Electronic Disease Notification



EDN Tuberculosis Follow-Up Guide

This guidance document is intended for EDN users who use the TB follow-up module in EDN. The guide is designed to train EDN users on worksheet follow-up reporting and worksheet completion.

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Introduction to Electronic Disease Notification, Tuberculosis Follow-Up Module

Document Purpose and Audience

This document is intended as a guideline for health departments and grantees that use the CDC's web-based Electronic Disease Notification (EDN) system. Specifically, the document outlines directions for completing the revised TB follow-up worksheet.

Background

The Division of Global Migration and Quarantine (DGMQ) at the Centers for Disease Control and Prevention has the regulatory mission of preventing the introduction, transmission, and interstate spread of communicable diseases into the United States and its territories. In order to achieve this mission, CDC notifies U.S. health departments about immigrants and refugees relocating to the United States who have conditions of public health significance, including tuberculosis (TB); CDC highly recommends that immigrants and refugees classified overseas with TB conditions be screened for TB during domestic medical follow-up examinations.

The platform used to notify health departments is the web-based Electronic Disease Notification (EDN) system. EDN collects demographic and overseas medical screening information from several overseas partners, including the International Organization for Migration (IOM). U.S. health departments with access to EDN are able to obtain electronic copies of the overseas medical documentation. The TB Follow-Up Module in EDN functions as a method of collecting domestic TB follow-up examination data from U.S. health departments.

EDN is used to

- Obtaining and storing information recorded electronically on the U.S. Department of State (DoS) Medical Examination for Immigrant and Refugee Applicant forms and other additional supporting medical documentation from external partners
- Notifying U.S. health departments of immigrants identified overseas as having conditions of public health significance and all refugees
- Providing U.S. health departments with electronic access to overseas medical documentation
- Providing U.S. health departments with an electronic system to record and evaluate the outcome of domestic TB follow-up examinations
- Informing U.S. health departments when an immigrant or refugee moves to a different jurisdiction (secondary migration)

Tuberculosis Follow-Up Worksheet

The Tuberculosis (TB) follow-up worksheet collects information on outcomes from the domestic TB follow-up evaluation for immigrants and refugees who relocated to the United States and who have a TB condition.

Information collected on the worksheet provides disease surveillance data for domestic TB control programs. These data will be important for measuring the efficiency and effectiveness of global TB prevention activities.

The 2007 TB follow-up worksheet was revised by the EDN Workgroup and several CDC partners to increase the level of user friendliness by—

- Reorganizing and simplifying sections
- Updating content to reflect current terminology

Quality Assurance

EDN staff implements data quality control measures to ensure the accuracy of overseas medical screening information submitted by external partners. Any questions or concerns regarding the accuracy of overseas medical screening data retrieved through EDN should be sent to the EDN help desk at EDNhelpdesk@cdc.gov.

Assuring data completeness and quality is strongly encouraged for all TB follow-up reporting. Each reporting jurisdiction is expected to implement measures for reviewing and updating data. Activities should include ensuring that TB follow-up data are collected and entered into EDN accurately.

Although health departments share TB follow-up data with CDC, the responsibility and authority for TB follow- up reporting rest solely on the health department. States vary in the structure and organization of their surveillance systems and often in the quality assurance of their case reporting. As with any reportable disease, the completeness of TB reporting reflects how actively health departments solicit case report information.

Data Entry and Security

Data collected on the TB follow-up worksheet are entered and transmitted directly to CDC through the data entry section of EDN. Maintaining data security is the responsibility of the reporting state or local health department.

Access to TB follow-up worksheets and EDN should be restricted to persons authorized to perform TB follow- up-related duties. Hard copies should be stored and secured in a locked area. Approved access to any database containing TB follow-up outcome data should be controlled though the use of local user identification (user ID) and challenge phrases. All other electronic surveillance files should also be protected with passwords known only to designated surveillance staff.

Patient Confidentiality

The TB follow-up worksheet provides personally identifiable information to U.S. health departments for locating arriving refugees and immigrants who have TB conditions. Due to the highly confidential nature of TB follow-up data, CDC implements several measures to protect patient privacy, including—

<u>Access Restricted to Authorized users:</u> Only authorized users directly involved with TB follow-up examinations for U.S.-bound aliens at the state, local or federal level can have access to domestic TB follow-up data.

Authorized users at the federal level include EDN staff, information technology staff, and other partners directly involved in TB follow-up. Authorized users at the state and local level will have access only to records belonging to their jurisdiction.

A database security package is implemented on CDC's mainframe computer to control unauthorized access to the system. Attempts to gain access by unauthorized persons are automatically recorded and reviewed regularly. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of CDC or its contractors, as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected.

<u>A Secure Data Network:</u> EDN is accessible only though the secured data network (SDN) connection. SDN is a secure data transfer service offered by CDC. SDN has a highly sophisticated firewall system in place to protect personally identifiable information and provide a high level of data integrity. The server, which is physically located at the National Center for Health Statistics, is protected under both a Windows firewall system security feature and the CDC firewall. The SDN monitors EDN system 24 hours a day, 7 days a week for data redundancy features and disaster recovery features.

<u>Digital Certificates:</u> A digital certificate is required for all EDN users to gain access to the EDN website on the SDN server. The digital certificate must be installed on users' work computers to provide assurances of their identity every time they log on. Each digital certificate must be renewed annual basis. To gain access to EDN, an authorized user must select a challenge phrase, which will be routinely updated.

CDC has provided an Assurance of Confidentiality for the TB follow-up module of EDN. Information on the TB follow-up worksheets that would permit identification of any individual will be held in confidence and will not be released without that person's consent, in accordance with section 306 and 308 (d) of the Public Health Services Act (42 U.S.C. 242k and 242m).

Privacy Act

Please see Appendix C, entitled *Privacy Act System Notice 09-20-0103*, for information regarding the Privacy Act as it applies to EDN.

Revised TB Follow-Up Worksheet

The TB follow-up worksheet was revised by the EDN Working Group in coordination with CDC to improve its organization, increase user friendliness, and update content to reflect current terminology. This section will outline the changes to the worksheet.

