fields, SEOIB staff will immediately delete the identifiers, and remind health department personnel of the appropriate procedures to follow to delete such identifiers prior to transmitting records and forms to CDC.

• Except as needed for operational purposes, photocopies of confidential records are not to be made. If photocopies are necessary, care should be taken that all copies and originals are recovered from the copy machines and work areas. Correspondence containing sensitive patient specific information shall be maintained in a locked file cabinet. All confidential paper records will be destroyed as soon as operational requirements permit by shredding the documents.

• E-mail, memoranda, reports, publications, slides, and presentations that contain data collected through NTSS, TB GIMS, and NSSAE shall not contain data or information that could directly or indirectly identify any person on whom a record is maintained by CDC. In particular, specifics of case patient characteristics or specific geographic identifying information are highly sensitive material. It shall be the responsibility of all CDC employees, their contractors or non-employees, e.g. guest researchers, visiting fellows, students, etc., who are granted access to sensitive surveillance information to safeguard such data. Telephone conversations with local/State/Territorial health department personnel that include discussions of sensitive information shall be conducted discreetly, preferably in private walled offices.

Enhanced Protection of Computerized Files:

All data will be protected in confidential computer files. The following safeguards are implemented to protect NTSS, TB GIMS, and NSSAE files so that the accuracy and the confidentiality of the data can be maintained:

• Computer files containing programs, documents, or confidential data will be stored in computer systems that are protected from accidental alteration and unauthorized access. Computer files will be protected by password systems, virus detection procedures, and routine backup procedures. Data stored at state and local health departments using CDC-supplied software designed to manage data for surveillance program activities are protected by security requirements; the software ensures that the data transmitted to CDC will be in a format that is compatible with the security and confidentiality requirements of NTSS databases maintained by CDC.

• The SEOIB & DMSB local area network (LAN) maintained by CDC's Information Technology Services Office comply with Federal policies, statutes, regulations, and other directives for the collection, maintenance, use, and dissemination of data, including the Department of Health and Human Services Automated Information Systems Security Program and the Computer Security Act of 1987 (Public Law 100-235). Additionally, the LAN is in compliance with CDC's IRMO Security Policy. The DTBE LAN currently operates under Windows 2003 Server. Security features implemented include user ID and password protection, mandatory password changes; limited logins; user rights/ file attribute restrictions and virus protection.

• Data are maintained on the LAN. SEOIB and DMSB employees or contractors, and other CDC employees or contractors who service or maintain the systems or components necessary to support data management of NTSS, TB GIMS, and NSSAE files will be granted access to the files only upon express written approval by the Data Steward or his/her designee. The list of authorized users will be maintained by the LAN administrator, and the Technical and Data Stewards or their designees who will review the list at least on an annual basis to remove those no longer needing access. Access is removed when staff no longer requires it by notification to the LAN administrator by the Technical or Data Stewards or their designees.

• Data collected are maintained in the CDC Common Data Store. DTBE has transitioned from its previous data collecting and reporting system (TIMS) to the CDC-developed National Electronic Disease Surveillance System (NEDSS) or other state-developed systems. NEDSS is a part of the Public Health Information Network (PHIN), which enables consistent exchange of response, health, and disease tracking data between public health partners. PHIN is composed of five key components: detection and monitoring, data analysis, knowledge management, alerting and response. Data collected via PHIN/NEDSS is reported via the Internet on a "real time" basis to the CDC. Once at CDC, TB data reside in a Common Data Store (CDS) along with data from other disease surveillance programs at CDC. From the Common Data Store, the TB Data are extracted into the TB Data Mart. These data are managed by CDC Information Technology personnel, and access to the CDS and Data Mart are granted via Internet server technology to the TB program for data analysis and maintenance. PHIN/NEDSS uses best practices security standards, and data communication and storage are assured of data integrity, confidentiality, and availability through completion of the mandatory Certification and Accreditation (C&A) process.

• Data collected and integrated with TB GIMS are maintained at an ITSO Designated Server Site (DSS) along with other CDC firewall-protected databases. These data are managed by CDC Information Technology personnel, and access to the TB GIMS is granted via Internet server technology to the TB program for data analysis and maintenance. TB GIMS uses best practices security standards, and data communication and storage are assured of data integrity, confidentiality, and availability through completion of the mandatory C&A process.

• Backup copies of LAN data are made by the LAN tape backup system; data on servers and workstations are backed up by the ITSO or its successor organizational unit backup system. Backup services are provided under a separate CDC-wide contract. These files are kept for a minimum of three months. Contractor facilities and staff are subject to the same Federal policies, statutes, regulations, and other directives, as well as to departmental and CDC security policies, which apply to CDC servers and LAN computers and staff. Access to LAN backup tapes is restricted to three DMSB staff (the LAN administrator, Network administrator, computer help-desk coordinator). Contractors are prohibited from any access to backup tapes without written permission from the Business or Technical Stewards.

Dissemination of Data from NTSS, TB GIMS, and NSSAE

State and local health departments receive confirmation of their transmittals of data to CDC. -SEOIB staff is responsible for timely dissemination of aggregate data at the national level, state, or Metropolitan Statistical Area level, consistent with the data release policies described in Attachment 3. Data will generally be reported only in aggregate form as summary statistics including restrictions on small cell sizes and geographic identifiers; such statistics could not be used to indirectly identify an individual. Modes of disseminating data include reports, articles in the Morbidity and Mortality Weekly Report publications, public

use slide sets, and public use data sets such as in the Online Tuberculosis Information System. SEOIB staff may provide data in response to special requests from Congress, the Department of Health and Human Services, other government agencies, and other programs within CDC on a priority basis with the approval of the Director, DTBE or the Business or Technical Stewards.

SEOIB staff is also responsible for timely updating of the TB GIMS datasets, so that up- to-date NTSS data are included. CDC, state, and local users of TB GIMS will generally have access to line listed patient data linked to genotype results, as well as aggregate reports on demographic, risk factor and geographic information. State and local users will only have access to their assigned jurisdiction, and will only be able to view data based on their user role. The geographic jurisdiction and user role for state and local users are determined by the state TB controller or their designee. CDC staff will have access to the entire country. The user role for CDC users is determined according to the Policy for Granting TB GIMS Access to CDC Employees, Contractors, and Non-employees.

Records Disposition for the National Archives and Records Administration

Records that are determined to be permanently valuable are sent to the National Archives and Records Administration (NARA). Transfers of such records and files will be done in accordance with the May 1996 agreement stating that CDC will transfer to NARA all permanent data sets in accordance with approved schedules contained in part IV of the CDC Records Control Schedule B-321, with the exception of identifying information collected under an Assurance of Confidentiality agreement as specified under the Public Health Service Act, Sections 301(d) and 308(d).