A. Demographic		EDN TB Follo	EDN TB Follow-Up Worksheet			Worksheet Last reviewed		
A1. Name (Last,		A2. Alien #:	T 4	43. V	isa type:	A4. Initial U.	S. entry date:	
A5. Age:	A6. Gender:	A7. DOB:	-	V8. TE	3 Class:			
A9.Country of ex			133333		try of birth:			
A11a. Address	t i		A12.	a. S	ponsor agency	name:		
A11b. Phone:				b. P	hone(s):			
A11c. Other:				c. A	ddress:			
B. Jurisdictional	Information		50					
B1. Arrival juris			B2.	Cum	ent jurisdiction:			
C. U.S. Evaluation								
MACHINE MARKET DESCRIPTION	tial U.S. medical evaluat	950007						
	antoux Tuberculin Skir					-Gamma Release A		
r YES, C2b. C2c. C2d.	TST placement date: Placement TST mm: TST interpretation:	nt date unknown	If YE	es, C	GIGRA adminis GIB. Date collect GIB. IGRA bran GIB. Result:	cted: _/_/ d:QuantiFEROIOther (specifiPositiveNegaInvalidUnkn	y): ative Indeterminate	
U.S Re	eview of Pre-Immigration	on CXR		υ	.S. Domestic (CXR	Comparison	
C5. U.S. inter Normal Abnorm		w): re TB : with TB	If YES, C8. C9. Interpreta Normal Abnorm	No Date ation of al (molot co- lon-ca cavital	Unknown of U.S. CXR:	below): ctive TB ent with TB	C11. U.S. domestic CXR comparison to pre-immigration CXR: Stable Worsening Improving Unknown	
Volume loss Adenopathy	Other (specify)	nuloma(ta)	C10. U.S. do Volume k	055	Infiltrate Other (spe	Granuloma(ta)		
	re-Immigration Treatm	SM1 1000	534					
Ir YES, Treatr C12b. Treatr C12c. Treatr C12d. Treatr	ted treatment pre-immig eated for TB disease [ment start date:/_ ment end date:/_ ment reported by: Treatment documented of Patient reported treatment panel physician examination. Both-documented on DS Unknown I and TB treatment regim No Unable to veri	Treated for LTBI	te unknown e unknown before	ff C14:	C13a. Start da Pre-Immigratio Yes No YES, Treatmen	Unknown isease LTBI ate:/ [on treatment concern	Start date unknown	

Alien	1#		EDN TB Follo	w-Up Work	sheet (Cor	nt)		Last	reviewed: 6/21/2013
C15.	U.S. Microscopy/	py/Bacteriology* Sputa collected		Sputa collected in U.S.? Yes No		No "Covers all results regardless of sputa collection method.			
#	Date Collected	AFB Sr	near	Sputum Culture Drug Susceptibility Testing			ptibility Testing		
1	_/_/_	Positive Not Done	Negative Unknown	NTM Contain	ninated [Ne	B Complex gative known	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done
2		Positive Not Done	Negative Unknown	NTM Contan	ninated [Ne	B Complex gative known	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done
3		Positive Not Done	Negative Unknown	NTM Contan	ninated [Ne	TB Complex gative known	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done
D. E	valuation Disposit	ion							
D1.	Evaluation disposi	ion date:/_							
		olluation completed, was sended? No BI	Not Located Lost to Folio Refused Ev	ow-Up raluation	Moved w Moved of Died Other, sp	vithin U outside pecify			
D3.	Diagnosis	Class 0 - No TB	exposure, not infe	cted	Cla	ss 1 -	TB exposure,	no evidence of in	fection
		Class 2 - TB infe	ection, no disease		\sqcup \Box		TB, TB diseas	_	_
		Class 4 - TB, ina	active disease			Pulmo	onary Extr	ra-pulmonary	Both sites
D	If diagnosed with Ti	3 disease, F	RVCT Reported	D5. F	RVCT#:			RVCT	# unknown
E. U.	.S. Treatment								
E1	. U.S. treatment ini	tiated: Yes	No	Unknown					
If	NO, specify the reason	Ε			_				
1	Died Unknown TYES: TB disea		Lost to fo		닏	d within	n U.S, tranferred t	toc	
			<i>'</i> '	, -	_				
		eatment completed:	Yes	No	Unknow	vn			
	Patie Prov Died		Moved o Unknown	Treatment (Ott	her (sp date:	Adverse effect ithin U.S, tranferm lecify)		
F. Co	omments								
G. S	creen Site Informa	ation							
Prov	ider's Name:								
Clini	c Name:								
Tele	phone Number:								

The revised TB follow-up worksheet contains seven sections:

- 1. Section A Demographic Information
- 2. Section B Jurisdictional Information
- 3. Section C U.S. Evaluation
 - Mantoux Tuberculin Skin Test (TST)
 - Interferon Gamma Release Assay (IGRA)
 - U.S. Review of Pre-Immigration Chest Radiograph (CXR)
 - U.S. Domestic CXR
 - Comparison
 - U.S. Review of Pre-Immigration Treatment
 - U.S. Microscopy/Bacteriology
- 4. Section D Evaluation Disposition
- 5. Section E U.S. Treatment
- 6. Section F Comments
- 7. Section G Screen Site Information

TB Follow-Up Worksheet Revisions

Section A. Demographic

A. Demographic		EDN TB Follow-U	p Worksheet	Last reviewed: 6/21/2013			
A1. Name (Las	A1. Name (Last, First, Middle):		A3. Visa type:	A4. Initial U.S. entry date:			
,							
A5. Age:	A6. Gender:	A7. DOB:	A8. TB Class:	·			
A9.Country of e	examination:	•	A10.Country of birth:				
A11a. Address	S:		A12. a. Sponsor agency name:				
A11b. Phone:			b. Phone(s):	b. Phone(s):			
A11c. Other:			c. Address:				

- 1. Data items A1 through A4 were set in bold to help health departments clearly locate the name, alien number, visa type, and initial U.S. entry date of the arriving refugee or immigrant with a TB condition
- 2. Date format line has been added to A7, DOB.
- 3. Quarantine station information has been removed but will still be available electronically in EDN.