If 308(d) records for this project are being sent to the Federal Records Center for temporary storage (in which CDC maintains control of the data), they will be clearly identified as 308(d) protected records. The SF 135 will state: "This accession contains records protected by a confidentiality assurance under Section 308(d) of the PHS Act." The boxes will have a label stating: "This accession contains records protected by a confidentiality assurance under Section 308(d) of the PHS Act. The records can be released only to authorized staff from the National Center for HIV, STD, and TB Prevention with responsibility for the "National Tuberculosis Surveillance System, and/or TB GIMS, and/or NSSAE."

Appendix 2: Policy on Access to Genotyping Data for Research Purposes

Policy on Access to Genotyping Data for Research Purposes

Purpose

The purpose of this policy is to describe the protocol for CDC employees, contractors and other nonemployees (e.g., guest researchers, visiting fellows, students, etc.) to request and be granted access to TB genotyping data, specifically data from the TB Genotyping Information Management System (TB GIMS) that is included in the frozen dataset. The frozen dataset consists of patient-level data reported to CDC via the National TB Surveillance System (NTSS) linked to genotyping results from the National TB Genotyping Service (NTGS). Use of the genotyping data in the frozen dataset for research purposes must meet the same requirements as use of NTSS data for research purposes.

This policy only applies to access to the frozen dataset, not access to the TB GIMS Internet-based application. For information on how to access the TB GIMS application, please review the Policy for Granting TB GIMS Access to CDC Employees, Contractors, and Non-employees.

This policy does not apply to research projects that only involve isolate-level NTGS data (i.e., data that is not linked to individual level case data). For questions about conducting research on NTGS data, please contact the NTGS Project Officer (Lauren Cowan, Laboratory Branch, los4@cdc.gov). This policy does not apply to CDC employees and contractors assigned to the Molecular Epidemiology Activity (MEA) who are performing exploratory analyses or analyses related to programmatic functions. However, CDC employees and contractors assigned to MEA who are conducting research must still abide by this policy for formal research projects.

Appropriate uses of TB genotyping data for research

TB genotyping data from the frozen dataset may be used by CDC employees, contractors and nonemployees to conduct public health research. Research projects conducted on the frozen dataset must comply with all CDC and Division of TB Elimination (DTBE) policies on research, including human subjects review requirements and the policies of DTBE's Analytic Steering Committee (ASC). Researchers must obtain ASC approval of their project proposal and analytic plan before starting any analysis.

Research projects approved under this policy are limited to data available at CDC. If researchers need to analyze additional data that are only available at the state or local level, or need to examine patient identifiers, then they must engage directly with the appropriate state or local jurisdiction. The state or local jurisdiction must be able to supply the complete dataset with all the necessary variables. Researchers may not match patient data from the frozen dataset with patient-level data from non-CDC databases.

Researchers must use the SEOIB-provided frozen data sets for their analyses. The surveillance team will create a frozen dataset annually including NTSS and NTGS data for the year. Researchers may not export data directly from TB GIMS to use for research projects.

Process to obtain access

As with all projects involving NTSS data, persons who wish to perform research projects on the frozen dataset must have a proposal and analytic plan approved by the Analytic Steering Committee. For more information about the ASC, including the project proposal form, please see: http://www. nchhstp.cdc.gov/dtbe/publications/asc.asp. Proposals must also undergo CDC human subjects review and, if required, be approved by the CDC Institutional Review Board (IRB). Investigators who seek access to genotyping data must also complete the CDC Assurance of Confidentiality training. Data

confidentiality trainings must be repeated annually. The training can be found at: http://nchhstp/dtbe/ org/seoib/default.asp.

Before you submit a proposal to the ASC or IRB, you must schedule a data orientation session through the MEA lead with a MEA scientist to discuss your proposal. The MEA lead may also require that a Laboratory Branch (LB) scientist also be present at the data orientation session. You will also need to schedule a similar data orientation with the Surveillance Team (S-team). These orientations can be done simultaneously if schedules permit. The scientists with MEA, LB and S-team can assist you in reviewing the plausibility and usability of your proposal against what's available in the dataset.

After your proposal is approved by the ASC and IRB (if required), and you have completed the data confidentiality training, you must schedule another meeting with the MEA and LB scientists assigned to you by the MEA lead. The meeting will allow you to obtain an orientation to the data for the years you requested and assist you will starting development of your analytic plan. At this meeting, be prepared to discuss the following:

- 1. Variables you intend to use
- 2. Your proposed analysis
- 3. What, if any, additional assistance you will need (e.g. interpretation of results, SAS coding, statistical assistance)
- 4. Project timeline

If you intend to seek ongoing support from the MEA and/or LB scientists, you should make clear what you envision their role to be up front and consider this role when determining co-authorship or acknowledgments for presentations or publications. A preliminary determination of co-authorship should be made during this meeting; it should be a joint decision by the Primary Investigator on the project and the MEA and LB scientists. Any disagreements about co-authorship should be brought to the MEA Lead.

Following the second meeting with the MEA and LB scientists assigned to the project, and approval of the analytic plan by the ASC, researchers should send a written request to the MEA Lead (or designee) with the following information:

- a) Project title
- b) Name of the principal investigator and any co-investigators
- c) Name and CDC user ID of persons needing access to the dataset
- d) Variable names needed for the analysis
- e) Inclusive dates needed for the analysis
- f) Approximate time frame for the project

The MEA lead or their designee will confirm that any persons requesting access to the dataset have completed data confidentiality training and that the project and analytic plan have been approved by the ASC. Once this has been confirmed, the MEA lead will inform the MEA data manager that access to the requested data has been approved.
The data manager will create a restricted access project folder on the CDC network; co-investigators will use this folder for all project-related files. The MEA data manager will grant the requestor and other co-investigators needing access to the dataset access to the project folder; the S-team data manager will grant access to the frozen file.

Data management including data cleaning and recoding, as well as data analysis, are the responsibility of the researchers. The MEA scientist will not review your analytic methods or statistical software code for accuracy or appropriateness. However, if you do request a larger role from your MEA scientist that includes assistance with these tasks, then please negotiate those responsibilities, and appropriate co-authorship, at your data orientation session. Assistance with advanced statistical methods might require involvement of the Data Management and Statistics Branch (DMSB). DMSB resources should be requested using the procedure outlined in the DTBE Biostatistical Support Procedure (http://intranet.cdc.gov/nchhstp/dtbe/org/dmsb/biostat.asp).

Engaging MEA and LB staff early in your project analysis will provide you valuable perspective from scientists who work with TB GIMS data on a daily basis. This perspective will likely save valuable time and improve your project overall.

Publication and presentation of projects using genotyping data

All abstracts, presentations, posters, and publications involving research conducted on the frozen dataset must be reviewed by the Surveillance, Epidemiology and Outbreak Investigations Branch Chief (or his/her designee) prior to submission or presentation. The PI on the project is responsible for ensuring that this review occurs.

Annual review of CDC staff with access to genotyping data

The list of all CDC staff with access to genotyping data for analytic or research projects will be reviewed annually at the start of each fiscal year by the MEA Lead. The MEA Lead will ensure that the researcher has completed data confidentiality training in the past year and has an approved research protocol and analytic plan on file. The MEA Lead will ensure that the Surveillance Team Lead receives a list of all persons with current access to the dataset on an annual basis. As with all ASC-approved projects, projects using genotyping data are expected to show reasonable progress consistent with their research protocols and analytic plans. Projects that are not demonstrating reasonable progress. The ASC may allow the project to continue without modification or require that the researchers submit a revised research protocol and analytic plan, or may terminate the project's access to TB GIMS data.

Appendix 3: Codes

Anatomic Codes

Dermal System

- 00 Skin and skin appendages
- 01 Subcutaneous Tissue
- 02 Breast
- 03 Milk

Hematopoietic System

- 04 Bone marrow
- 05 Spleen
- 06 Blood

Lymphatic System

07 Lymph node

Musculoskeletal System

- 08 Bone NOS (Not Otherwise Specified)
- 09 Skeletal system (Bones of head ribcage and vertebral column)
- 10 Skeletal system (Bones of shoulder Girdle pelvis and extremities)
- 11 Soft tissue NOS (Not Otherwise specified
- 12 Soft tissue (Muscles of head neck mouth and upper extremity)
- 13 Soft tissue (Muscles of trunk perineum and lower extremity)
- 14 Tendon and tendon sheath
- 15 Ligament and fascia
- 16 Joints (Synovial tissue)
- 17 Synovial fluid

Respiratory System

- 18 Nose
- 19 Accessory Sinus
- 20 Nasopharynx
- 21 Epiglottis and larynx
- 22 Trachea
- 23 Bronchus

26 Pleura 27 Upper respiratory fluids 28 Bronchial fluid 29 Pleural fluid **Cardiovascular System** 30 Pericardium 31 Heart 32 Cardiac valve

24 Bronchiole

25 Lung

- 33 Pericardial fluid
- 34 Blood vessel

Gastrointestinal System	70 Male genital fluids
	71 Vulva labia clitoris and Bartholin's
35 Mouth	gland
36 Lip	72 Vagina
37 Tongue	73 Uterus
38 Tooth gum and supporting structures	74 Cervix
of the tooth	75 Endometrium
39 Salivary gland	76 Myometrium
40 Liver	77 Fallopian tube broad ligament
41 Gallbladder	parametrium parovarian region
42 Extrahepatic bile duct	78 Ovary
43 Pancreas	79 Female genital fluids
44 Saliva	Fetal Structures
45 Bile and pancreatic fluid	80 Placenta umbilical cord and
46 Pharynx oropharynx and	implantation site
hypopharynx	81 Fetus and embryo
4/ I onsils and adenoids	Endocrine System
48 Esophagus	82 Pituitary gland
49 Stomacn	83 Adrenal gland
50 Small intestine - duodenum	84 Thyroid of parainyroid gland(s)
52 Appendix	Neurological System
52 Appendix 53 Colon	86 CSE (Cerebral spinal fluid)
54 Rectum	87 Meninges, dural sinus, choroid plexus
55 Anus	88 Brain
56 Gastric aspirate	89 Spinal cord
57 Gastrointestinal contents (feces)	90 Cranial spinal and peripheral nerve
58 Omentum and peritoneum	91 Eye and ear appendages
59 Peritoneal fluid	92 Ear and mastoid cells
Urogenital System	89 Spinal cord
60 Kidney	90 Cranial spinal and peripheral nerve
61 Renal pelvis	91 Eye and ear appendages
62 Ureter	92 Ear and mastoid cells
63 Urinary bladder	
64 Urethra	Other
65 Penis	93 Pus
66 Prostate and seminal vesicle	94 Other
67 Testis	95 Multiple Sites
68 Epididymis vas deferens spermatic cord scrotum	99 Unknown
69 Urine	

Site of Disease

The following disease codes are listed as check-box options under Q16 Site of TB Disease; and should not be used as an Anatomic Other Site code.

- **PU** Pulmonary
- PL Pleural
- LC Lymphatic: Cervical
- LI Lymphatic: Intrathoracic
- LA Lymphatic: Axillary
- LO Lymphatic: Other
- LU Lymphatic: Unknown
- LX Larynx

- **BO** Bone and/or Joint
- GU Genitourinary
- ME Meningeal
- PT Peritoneal
- **OT** Other
 - NS Site not stated

Other Sites of TB Disease: If disease site = "other" on Q16, enter Disease code(s) from list below

Dermal System	Cardiovascular System
SK Skin and skin appendages	PE Pericardium
SU Subcutaneous Tissue	HE Heart
BR Breast	CA Cardiac valve
Hematopoietic System	BV Blood vessel
BM Bone marrow	Gastrointestinal System
SP Spleen	MO Mouth
BL Blood	LP Lip
Respiratory System	TO Tongue
AC Accessory Sinus AC Accessory Sinus NA Nasopharynx TR Trachea Neurological System BA Brain SC Spinal cord CR Cranial spinal and peripheral nerve EY Eye and ear appendages EA Ear and mastoid cells Fetal Structures (Female) PC Placenta umbilical cord and implantation site FE Fetus and embryo Endocrine System PI Pituitary gland	 TH Tooth gum and supporting structures of the tooth SA Salivary gland LV Liver GA Gallbladder EX Extrahepatic bile duct PA Pancreas PH Pharynx oropharynx and hypopharynx TS Tonsils and adenoids ES Esophagus ST Stomach SD Small intestine – duodenum SJ Small intestine – jejunum & ileum AP Appendix
AD Adrenal glandTY Thyroid or parathyroid gland(s)TM Thymus	CO Colon RE Rectum AN Anus Other OT Other