Section B: Jurisdictional Information

B. Jurisdictional Information	
B1. Arrival jurisdiction:	B2. Current jurisdiction:

1. Destination state has been removed, and arrival and current jurisdictions have been added.

Section C. U.S. Evaluation

Date of initial U.S. medical evaluation

C. U.S. Evaluation	
C1. Date of Initial U.S. medical evaluation:	

1. Date format line has been added to C1, Date of initiation U.S. medical evaluation

Mantoux Tuberculin Skin Test (TST)

	Mantoux Tuberculin Skin Test (TST)
C2a. Wa	as a TST administered? Yes No Unknown
If YES,	C2b. TST placement date://
	Placement date unknown
	C2c. TST mm: Unknown
	C2d. TST interpretation: Positive Negative Unknown
C2e. His	story of Previous Positive TST

- 1. Section heading was changed to Mantoux Tuberculin Skin Test (TST)
- 2. Date format line was added to C2b, TST placement date
- 3. Placement date unknown option was added to C2b, TST placement date
- 4. Unknown option was added to C2c, TST mm.

Interferon-Gamma Release Assay (IGRA)

Interferon-Gamma Release Assay	(IGRA)
C3a. Was IGRA administered? Yes No	Unknown
If YES, C3b. Date collected://	Date unknown
C3c. IGRA brand: QuantiFERON® Other (specify):	T-SPOT
C3d. Result: Positive Negative Invalid Unknown C3e. History of previous positive IGRA	Indeterminate

- 1. Section heading added
- 2. QuantiFERON®(QFT) test has been changed to Interferon-Gamma Release Assay (IGRA) to accommodate different brands of IGRA
- 3. Date format line was added to C3b, Date collected.
- 4. Date unknown option was added to C3b, Date collected
- 5. IGRA brand options were added to C3c, IGRA brand

6. Invalid result option added to C3d, Result

U.S. Review of Pre-Immigration CXR

U.S Review of Pre-Immigration CXR
C4. Pre-immigration CXR available?
Yes No Not Verifiable
C5. U.S. interpretation of pre-immigration CXR:
Normal
Abnormal (must select one below):
Not consistent with active TB
Non-cavitary, consistent with TB
Cavitary, consistent with TB
Poor Quality
Unknown
C6. Other pre-immigration CXR abnormalities:
Volume loss Infiltrate Granuloma(ta)
Adenopathy Other (specify)

- 1. Section subheading changed from U.S. Review of Overseas CXR to U.S. Review of Pre-lmmigration CXR
- 2. Date format line added to C8, Date of U.S. CXR
- 3. Abnormalities in C5 were updated to reflect abnormalities listed on the Report of Verified Cases of Tuberculosis (RVCT)
- 4. Other pre-immigrant CXR abnormalities from the old worksheet are listed on C6, Other pre-immigration CXR abnormalities
- 5. Fibrosis was removed from the list of abnormalities in C6.
- 6. Volume loss was added to the list of abnormalities in C6.

U.S. Domestic CXR

U.S. Domestic CXR
C7. U.S. domestic CXR done?
Yes No Unknown
If YES, C8. Date of U.S. CXR://
C9. Interpretation of U.S. CXR:
Normal
Abnormal (must select one below):
Not consistent with active TB
Non-cavitary, consistent with TB
Cavitary, consistent with TB
Unknown

- 1. Abnormalities in C9 were changed to reflect those listed in the Report of Verified Cases of Tuberculosis
- 2. Other pre-immigrant CXR abnormalities from the old worksheet are listed in C8.
- 3. Fibrosis was removed from the list of abnormalities in C10.
- 4. Volume loss was added to the list of abnormalities in C10.

U.S. Review of Pre-Immigration Treatment

- 1. Section subheading was changed to U.S. Review of Pre-Immigration Treatment
- 2. Section was moved from the second page to the first page
- 3. Active TB disease and latent TB infection (LTBI) check boxes were added to differentiate between TB disease treatment and LTBI treatment
- 4. Date format lines were added to C12b, Treatment start date, and C12c, Treatment end date
- 5. Options for C12d. were further clarified to include historic TB treatment
- 6. Unknown option was added to C12d.
- 7. New data item, C12e, Standard TB treatment regimen was administered, was added.
- 8. TB treatment type and start date were added to C13, Arrived on treatment
- 9. New data item, C14, Pre-immigration treatment concerns, was added.

U.S. Microscopy/Bacteriology*

Alien#			EDN TB Follow-Up Worksheet (Cont)		Last reviewed: 6/21/2013				
C15. U.S. Microscopy/Bacteriology*			Sputa collected in U.S.? Yes		No *Covers all results regardless of sputa collection method.				
#	Date Collected	AFB Sm	ear	ear Sputum Cultur		ıre	Drug Susceptibility Testing		
1	_!_!	Positive Not Done	Negative Unknown	NTM Contai	minated one	Ne	TB Complex egative nknown	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done
2	!!	Positive Not Done	Negative Unknown	NTM Contai	minated one	Ne	TB Complex egative nknown	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done
3		Positive Not Done	Negative Unknown	NTM Contai	minated one	Ne	TB Complex egative nknown	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done

- 1. Section moved from first page to second page
- 2. Alien number was added to the top of the worksheet
- 3. "Specimen not collected in U.S." on the old worksheet was reworded as 'Sputa collected in U.S.,' and yes and no options were added
- 4. Date format lines were added

Section D. Evaluation Disposition

D1. Evaluation disposition date

D. Evaluation Disposition	
D1. Evaluation disposition date:	

1. Date format line was added

D2. Evaluation disposition

D2. Evaluation disposition:				
Completed evaluation	Initiated Evaluation / Not completed Did not initate evaluation			
If evaluation was completed, was treatment recommended?	If evaluation was <u>NOT</u> completed, why not?			
	Not Located Moved within U.S., transferred to:			
Yes No	Lost to Follow-Up Moved outside U.S.			
LTBI	Refused Evaluation Died			
Active TB	Unknown Other, specify			