State Code List

Name	Alpha	FIPS	Name	Alpha	FIPS
Alabama	AL	01	Alaska	АК	02
Arizona	AZ	04	Arkansas	AR	05
California	CA	06	Colorado	CO	08
Connecticut	CT	09	Delaware	DE	10
Florida	FL	12	Georgia	GA	13
Hawaii	HI	15	Idaho	ID	16
Illinois	IL	17	Indiana	IN	18
Iowa	IA	19	Kansas	KS	20
Kentucky	KY	21	Louisiana	LA	22
Maine	ME	23	Maryland	MD	24
Massachusetts	MA	25	Michigan	MI	26
Minnesota	MN	27	Mississippi	MS	28
Missouri	MO	29	Montana	MT	30
Nebraska	NE	31	Nevada	NV	32
New Hampshire	NH	33	New Jersey	NJ	34
New Mexico	NM	35	New York	NY	36
New York City	NO	70	North Carolina	NC	37
North Dakota	ND	38	Ohio	OH	39
Oklahoma	OK	40	Oregon	OR	41
Pennsylvania	PA	42	Rhode Island	RI	44
South Carolina	SC	45	South Dakota	SD	46
Tennessee	ΤN	47	Texas	ТХ	48
Utah	UT	49	Vermont	VT	50
Virginia	VA	51	Washington	WA	53
Washington D.C.	DC	11	West Virginia	WV	54
Wisconsin	WI	55	Wyoming	WY	56
American Samoa	AQ	60	Federated States o Micronesia	f FM	63
Guam	GU	66	Northern Mariana Islands	CQ	69
Palau	PS	75	Puerto Rico	PR	72
Republic of	RM	73	Virgin Islands	VQ	78
Marshall Islands		-	5	- •	-

Country Code List

Country	Nation Code
(as appears in dataset)	
AFGHANISTAN	AFG
ALBANIA	ALB
ALGERIA	DZA
AMERICAN SAMOA	ASM
ANDORRA	AND
ANGOLA	AGO
ANGUILLA	AIA
ANTARCTICA	ATA
ANTIGUA AND BARBUDA	ATG
ARGENTINA	ARG
ARMENIA	ARM
ARUBA	ABW
ASHMORE AND CARTIER ISL	AT
AUSTRALIA	AUS
AUSTRIA	AUT
AZERBAIJAN	AZE
BAHAMAS THE	BHS
BAHRAIN	BHR
BAKER ISLAND	FQ
BANGLADESH	BGD
BARBADOS	BRB
BASSAS DA INDIA	BS
BELARUS	BLR
BELGIUM	BEL
BELIZE	BLZ
BENIN	BEN
BERMUDA	BMU
BHUTAN	BTN
BOLIVIA	BOL
BOSNIA AND HERCEGOVINA	BIH
BOTSWANA	BWA
BOUVET ISLAND	BVT
BR INDIAN OCEAN TERR	IOT
BRAZIL	BRA
BRITISH VIRGIN IS.	VGB
BRUNEI	BRN

Country	Nation Code
(as appears in dataset)	
BULGARIA	BGR
BURKINA (UPPER VOLTA)	BFA
BURMA	BUMM
BURUNDI	BDI
CAMBODIA	KHM
CAMEROON	CMR
CANADA	CAN
CAPE VERDE	CPV
CAYMAN ISLANDS	СҮМ
CENTRAL AFRICAN REPUBLIC	CAF
CHAD	TCD
CHILE	CHL
CHINA	CHN
CHRISTMAS ISLAND	CXR
CLIPPERTON ISLAND	IP
COCOS (KEELING) ISLANDS	ССК
COLOMBIA	COL
COMOROS	СОМ
CONGO	COG
CONGO THE DEMOCRATIC REPUBLIC OF THE	COD
COOK ISLANDS	COK
CORAL SEA ISLANDS	CR
COSTA RICA	CRI
CROATIA	HRV
CUBA	CUB
CYPRUS	СҮР
CZECH REPUBLIC	CZE
CZECHOSLOVAKIA	CSHH
DENMARK	DNK
DJIBOUTI	DJI
DOMINICA	DMA
DOMINICAN REPUBLIC	DOM
ECUADOR	ECU
EGYPT	EGY

Country	Nation Code
(as appears in dataset)	CLV
	SLV
EQUATORIAL GUINEA	GNQ
ERITREA	EKI
ESTONIA	EST
ETHIOPIA	ETH
EUROPA ISLAND	EU
FALKLAND (IS MALVINAS)	FLK
FAROE ISLANDS	FRO
FED STATES MICRONESIA	FSM
FIJI	FJI
FINLAND	FIN
FR SO & ANTARCTIC LNDS	ATF
FRANCE	FRA
FRENCH GUIANA	GUF
FRENCH POLYNESIA	PYF
GABON	GAB
GAMBIA THE	GMB
GAZA STRIP	GZ
GEORGIA	GEO
GERMANY	DEU
GHANA	GHA
GIBRALTAR	GIB
GLORIOSO ISLANDS	GO
GREECE	GRC
GREENLAND	GRL
GRENADA	GRD
GUADELOUPE	GLP
GUAM	GUM
GUATEMALA	GTM
GUERNSEY	GGY
GUINEA	GIN
GUINEA-BISSAU	GNB
GUYANA	GUY
HAITI	HTI
HEARD IS & MCDONALD ISLS	HMD
HONDURAS	HND

Country	Nation Code
(as appears in dataset)	
HONG KONG	HKG
HOWLAND ISLAND	HQ
HUNGARY	HUN
ICELAND	ISL
INDIA	IND
INDONESIA	IDN
IRAN	IRN
IRAQ	IRQ
IRAQ-S ARABIA NEUTRAL Z	NTHH
IRELAND	IRL
ISRAEL	ISR
ITALY	ITA
IVORY COAST	CIV
JAMAICA	JAM
JAN MAYEN	JN
JAPAN	JPN
JARVIS ISLAND	DQ
JERSEY	JEY
JOHNSTON ATOLL	JQ
JORDAN	JOR
JUAN DE NOVA ISLAND	JU
KAZAKHSTAN	KAZ
KENYA	KEN
KINGMAN REEF	KQ
KIRIBATI	KIR
KOREA REPUBLIC OF	KOR
KOREA DEM PEOPLES REP	PRK
KUWAIT	KWT
KYRGYZSTAN	KGZ
LAOS	LAO
LATVIA	LVA
LEBANON	LBN
LESOTHO	LSO
LIBERIA	LBR
LIBYA	LBY
LIECHTENSTEIN	LIE
LITHUANIA	LTU

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MALTAMLTMAN ISLE OFIMNMARSHALL ISLANDSMUL
MAN ISLE OF IMN
MARSHALL ISLANDS MHL
MARTINIQUE MTQ
MAURITANIA MRT
MAURITIUS MUS
MAYOTTE MYT
MEXICO MEX
MIDWAY ISLAND MIUM
MOLDOVA MDA
MONACO MCO
MONGOLIA MNG
MONTENEGRO MNE
MONTSERRAT MSR
MOROCCO MAR
MOZAMBIQUE MOZ
MYANMAR MMR
NAMIBIA NAM
NAURU NRU
NAVASSA ISLAND BQ
NEPAL NPL
NETHERLANDS NLD
NETHERLANDS ANTILLES ANT
NEW CALEDONIA NCL
NEW ZEALAND NZL
NICARAGUA
NIGER NER
NIGERIA NGA
NILIE NILI
NORFOLK ISLAND NFK

Country	Nation Code
(as appears in dataset)	
NORTHERN MARIANA ISLANDS	MNP
NORWAY	NOR
NOT SPECIFIED	NI
OMAN	OMN
PAKISTAN	PAK
PALAU	PLW
PALMYRA ATOLL	LQ
PANAMA	PAN
PAPUA NEW GUINEA	PNG
PARACEL ISLANDS	PF
PARAGUAY	PRY
PERU	PER
PHILIPPINES	PHL
PITCAIRN ISLANDS	PCN
POLAND	POL
PORTUGAL	PRT
PORTUGUESE TIMOR	TPTL
PUERTO RICO	PRI
QATAR	QAT
REUNION	REU
ROMANIA	ROU
RUSSIA	RUS
RWANDA	RWA
S.GEORGIA/S.SANDWIC IS	SGS
SAN MARINO	SMR
SAO TOME AND PRINCIPE	STP
SAUDI ARABIA	SAU
SENEGAL	SEN
SERBIA	SRB
SEYCHELLES	SYC
SIERRA LEONE	SLE
SINGAPORE	SGP
SLOVAK REPUBLIC	SVK
SLOVENIA	SVN
SOLOMON ISLANDS	SLB
SOMALIA	SOM

Country	Nation Code
(as appears in dataset)	
SOUTH AFRICA	ZAF
SOVIET UNION	SUHH
SPAIN	ESP
SPRATLY ISLANDS	PG
SRI LANKA	LKA
ST. LUCIA	LCA
ST. HELENA	SHN
ST. KITTS AND NEVIS	KNA
ST. PIERRE AND MIQUELON	SPM
ST. VINCENT/GRENADINES	VCT
SUDAN	SDN
SURINAME	SUR
SVALBARD	SJM
SWAZILAND	SWZ
SWEDEN	SWE
SWITZERLAND	CHE
SYRIA	SYR
TAIWAN	TWN
TAJIKISTAN	TJK
TANZANIA UNITED REP OF	TZA
THAILAND	THA
TIMOR- LESTE	TLS
TOGO	TGO
TOKELAU	TKL
TONGA	TON
TRINIDAD AND TOBAGO	TTO
TROMELIN ISLAND	TE
TUNISIA	TUN
TURKMENISTAN	TKM
TURKS AND CAICOS ISL	TCA
TUVALU	TUV
U.S. MINOR OUTLYING ISL	UMI
UGANDA	UGA

Country	Nation Code
(as appears in dataset)	
UKRAINE	UKR
UNITED ARAB EMIRATES	ARE
UNITED KINGDOM	GBR
UNITED STATES	USA
URUGUAY	URY
US MISC PACIFIC ISLANDS	PUUM
UZBEKISTAN	UZB
VANUATU (NEW HEBRIDES)	VUT
VATICAN CITY	VAT
VENEZUELA	VEN
VIETNAM	VNM
VIRGIN ISLANDS	VIR
WAKE ISLAND	WKUM
WALLIS AND FUTUNA	WLF
WEST BANK	WE
WESTERN SAHARA	ESH
WESTERN SAMOA	WSM
YEMEN	YEM
YUGOSLAVIA	YUCS
ZAIRE	ZRCD
ZAMBIA	ZMB
ZIMBABWE	ZWE

Asian and Native Hawaiian/Pacific Islander Race Codes

Race	Code	Race	Code
		Native Hawaiian or Pacific	
Asian	2028-9	Islander	2076-8
Asian Indian	2029-7	Polynesian	2078-4
Bangladeshi	2030-5	Native Hawaiian	2079-2
Bhutanese	2031-3	Samoan	2080-0
Burmese	2032-1	Tahitian	2081-8
Cambodian	2033-9	Tongan	2082-6
Chinese	2034-7	Tokelauan	2083-4
Taiwanese	2035-4	Micronesian	2085-9
Filipino	2036-2	Guamanian or Chamorro	2086-7
Hmong	2037-0	Guamanian	2087-5
Indonesian	2038-8	Chamorro	2088-3
Japanese	2039-6	Mariana Islander	2089-1
Korean	2040-4	Marshallese	2090-9
Laotian	2041-2	Palauan	2091-7
Malaysian	2042-0	Carolinian	2092-5
Okinawan	2043-8	Kosraean	2093-3
Pakistani	2044-6	Pohnpeian	2094-1
Sri Lankan	2045-3	Saipanese	2095-8
Thai	2046-1	Kiribati	2096-6
Vietnamese	2047-9	Chuukese	2097-4
Iwo Jiman	2048-7	Yapese	2098-2
Maldivian	2049-5	Melanesian	2100-6
Nepalese	2050-3	Fijian	2101-4
Singaporean	2051-1	Papua New Guinean	2102-2
Madagascar	2052-9	Solomon Islander	2103-0
Black or African American	2054-5	New Hebrides	2104-8
Black	2056-0		
African American	2058-6		
African	2060-2		
Botswanan	2061-0		
Ethiopian	2062-8		
Liberian	2063-6		
Namibian	2064-4		
Nigerian	2065-1		
Zairean	2066-9		
Bahamian	2067-7		
Barbadian	2068-5		
Dominican	2069-3		
Dominica Islander	2070-1		
Haitian	2071-9		
Jamaican	2072-7		
Tobagoan	2073-5		
Trinidadian	2074-3		
West Indian	2075-0		

Appendix 4: Annotated RVCT Form

Patient's Name			
	(Last)	(First)	(M.L)
Street Address			

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES-FORM APPROVED OMB NO. 0920-0026 Exp. Date 05/31/2011

(ZIP CODE)