- 1. Section was reorganized for simplicity
- 2. Transfer field was added

Section E. U.S. Treatment

E. U.S. Treatment
E1. U.S. treatment initiated: Yes No Unknown
If NO, specify the reason:
Patient declined against medical advice Lost to follow-up Moved within U.S, tranferred to:
Died Moved outside the U.S. Other (specify)
Unknown
If YES: TB disease LTBI
E2. Treatment start date://
E3. U.S. treatment completed: Yes No Unknown
If NO, specify the reason:
Patient stopped against medical advice Lost to follow-up Adverse effect
Provider decision Moved outside the U.S. Moved within U.S, tranferred to:
Died Unknown Other (specify)
If treatment was completed, E4. Treatment completion date:/
If treatment was iniated but NOT completed, E5. Treatment end date://

- 1. Section was reorganized for simplicity
- 2. Reasons for not initiating treatment for TB disease or LTBI were added
- 3. Transfer information field was added to reasons for not initiating or completing treatment.
- 4. Date format lines were added.
- 5. Treatment end date field from old worksheet has been separated into two fields:
 - a. Treatment completion date
 - b. Treatment end date

Section G. Screen Site Information

G. Screen Site Information	
Provider's Name:	
Clinic Name:	
Telephone Number:	

1. Physician's signature and date were removed.

TB Follow-Up Evaluation End-Points

The TB follow-up worksheet should be completed until an **evaluation end-point** has been reached. An exception to this would be if an evaluation was *not initiated* for an immigrant or refugee. Evaluation end-points are recorded under **Section D:** Evaluation Disposition. TB follow-up evaluation end points are explained briefly below. End-points are discussed in greater detail on **page 39.**

Evaluation completed

A follow-up evaluation for TB has been completed for an arriving immigrant or refugee with a TB condition for which a final American Thoracic Society diagnosis has been made. Treatment may or may not have been recommended.

Initiated evaluation, not completed

A follow-up evaluation for TB had been started for the arriving immigrant or refugee with a TB condition; however, the evaluation could not be completed for one of the reasons listed below.

The immigrant or refugee—

- a. Moved within the United States
- b. Was lost to follow-up
- c. Moved outside the United States
- d. Refused to be evaluated
- e. Died

Evaluation not initiated

A follow-up evaluation for TB has not been initiated for the arriving immigrant or refugee with a TB condition, for one of the reasons listed below.

The immigrant or refugee—

- a. Could not be located
- b. Moved within the United States
- c. Was lost to follow-up
- d. Refused to be evaluated
- e. Died

Domestic TB Follow-Up Evaluation and Reporting Timeline

Upon arrival to the United States, arriving immigrants and refugees with a TB condition should be screened for TB within 30 days of their arrival date. Domestic evaluation outcomes should be reported promptly in EDN.

The domestic TB follow-up timeline is discussed in further detail below.

- The initial medical evaluation should occur within <u>30 days</u> of arrival. This initial evaluation often includes a U.S. review of pre-departure medical information and previous treatment, TST or IGRA, domestic CXR, and sputum collection, if indicated.
- 2. The domestic TB follow-up evaluation should be completed within <u>90 days</u> of arrival. This includes comparison of pre-departure and U.S. exam results, results of U.S. microscopy/bacteriology, and determination of a disposition.
- 3. If treatment is recommended for TB disease or LTBI, the treatment start and end dates should be documented in the U.S. Treatment section. Since treatment for TB can take up to 9 months on average, the treatment end date should be reported within <u>1 year</u> of the treatment start date.

TB Follow-Up Worksheet Sections	Timeline (within x days of U.S. arrival)
Section C U.S. Evaluation	
Initial U.S. Medical Evaluation (C1 – C3)	30 days
U.S. Review of Overseas CXR (C4 – C6)	30 days
Domestic CXR (C7 – C10)	30 days
Comparison (C11)	30 days
U.S. Microscopy/Bacteriology (C12)	<12 weeks
U.S. Review of Overseas Treatment (C13 – C16)	30 days
Section D Evaluation Disposition	
Disposition (D1 – D2)	90 days
Diagnosis (D3 – D4)	90 days
Section E. – U .S. Treatment	
U.S. Treatment Initiated (E1 – E2)	90 days
U.S. Treatment Completed (E3 – E4)	<9 months

Reporting

Follow-up examination outcomes should be reported to EDN promptly. TB follow-up evaluation results can be saved in EDN continuously, regardless of evaluation completion. Once available, TB follow-up evaluation results should be reported to EDN within **5** business days to ensure accurate and speedy reporting. For patients receiving treatment, it may take several months before treatment outcomes may be reported; however, other sections, such as TB Screening (TST, IGRA) and Evaluation Disposition, should be reported to EDN as soon as available. Providing local health departments with EDN access may alleviate the burden of TB follow-up reporting for state health departments. Please contact the EDN help desk at EDNhelpdesk@cdc.gov for more information.

TB Follow-Up Worksheet Instructions

The following contains detailed descriptions of each data item on the new revised TB follow-up worksheet.

Section A: Demographic Information

Introduction

Section A of the tuberculosis follow-up worksheet contains alien demographic information. This section is **pre-populated by the EDN system**. If this form is used by a provider to complete the evaluation, manually completing all the fields in section A may be advantageous.

Alien contact information is located in this section. Additional contact information may have been recorded on the person's scanned documents by a U.S. quarantine station official.

Data Item	Description	Instructions/Comments
Name (Last, First, Middle)	Complete name	The system will automatically populate this field.
Alien #	Unique identification number assigned by the U.S. Department of State.	The system will automatically populate this field.
Visa Type	Visa classification as determined by the Department of State. Visa types are explained in Table 2 on the next page.	The system will automatically populate this field.
Initial Entry Date	The date arrived in the U.S., as documented by CDC Quarantine Stations or U.S. Bureau of Citizenship agents.	The system will automatically populate this field.
Age	Age at the time of U.S. arrival.	The system will automatically populate this field. Age is calculated by the system using the date of birth and the date of arrival.
Gender-Male, Female (e.g., m, f)		The system will automatically populate this field.
DOB (mm/dd/yyyy)		The system will automatically populate this field.
TB Class	TB classification as determined by the overseas panel physician.	The system will automatically populate this field.
Class Condition	Condition of public health significance as determined by the panel physician.	The system will automatically populate this field.