VONCN

REPORT OF VERIFIED CASE OF TUBERCULOSIS

1. Date Reported	3. Case Numbers STCASEYR	STCASEST	
Month Day Year	State Case Number	CCCASES CCCASEID	0 NO
2. Date Submitted	Linking State Case Number	LKCASE IND Reason:	ENSI
	Case Number	LKCASEZ ST	
4. Reporting Address for Case Counting City City Within City Limits (select one)		8. Date of Birth DoB Month Day Year	
COUNTY	ZIPSVEFIX	9. Sex at Birth (select one) 11. Race (select one or more) PACECAL Male Female American Indian or Alaska Native 10. Ethnicity (select one) Asian: Specify Black or African American	C
5. Count Status (select one) 6. [Countable TB Case Count as a TB case	Date Counted COUNTDATE Month Day Year	Hispanic or Latino Not Hispanic or Latino Not Hispanic Other Pacific Islander: Specify White	
Verified Case: Counted by another U.S. area (e.g., county, state)	Previous Diagnosis of TB Disease (select PREVTB	12. Country of Birth VSBORN "U.Sborn" (or born abroad to a parent who was a U.S. citizen) (select one) Yes No Country of birth: Specify	
initiated in another country If Specify NONSTEC Verified Case: Recurrent TB within 12 months after completion of therapy	YES, enter year of previous TB disease di	agnosis: 13. Month-Year Arrived in U.S. USDATE Month Year	
14. Pediatric TB Patients (<15 years old)		te of TB Disease (select all that apply) Pulmonary Pulmonary Pleural Cymphatic: Cervical Cymphatic: Axillary Cymphatic: Axillary Content Enter anatomic code(s) Content Enter anatomic co	
Alive Dead Month Da	ay Year	Lymphatic: Unknown	

Public reporting burden of this collection of information is estimated to average 35 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, Project Clearance Officer, 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-0026). Do not send the completed form to this address.

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 only 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).

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TBCAUSE

If DEAD, was TB a cause of death? (select one)

□ No

Unknown

Yes

Patient's Name			State Case No.	REPORT OF VERIFIED CASE
	(Last)	(First)	(M.I.)	OF TUBERCULOSIS

The other of the the other of tobe tobe of the	REPORT	OF	VERIFIED	CASE OF	TUBERCULOSIS
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17. Sputum Smear (select one) SPSMER Date Collected: SPSMRCOL Positive Not Done Month Day Year Negative Unknown Date Collected: SPSMRCOL 18. Sputum Culture (select one) Date Collected: SPCULTCOL Date F Positive Not Done Month Day Year Moith Negative Unknown Date Collected: SPCULTCOL Date F Reporting Laboratory Type (select one) Benorting Laboratory Type (select one) Public Health	Result Reported: SPCULTREP Inth Day Year
Image: Second construction Image: Second construction Image: Second construction Image: Second construction 19. Smear/Pathology/Cytology of Tissue and Other Body Fluids (select one) MICR EXAM Image: Desitive in Not Done in Not Do	anatomic code Type of exam (select all that apply): st): Smear Pathology/Cytology MICRSMR
20. Culture of Tissue and Other Body Fluids (select one) Positive Not Done Negative Unknown Month Day Year Reporting Laboratory Type (select one): Public Health Laboratory	mic code st): Date Result Reported: CVLTREP Month Day Year Commercial Laboratory Other
21. Nucleic Acid Amplification Test Result (select one) NATEST Positive Not Done Date Collected: NACOL D Negative Unknown Month Day Year D Indeterminate Enter specimen type: Sputum R D OR If not Sputum, enter anatomic code (see list): NAANA	Date Result Reported: NAREP Month Day Year Particle Select one): NARCES Reporting Laboratory Type (select one): NARCES Public Health Commercial Laboratory Other
22A. Initial Chest Radiograph (select one) Normal Abnormal* (consistent with TB) Not Done * For ABNORMAL Initial Chest Radiograph: Evidence of Evidence of Other Chest Imaging Study (select one) Normal Abnormal* (consistent with TB) Not Done * For ABNORMAL Initial Chest CT Scan or Other Chest Imaging Study (select one) Normal Abnormal* (consistent with TB) Not Done * For ABNORMAL Initial Chest Radiograph: * For ABNORMAL Initial Chest Radiograph: Evidence of Evidence of * For ABNORMAL Initial Chest Radiograph:	Unknown of a cavity (select one): Yes No Unknown of miliary TB (select one): Yes No Unknown Unknown of a cavity (select one): Yes No Unknown of miliary TB (select one): Yes No Unknown
23. Tuberculin (Mantoux) Skin Test at Diagnosis (select one) TBTEST Date Tuberculin Skin Test (TST) Placed: TBTESTMM Millimeters (mm) of induration: Positive Not Done Month Day Year Millimeters (mm) of induration: Negative Unknown Date Tuberculin Skin Test (TST) Placed: Millimeters (mm) of induration: Negative Unknown Date Collected: INTEGECOL Month 1 Date Collected: INTEGECOL Month Positive Not Done Month Day Positive Unknown Test type: INTEGESPEC Indeterminate Specify	25. Primary Reason Evaluated for TB Disease (select one) REASONEVAL TB Symptoms Abnormal Chest Radiograph (consistent with TB) Contact Investigation Targeted Testing Health Care Worker Employment/Administrative Testing Immigration Medical Exam Incidental Lab Result Unknown

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Patient's	Name

REPORT OF VERIFIED CASE OF TUBERCULOSIS

(First)

(Last)

26. HIV Status at Time of Diagnosis (select one)	HIVSTAT
Negative L Indeterminate L	
	L Test Done, Results Unknown
If POSITIVE, enter: HIV STATIO	
Patient Number:	Patient Number:
27. Homeless Within Past Year (select one) HOMELESS If YE	dent of Correctional Facility at Time of Diagnosis (select one) No Yes Unknown iS, (select one): CORRINST If YES, under custody indexel Prises Local Init Other Correctional Facility
	itate Prison Juvenile Correction Facility Unknown No Yes
29. Resident of Long-Term Care Facility at Time of	of Diagnosis (select one) No Yes Unknown
Nursing Home Besidential Fac	
Hospital-Based Facility Mental Health F	Residential Facility Other Long-Term Care Facility
30. Primary Occupation Within the Past Year (sele	act one) PRIMARYDCC
Health Care Worker	
21 Injecting Drug Lies Within Part You 121	
(select one)	32. Non-injecting Drug use within Past Year (select one) 33. Excess Alcohol Use Within Past Year (select one) n No Yes Unknown No
S5. Immigration Status at First Entry to the U.S. (s Not Applicable	Post-organ Transplantation Immunosuppression (not HIV/AIDS) select one) The select one immunosuppression (not HIV/AIDS)
• "IIS -born" (or born abroad to a parent	
Born in 1 of the U.S. Territories, U.S. Isla	and Areas, or U.S. Outlying Areas Employment Visa Refugee Unknown
<u> </u>	
36. Date Therapy Started CHRXDATE	37. Initial Drug Regimen (select one option for each drug)
Month Day Year	No Yes Unk No Yes Unk No Yes Unk
<u></u>	
Comments:	
C 72 04 Bev 09/15/2008 CS121221	
2 12.01 Her 00/10/2000 00121021	HEPORI OF VEHIFIED CASE OF TUBERCULOSIS Page