Data Item	Description	Instructions/Comments
Country of Examination	The country in which the person was examined by a panel physician.	The system will automatically populate this field.
		List of country
		abbreviations is located in Appendix C.
Country of Birth		The system will automatically populate this field.
		List of country abbreviations is located in Appendix C .
Sponsor Address, Phone, Other	The contact information of the person's sponsor.	The system will automatically populate this field.
Sponsor Agency Name, Address, Phone	Sponsor <i>agency's</i> contact information.	The system will automatically populate this field.
		Refugees often have a sponsoring agency; immigrants do not .

Table 1. Visa Explanations

Visa Type	Description
Immigrant	An immigrant is a foreign-born person in the United States with permanent resident status.
Asylee	An asylee is a foreign-born person in the United States who is unable or unwilling to return to his or her country of nationality because of persecution or a well-founded fear of persecution. An asylee meets the same criteria as those for a refugee; the difference is the person's location at the time of application –the potential asylee is in the United States or applying for admission at a port of entry, and the potential refugee is outside the United States.
Parolee	A parolee is a foreign-born person allowed to enter the United States for urgent humanitarian reasons or because entry is determined to be of significant public benefit.
Fiancé/Family	The V visa (in the nonimmigrant category) allows the spouse or child of a U.S. legal permanent resident to live and work in the United States. The K visa (in the nonimmigrant category) allows the fiancé of a U.S. citizen to enter the United States for a specific period and specifically for the purpose of marriage.

Visa Type	Description
Refugee	A refugee is a foreign-born person who is in a country other than his or her country of nationality and who is unable or unwilling to return to that country because of persecution or a well-founded fear of persecution.

Figure 1. Pre-Immigration Class A Conditions identified during overseas health screenings

Class A Condition

Description

U.S. Visa applicants identified overseas with Class A conditions during their pre-departure exams usually remain in their current country of residence until the condition has been treated or is in remission. Upon completion of treatment, these applicants are then reclassified as a Class B. In unusual circumstances, applicants with a Class A condition may be granted a **waiver** as long as testing indicates they are not contagious and will not expose others to their condition while traveling. The expectation is that Class A arrivals will seek medical care within 1 week of arrival in the United States. Class A conditions are listed below.

- Infectious tuberculosis
- Syphilis, untreated
- Chancroid, untreated
- Gonorrhea, untreated
- Granuloma inguinale, untreated
- · Lymphogranuloma venereum, untreated
- Hansen disease, untreated multibacillary
- Addiction or abuse of a specific substance
- Any physical or mental disorder (including other substance-related disorder) with harmful behavior or history of such behavior likely to recur

^{*} HIV was removed from this list in January 2010

Figure 2. Pre-Immigration Class B Conditions identified during overseas health screenings

Class B Condition

Description

Class B conditions are not inadmissible, but represent a significant departure from normal health with the exception of pregnancy. Class B conditions are listed below.

- Syphilis (with residual defect) treated within the last year
- Current pregnancy
- Any physical or mental disorder (excluding addiction or abuse of specific substance but including other substance- related disorder) without harmful behavior or history of such behavior unlikely to recur
- Hansen disease, treated multibacillary
- Hansen disease, paucibacillary
- Sustained, full remission of addiction or abuse of specific substances
- Noninfectious pulmonary tuberculosis
- Noninfectious extrapulmonary tuberculosis
- Latent tuberculosis infection evaluation
- Tuberculosis contact evaluation

Section B: Jurisdictional Information

Section B. Introduction

Section B of the tuberculosis follow-up worksheet contains information on the assigned U.S. jurisdiction for the immigrant or refugee. U.S. jurisdiction assignment is based on the immigrant or refugee's self–reported U.S. address pre-immigration. This section is pre-populated by EDN.

B. Jurisdictional Information	
B1. Arrival jurisdiction:	B2. Current jurisdiction:

Data Item	Description	Instructions/Comments
Arrival Jurisdiction	The primary health jurisdiction (local, state) where the immigrant or refugee initially resettled.	The system will automatically populate this field.
Current Jurisdiction	In the event of secondary migration (the immigrant or refugee moves to another area outside the arrival jurisdiction), this is the secondary health jurisdiction the arriver moved to.	The system will automatically populate this field. In the event the TB Class arriver did <u>not</u> move to a different jurisdiction, this section will be remain blank. A transfer must be made by the former jurisdiction. Please refer to the EDN interjurisdictional transfer protocol for more information, located in the appendices section on pg XX for more detail.

Section C. Introduction

The U.S. Evaluation section should be completed by a local health professional in the jurisdiction. It is recommended that the U.S. evaluation be initiated within <u>30 days</u> of the person's arrival date. Data should be reported to CDC promptly.

C. U.S. Evaluation			
C1. Date of Initial U.S. medical evaluation://			
Mantoux Tuberculin Skin Test (TST)		Interferon-Gamma Release As	ssay (IGRA)
# YES, C2b. TST placement date:/_/ Placement date unknown C2c. TST mm: Unknown	egative	C3a. Was IGRA administered? Yes	y): tive Indeterminate
U.S Review of Pre-Immigration CXR		U.S. Domestic CXR	Comparison
C4. Pre-immigration CXR available? Yes No Not Verifiable C5. U.S. interpretation of pre-immigration CXR: Normal Abnormal (must select one below): Not consistent with active TB Non-cavitary, consistent with TB Cavitary, consistent with TB Poor Quality Unknown C6. Other pre-immigration CXR abnormalities: Volume loss Infiltrate Granuloma(ta)	Ye # YES, C9. Inte	c. domestic CXR done? cs No Unknown C8. Date of U.S. CXR://	C11. U.S. domestic CXR comparison to pre-immigration CXR: Stable Worsening Improving Unknown
		nopathy Other (specify)	
U.S. Review of Pre-Immigration Treatment C12a. Completed treatment pre-immigration? Yes No If YES, Treated for TB disease Treated for LTBI C12b. Treatment start date:// Start date unknown C12c. Treatment end date:/_/ End date unknown C12d. Treatment reported by: Treatment documented on DS forms Patient reported treatment completion at or before panel physician examination Both-documented on DS forms & patient reported Unknown C12e. Standard TB treatment regimen was administered? Yes No Unable to verify		# 125, L 15 4155455 L 2151	Start date unknown

Ali	en #		EDN TB Follo	w-Up Worl	ksheet	(Cont)		Last	reviewed: 6/21/2013
C1	5. U.S. Microscopy	Bacteriology*	Sputa collected	in U.S.?	Ye	s	No *Cover	s all results regardless of sput	a collection method.
#	Date Collected	AFB Sr	mear		Spi	tum Cul	ture	Drug Susce	otibility Testing
1	_/_/_	Positive Not Done	Negative Unknown	NTM Conta	minate one	d N	ITB Complex egative nknown	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done
2		Positive Not Done	Negative Unknown	NTM Conta	minate one	d 📙 N	ITB Complex legative Inknown	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done
3		Positive Not Done	Negative Unknown	NTM Conta	minate one	d N	ITB Complex legative Inknown	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done

C1. Date of Initial U.S. Medical Evaluation

C1. Date of Initial U.S. medical evaluation:	

Data Item	Description	Instructions/Comments
Date of Initiate U.S. Medical Evaluation (mm/dd/yyyy)		Indicate the date the domestic medical evaluation was initiated by a U.S. medical provider, resulting in initial diagnostic test during post-U.S. arrival domestic screening for TB.
		Please note that this is not the date when the health department first contacted the immigrant or refugee.

C2. Mantoux Tuberculin Skin Test (TST)

Mantoux Tuberculin Skin Test (TST)				
C2a. Was	s a TST administered? Yes No Unknown			
If YES,	C2b. TST placement date://			
	Placement date unknown			
	C2c. TST mm: Unknown			
	C2d. TST interpretation: Positive Negative Unknown			
C2e. Histo	ory of Previous Positive TST			

Data Item	Description	Instructions/Comments
Was a TST administered? - Yes, No, Unknown	Inquiry as to whether a TST was administered post-U.S. arrival during domestic screening for TB. • Yes – means a TST was placed. • No - means a TST was not placed.	Indicate if a TST was administered during the domestic screening for TB. Note: If a TST was not administered, please leave the rest of the section blank and proceed to the QFT section.
TST Placement Date - Month, Day, Year (e.g., 01/01/2010)	The month, day, and year the tuberculin skin test (TST) was placed in the United States.	Indicate the date the TST was placed. Refers to the date the TST was placed, not read.
TST mm		Indicate the millimeters of induration for the TST.

Data Item	Description	Instructions/Comments
TST Interpretation – Positive, Negative, Unknown	Interpretation of TST reaction, per CDC guidelines. Positive – means that the person is likely infected with <i>M. tuberculosis</i> Negative – means the skin test did not meet current criteria for a positive test Unknown – means it is not known whether the skin test was performed or the results are unknown for a reason other than results pending	Indicate if there is a history of a previous positive TST. Indicate a previous positive history only if it is documented on a medical record.
History of Previous Positive TST	Inquiry of whether the person has a medical history of a previous positive TST result. • — An unmarked check box means there is no history of a previous positive TST • — A marked check box means there is a history of a previous positive TST	Can be confirmed with information from the DS forms or by the patient's verbal history.

C3. Interferon Gamma Release Assay (IGRA)

Interferon-Gamma Release Assay (IGRA)				
C3a. Was IGRA administered? Yes	No Unknown			
If YES, C3b. Date collected://	Date unknown			
C3c. IGRA brand: QuantiFEF Other (spe	ш			
C3d. Result: Positive Ne	egative Indeterminate nknown			

Data Item	Description	Instructions/Comments
Was IGRA administered? – Yes, No, Unknown	Inquiry of whether an IGRA was administered post-U.S. arrival during domestic screening for TB.	Indicate whether an IGRA was administered during the domestic screening for TB.
		If a different brand was used, please indicate the results in this section AND indicate the brand used in the comments section, section F.
If Yes		Only complete data items C3b – C3d if an IGRA was administered during domestic screening for TB.
Date Collected Month, Day, Year (e.g., 01/01/2010)		Indicate the date the IGRA was administered during domestic screening for TB.
IGRA Brand – QuantiFERON, T- SPOT, Other (specify)		Indicate the specific brand of IGRA administered. If the specific brand is not on the provided list, select "Other, specify" and indicate the brand.

Data Item	Description	Instructions/Comments
Result – Positive, Negative, Indeterminate, Invalid, Unknown	 The result of the IGRA test 'Positive' – means that it is probable that the person is infected with <i>M. tuberculosis</i>. 'Negative' – means that it is unlikely that the person is infected with <i>M. tuberculosis</i>. 'Unknown' – means it is not known whether the QFT was performed, or if the results are not known 'Indeterminate' – means it was uncertain if the person is infected with <i>M. tuberculosis</i>. 	Indicate the result of the IGRA test administered during domestic screening for TB.

U.S Review of Pre-Immigration CXR		
C4. Pre-immigration CXR available?		
Yes No Not Verifiable		
C5. U.S. interpretation of pre-immigration CXR:		
Normal		
Abnormal (must select one below):		
Not consistent with active TB		
Non-cavitary, consistent with TB		
Cavitary, consistent with TB		
Poor Quality		
Unknown		
C6. Other pre-immigration CXR abnormalities:		
Volume loss Infiltrate Granuloma(ta)		
Adenopathy Other (specify)		

Data Item	Description	Comment
Pre-immigration CXR Available – Yes, No, Unknown, Not Verifiable	 Inquiry as to whether the overseas chest X-ray was physically available. Unknown – means the overseas it is unknown whether or not the overseas CXR was available to the U.S. clinician Not Verifiable – means the overseas CXR did not have both the person's name and date of birth 	Indicate whether the overseas CXR is available and that it has both the person's name and date of birth. If these are not documented on the X-ray, please indicate "not verifiable."
U.S. Interpretation of pre- immigration CXR – Normal Abnormal, Poor Quality, Unknown,	Unknown – means the U.S. clinician's interpretation of the overseas CXR is unknown for reasons other than 'results pending'	Indicate the U.S. clinician's interpretation of the overseas CXR. If no CXR is physically available, indicate "unknown." Please do not transcribe what was reported on the overseas medical evaluation to complete this section.