Patient's Na	ime	(Last)		(First)					REPORT	OF VERIFIED CASE
Street Addre	ess			(Number	Street, City, State)		(ZIP CODE)		OF TUBERCULOSIS
CD)		REPO	RT OF V	ERIFIE	D CASE	OF TUBERCULO	u. SIS	5. DEPARTMEN	T OF HEALTH CENTERS A ED OMB NO. 05	AND HUMAN SERVICES FOR DISEASE CONTROL AND PREVENTION (CDC) IILANIA, GEORGIA 30333 20-0026 Exp. Date 05/31/2011
Initial D	rug Susco	eptibility	Report					(F	ollow L	Jp Report – 1)
Year Cour	nted	State Case Numl City/Count Case Numt	y ber]	
Submit	this repo	rt for all	culture-	positiv	e cases.					
38. Genoty Isolate If YES, 39. Initial E Was dra	vping Accessio submitted for ge CENOTY genotyping acc Drug Susceptib ug susceptibility	n Number enotyping (sei ession number ility Testing r testing done	ect one): [er for episode: SVSTES ? (select one)]n₀ [[□n₀	Yes				AENOI	NVMB
If NO c	or UNKNOWN	, do not cor	nplete the re	st of Follo	w Up Repo	rt −1				
Mon	th Day	SVSDAT	ected for which	n drug susc	eptibility	Enter specimen type:	OR If not Sputum	, enter anatom	nic code (see	ə list):
40. Initial D	orug Susceptib	ility Results (select one op	tion for eac	h drug)			_		
ISVSINH ISVSRIF ISVSP2A ISVSEMB ISVSEMB ISVSRIE ISVSRIE ISVSRIF ISVSAM ISVSAM ISVSAM	Isoniazid Rifampin Pyrazinamide Ethambutol Streptomycin Rifabutin Rifapentine Ethionamide Amikacin Kanamycin					Capreomycin Ciprofloxacin Levofloxacin Ofloxacin Moxifloxacin Other Quinolones Cycloserine Para-Amino Salicylic A Other Specify ISVSSPEC Other Specify ISVSSPEC	cid			ISVSCAP ISVSCIP ISVSCIP ISVSOFL ISVSOFL ISVSOFL ISVSOFL ISVSOFL ISVSOFL ISVSOFL ISVSOFL ISVSOFL
Public reporting taining the data displays a curre Project Clearan	burden of this col needed and comp ntly valid OMB col ce Officer, 1600 Cl	lection of inform pleting and revie ntrol number. Se lifton Road. MS	nation is estimate wing the collect and comments re D-74, Atlanta. G	ed to average ion of inform agarding this	35 minutes per ation. An agenc burden estimati TN: PRA (0920-1	response, including the time for re y may not conduct or sponsor, and o or any other aspect of this collec 0260. Do not send the completed	eviewing instructio d a person is not re tion of information form to this addre	ns, searching exi equired to respor , including sugge ss.	sting data sou id to a collecti astions for red	urces, gathering and main- on of information unless it ucing this burden to CDC,

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 only 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).