Data Item	Description	Comment
Abnormal – Not consistent with active TE Noncavitary, consistent with TB, Cavitary, consistent with TB	The U.S clinician's interpretation of abnormalities found on the overseas CXR. If a U.S. physician interprets the overseas CXR as abnormal, indicate type of abnormality (-ies) reported. Check all that apply.	If the U.S. clinician indicated abnormalities in the overseas CXR, please indicate one If no CXR is available, leave this section blank. Please specify other abnormalities found, such as military, in the comments section. Do not transcribe what was reported on the overseas medical evaluation to complete this section.
Other pre-immigration CXR Abnormalities – Volume Loss Infiltrate, Granuloma(ta), Adenopathy, Other (Specify)	Please list other abnormalities found on the overseas CXR by the U.S. clinician. Check all that apply	If the U.S. clinician indicated other abnormalities, please indicate them here. If no CXR is available, leave this section blank. Please specify other abnormalities found, such as military, in the comments section. Please do not transcribe what was reported on the overseas medical evaluation to complete this section.

U.S. Domestic CXR		
C7. U.S. domestic CXR done?		
Yes No Unknown		
If YES, C8. Date of U.S. CXR://		
C9. Interpretation of U.S. CXR:		
Normal		
Abnormal (must select one below):		
Not consistent with active TB		
Non-cavitary, consistent with TB		
Cavitary, consistent with TB		
Unknown		

Data Item	Description	Instructions/Comments
U.S. domestic CXR Done? - Yes, No, Unknown		Indicate if a CXR was done during domestic screening for TB If it is not known whether a CXR was done for the TB Class arriver or the interpretation of the domestic CXR is not known for reasons other than 'results pending,' please indicate
Date of U.S. CXR		"unknown". If no chest X-ray was taken in the
(mm/dd/yyyy)		United States, leave blank.
Interpretation U.S. CXR - Normal, Abnormal, Unknown	Interpretation of the chest X-ray that was taken in the U.S.	The interpretation is considered "unknown" if the CXR or result is not available.

Data Item	Description	Instructions/Comments
Abnormal – Not consistent with active TB, Noncavitary, consistent with TB, Cavitary, consistent with TB	The U.S clinician's interpretation of abnormalities found on the domestic CXR. If a U.S. clinician interprets the domestic CXR as abnormal, indicate type of abnormality (ies) reported. Check all that apply. Not consistent with active TB Non-cavitary, consistent with TB Cavitary, consistent with TB	Please select one of the abnormalities. If no CXR is available, leave this section blank. Do not transcribe what was reported on the overseas medical evaluation to complete this section.
Other pre-immigration CXR Abnormalities – Volume Loss, Infilitrate, Granuloma(ta), Adenopathy, Other (Specify)	Please list other abnormalities found on the domestic CXR by the U.S. clinician. Check all that apply.	If other abnormalities are present, please indicate them. If no CXR is available, leave this section blank. Please specify other abnormalities found, such as military, in the comments section. Do not transcribe what was reported on the overseas medical evaluation to complete this section.

C11. U.S. Domestic CXR Comparison to Pre-immigration CXR

Comparison	
C11. U.S. domestic CXR comparison to pre-immigration CXR:	
Stable Worsening Improving Unknown	

Data Item	Description	Instructions/Comments
U.S. CXR Comparison to Overseas CXR Stable, Worsening, Improving, Unknown		Indicate whether the U.S clinician determined the CXR as stable, worsening, or improving.
		The section should be completed only if an overseas CXR is physically available and verifiable (the name and date of birth are on the CXR).

U.S. Review of Pre-Immigration Treatment					
C12a. Completed treatment pre-immigration? Yes No If YES, Treated for TB disease Treated for LTBI C12b. Treatment start date:/_/_ Start date unknown C12c. Treatment end date:/_/ End date unknown C12d. Treatment reported by: Treatment documented on DS forms Patient reported treatment completion at or before panel physician examination Both-documented on DS forms & patient reported Unknown C12e. Standard TB treatment regimen was administered? Yes No Unable to verify	C13. Arrived on treatment? Yes No Unknown If YES, TB disease LTBI C13a. Start date:/_/_ Start date unknown C14: Pre-Immigration treatment concerns? Yes No If YES, Treatment duration too short Incorrect treatment regimen Other, please specify:				

Data Item	Description	Instructions/Comment(s)
Completed treatment pre- immigration? – Yes (Treated for TB disease, Treated for LTBI), No	Indicate whether TB treatment was completed overseas before U.S. arrival.	If treatment for LTBI or active TB disease was completed pre- immigration, please indicate "Yes" and whether the person was treated for LTBI or active TB disease.
If yes,		Fill out data items C12b – C12e only if TB treatment was completed pre - immigration.
Treatment start date		Indicate the date the TB treatment was started. If the treatment start date is "unknown," check that box
Treatment end date		Indicate the date the TB treatment was ended. If the treatment end date is "unknown," check that box

Data Item	Description	Instructions/Comment(s)
Treatment Reported By		Indicate how the overseas treatment
		was reported.
U.S. Review of TB Disease	Indicates whether overseas	If no overseas treatment was
	treatment was reviewed by	recommended or
	U.S. clinician. Also	documented, indicate "no".
	determines whether	
	treatment was documented	
	by the panel physician on DS	
	forms, was reported by the	
	patient, or was reported by	
	both.	
Arrived on Treatment	Indicates if the patient arrived on	
	treatment from overseas.	
Completed Treatment	Indicates whether treatment was	
Overseas	completed overseas.	
Overseas Treatment	Indicates whether the U.S.	If there are concerns, the U.S.
Concerns	clinician has concerns regarding	clinician should provide comments in
	•	section F.
	prescribed by the overseas	
	panel physician.	