CDC 72.9B Rev 09/15/2008 CS121321

Street Address	
U.S. DEPARTMENT OF HEALTH AND H	DENCOLUSIS
REPORT OF VERIFIED CASE OF TUBERCULOSIS	UMAN SERVICES SEASE CONTROL REVENTION (CDC) , GEORGIA 30333 Exp. Date 05/31/2011
Case Completion Report (Follow Up R	eport – 2)
Year Counted State Case Number VEAR City/County City/County Case Number City/County	
Submit this report for all cases in which the patient was alive at diagnosis.	
41. Sputum Culture Conversion Documented (select one)	
If YES, enter date specimen collected for FIRST If NO, enter reason for not documenting sputum culture conversion (select one): CONVRE	AS
Month Day Year Sputum Despite Induction Patient Refused Patient Lost to Fo	bllow-Up
No Follow-up Sputum and No Induction Other Specify	
42. Moved	
Did the patient move during TB therapy? (select one)	
If YES, moved to where (select all that apply):	
In state, out of jurisdiction (enter city/county) Specify MOVCITY NMEI/MOVCITY NMEI Specify MOVCITY NME2. /MOVCITY NME2.	NMEZ
Out of state (enter state) Specify MOVSTATECD Specify MOVSTATECD2	
Out of the U.S. (enter country) Specify MOVCTPYCOL MOVCTPYNME Specify MOVCTPYCO2 MOVCTPYN	IME 2
If moved out of the U.S., transnational referral? (select one)	
43. Date Therapy Stopped 44. Reason Therapy Stopped or Never Started (select one) THERREAS	
Completed Therapy If DIED, indicate cause of death (select one	2
Month Day Year	
Momin Day Year Died Related to TB disease Unrelated	to TB disease
Moment Day Year Image: Day Image: Day	to TB disease
Momm Day Year Image: Day Image: Day	to TB disease
Mommin Day Year Image: Day Image: Day	to TB disease
Momm Day Year Image: Day Image: Day	to TB disease
Momm Day Year Image: StopTHER Image: Lost Died Related to TB disease Unrelated StopTHER Image: Uncooperative or Refused Other Related to TB therapy Unknown 45. Reason Therapy Extended >12 months (select all that apply) Image: Related to TB therapy Unknown 45. Reason Therapy Extended >12 months (select all that apply) Image: Clinically Indicated - other reasons EXTCUNIC Adverse Drug Reaction EXTRENCT Failure EXTOPLY Image: Clinically Indicated - other reasons EXTOPLY	to TB disease
Momin Day Year Image: Stoppther Image: Lost Died Related to TB disease Unrelated Stoppther Image: Lost Image: Died Related to TB disease Unrelated Stoppther Image: Died Related to TB disease Image: Died Related to TB disease Image: Died Stoppther Image: Died Related to TB disease Image: Died Related to TB disease Image: Died Stoppther Image: Died Related to TB disease Image: Died Image: Died Related to TB disease Image: Died 45. Reason Therapy Extended >12 months (select all that apply) Image: Died	to TB disease
Momm Day Year Image: StopTHER Image: Lost Died Related to TB disease Unrelated StopTHER Image: Lost Died Related to TB disease Unrelated StopTHER Image: Lost Image: Lo	to TB disease
Momm Day Year Image: Stop THER Image: Lost Died Related to TB disease Unrelated Stop THER Image: Uncooperative or Refused Other Related to TB therapy Unknown 45. Reason Therapy Extended >12 months (select all that apply) Image: Clinically Indicated - other reasons EXTCUNIC Adverse Drug Reaction Extrement Failure Extrement Other Specify Extrement 46. Type of Outpatient Health Care Provider (select all that apply) Image: Care Only PROVINCE PROVINCE Private Outpatient Institutional/Correctional Institutional/Correctional Image: Care Only PROVINCE	to TB disease
Momm Day Year Image: Construction of the state of the	to TB disease
Momm Lay Year Lost Died Related to TB disease Unrelated STOPTHER Uncooperative or Refused Other Related to TB therapy Unknown 45. Reason Therapy Extended >12 months (select all that apply) Adverse Treatment Event Unknown Clinically Indicated - other reasons EXTRUNC Adverse Drug Reaction Extrement Failure Other Specify Extrospec 46. Type of Outpatient Health Care Provider (select all that apply) Institutional/Correctional Institutional/Correctional PROVINSAT Private Outpatient Institutional/Correctional Institutional/Correctional Unknown	to TB disease
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Monun Uay Year Image: Comments: Lost Died Related to TB disease Unrelated Image: Comments:	to TB disease
Image: Monune Day Year I Lost Died Related to TB disease Unrelated STOPTHER I Uncooperative or Refused Other Related to TB therapy Unknown 45. Reason Therapy Extended >12 months (select all that apply) Adverse Treatment Event Unknown 45. Reason Therapy Extended >12 months (select all that apply) Clinically Indicated - other reasons EXTCUNIC Adverse Drug Reaction EXTREMENT Failure EXTENDED Clinically Indicated - other reasons EXTCUNIC Adverse Drug Reaction EXTREMENT Failure EXTENDED Other Specify EXTOTH EXTSPEC 46. Type of Outpatient Health Care Provider (select all that apply) Device Specify EXTOTH EXTSPEC 46. Type of Outpatient Health Care Provider (select all that apply) Provide Specify EXTOTH EXTSPEC 46. Type of Outpatient Health Care Provider (select all that apply) Provide Specify Institutional/Correctional Private Outpatient Institutional/Correctional Institutional/Correctional Comments: Comments: Comments: Provide Specify Extrement	to TB disease
Monun Lay Year Lost Died Related to TB disease Unrelated STOPTHER Uncooperative or Refused Other Related to TB therapy Unknown 45. Reason Therapy Extended >12 months (select all that apply) Adverse Treatment Event Unknown 45. Reason Therapy Extended >12 months (select all that apply) Clinically Indicated - other reasons EXTCUNIC Adverse Drug Reaction Extrement Failure Extrement Event Other Specify EXTOTH EXT SPEC 46. Type of Outpatient Health Care Provider (select all that apply) Died PROVINSAT PROVINSAT PROVINSAT Local/State Health Department (HD) Died IHS, Inbal Corporation Dipatient Care Only Unknown Private Outpatient Institutional/Correctional Other Other Other	to TB disease
Monun Lay Year Lost Died Related to TB disease Unrelated StopTHER Uncooperative or Refused Other Related to TB therapy Unknown 45. Reason Therapy Extended >12 months (select all that apply) Rifampin Resistance Other Clinically Indicated - other reasons EXTCLINIC Adverse Drug Reaction Extra Point Failure Extra Pailure Other Specify Extor Pailure Play 46. Type of Outpatient Health Care Provider (select all that apply) Died Corporation Inpatient Care Only Play Play <t< th=""><th>to TB disease</th></t<>	to TB disease

CDC 72.9C Rev 09/15/2008 CS121321

Patient's Name	(Last)	141 XI.	(First)		State Case No (M.L)		1.0 <u>-</u> 2	REPORT	OF VERIFIED CASE OF TUBERCULOSIS
CDC	REPO	ORT OF	VERIFIED	CASE	E OF TUBERCULOS	u.s IS	FORM APPROV	T OF HEALTH CENTERS /PED OMB NO. 09	AND HUMAN SERVICES FOR DISEASE CONTROL AND PREVENTION (CDC) ITLANTA, GEORGIA 30333 20-0026 Exp. Date 05/31/2011
Case Comple	tion Repor	t - Conti	nued				(F	ollow L	Jp Report – 2)
47. Directly Observe	ed Therapy (DOT If-Administered irectly Observed ectly Observed ar s of directly obser eptibility Testing) (select one) nd Self-Admini ved therapy (I	DOT istered DOT)		DOTWEEKS			-	
Was follow-up dr	ug susceptibility	testing done?	(select one)						
If YES, enter date testing was done Month	FINAL isolate co	Vear	lich drug suscep	tibility	Enter specimen type:	Sputum OR If not Sputum	o, enter anato	mic code (se	e list):
49. Final Drug Susc	eptibility Results	s (select one o	ption for each dr	rug)					
FSUSINH Isoniazid PSUSRIF Rifampin FSUSP2A Pyrazinam FSUSP3A Ethambuto FSUSEM Ethambuto FSUSEM Rifabutin FSUSEM Rifapenting FSUSEM Ethionamic FSUSEM Amikacin FSUSEM Kanamycir Comments:	Resistant				Capreomycin Ciprofloxacin Levofloxacin Ofloxacin Moxifloxacin Other Quinolones Cycloserine Para-Amino Salicylic Acid Other Specify FSUSSPECT	Resistant		Not Done	Unknown FSV SCAP FSVSCIP FSVSLEVO FSVS OFLO FSVS OFLO FSVS QVIN PSVSCHC FSVSOFHI FSVSOFHI FSVSOFHI
Public reporting burden of til taining the data needed and displays a currently valid ON Project Clearance Officer, 10	nis collection of info d completing and rev AB control number. 600 Clifton Road, M	mation is estimation is estimation is colle iowing the colle Send comments S D-74, Atlanta.	ated to average 35 r ction of information regarding this burc GA 30333, ATTN: F	minutes pe h. An agenci Jen estima PRA (0920	er response, including the time for revie by may not conduct or sponsor, and a te or any other aspect of this collection -0026). Do not send the completed for	wing instruction person is not rec n of information, m to this addres	s, searching ex quired to respor including sugge s.	isting data sou nd to a collecti estions for red	rces, gathering and main- on of information unless it ucing this burden to CDC,

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 only 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).