C15. U.S. Microscopy/Bacteriology

Alie	en#		EDN TB Follo	ow-Up Worksheet (Con	nt)	Last re	eviewed: 6/21/2013
C1	5. U.S. Microscopy/	Bacteriology*	Sputa collected	in U.S.? Yes	No *Covers	s all results regardless of sputa	collection method.
#	Date Collected	AFB S	Smear	Sputum	Culture	Drug Suscep	tibility Testing
1		Positive Not Done	Negative Unknown	NTM Contaminated Not Done	MTB Complex Negative Unknown	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done
2		Positive Not Done	Negative Unknown	NTM Contaminated Not Done	MTB Complex Negative Unknown	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done
3		Positive Not Done	Negative Unknown	NTM Contaminated Not Done	MTB Complex Negative Unknown	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done

Data Item	Description	Instructions/Comments
Specimen not collected in the United States.		
Specimen Source	'Sputum' includes spontaneous and induced sputum. Sputum or pulmonary secretions obtained by bronchoscopy procedures or gastric aspiration should also be included. Do NOT include tracheal suction.	include the following: sputum and bronchial washing.
Date (mm/dd/yyyy)	Date of specimen collection.	

Data Item	Description	Instructions/Comments
AFB Smear Result		
Not Done,		
Positive,		
Negative,		
Unknown		
Culture Result		Culture not performed
Not Done		·
Culture Result		Non-tuberculosis mycobacteria
NTM,		·
Culture Result		Results were negative for growth of
Negative		mycobacteria
Culture Result		Sputum culture test for AFB is known
Contaminated		to have been contaminated
Culture Result		Culture results are positive for growth
MTB Complex		of Mycobacterium tuberculosis
'		complex (M. tuberculosis, M. bovis,
		M. africanum)
Culture Result		If it is NOT known if a sputum smear
Unknown		was performed, or the results are
		NOT known for a reason other than
		'pending results'
Drug Resistance		Any specimen cultures resistant only
(DR)		to Rifampin. Specimen cultures
Mono-Rif		resistant to Rifampin and another
		drug (except Isoniazid) would be
David David Lance		noted under "Other Resistance)
Drug Resistance		Pansusceptible
(DR) No DR		
		Multiple drug registent tuberquesis
Drug Resistance		Multiple drug-resistant tuberculosis
(DR) MDR-TB		
Drug Resistance		Any specimen cultures resistant only
(DR)		to Isoniazid (regardless of
Mono-INH		concentration level of resistance).
		Specimen cultures resistant to
		Isonizaid and another drug (except
		Rifampin) would be noted under
		'Other Resistance'
Drug Resistance		Resistance to drugs or a drug
(DR)		combination not listed above. Please
Other DR		record the resistant pattern in
		Section F: Comments

Section D: Disposition

Section D: Introduction

This section collects information on whether a TB follow-up evaluation has been completed. The end points of an evaluation are indicated in D2 (i.e., Completed Evaluation, Initiated Evaluation/Not Completed, Did Not Initiate Evaluation).

D. Evaluation Disposition	
D1. Evaluation disposition date://	
D2. Evaluation disposition:	
Completed evaluation Initiated Eva	luation / Not completed Did not initate evaluation
If evaluation was completed, was treatment recommended?	OT completed, why not?
Not Located	Moved within U.S., transferred to:
Yes No Lost to Follo	w-Up Moved outside U.S.
LTBI Refused Eva	aluation Died
Active TB Unknown	Other, specify
D3. Diagnosis Class 0 - No TB exposure, not infec	ted Class 1 - TB exposure, no evidence of infection
Class 2 - TB infection, no disease	Class 3 - TB, TB disease
Class 4 - TB, inactive disease	Pulmonary Extra-pulmonary Both sites
D If diagnosed with TB disease, RVCT Reported	D5. RVCT #: RVCT # unknown

An Introduction to TB Follow-Up Evaluation End Points

Provided below are instructions on which sections to complete for each evaluation disposition. Please note that once a disposition is reached, these data should be reported to EDN promptly. If treatment for LTBI or active TB disease is recommended, treatment information should be reported as soon as it becomes available.

D1. - D2. Disposition Date and Evaluation Disposition

D. Evaluation Disposition	
D1. Evaluation disposition date:/_	<u></u>
D2. Evaluation disposition:	
Completed evaluation	Initiated Evaluation / Not completed Did not initate evaluation
If evaluation was completed, was treatment recommended?	If evaluation was <u>NOT</u> completed, why not?
п. п.	Not Located Moved within U.S., transferred to:
Yes No	Lost to Follow-Up Moved outside U.S.
LTBI	Refused Evaluation Died
Active TB	Unknown Other, specify

Domestic TB Follow-Up Evaluation End Points

Data Item	Description	Instructions/Comment
Disposition Date	Date when an evaluation end	
	point was reached.	
Evaluation Disposition	Please see descriptions and	
Completed Evaluation: Treatment Recommended, No Treatment Recommended	comments on page 42.	
Initiated Evaluation/Not Completed: Not located, Lost to Follow-up, Refused Evaluation, Unknown, Moved within U.S., Transferred to, Moved outside U.S., Died, Other, specify		
Did Not Initiate Evaluation: Not located, Lost to Follow-up, Refused Evaluation, Unknown, Moved within U.S., Transferred to, Moved outside U.S., Died, Other, specify		

Completed Evaluation

A domestic TB follow-up evaluation has been completed for an arriving immigrant or refugee for whom a final TB diagnosis has been made.

Data Item	Description	Comments
Treatment Recommended		If treatment is recommended, Section E. (U.S. treatment) should be completed.
No Treatment Recommended		If treatment is not recommended, Section E. (U.S. treatment) should not be completed.

Initiated Evaluation/Not Completed

A domestic TB follow-up had been initiated for an arriving immigrant or refugee for whom initial screenings for TB were done. However, screenings were not completed or a final TB diagnosis could not be made because of one of the following reasons.

Data Item	Description	Comments
Not Located	evaluations that not have been started	Only indicate not located for evaluations that not have been started.
Lost to Follow-up	The person failed to return to complete the evaluation.	Initial jurisdiction CANNOT provide locating information.
Refused Evaluation		
Moved outside United States.	The patient returned to the country of origin prior to completion of the evaluation.	
Moved within United	The patient moved to another EDN	Initial jurisdiction is able to transfer
States; transferred to:	jurisdiction before an evaluation could be completed.	the patient's record to the secondary jurisdiction in EDN.
Died		
Other, specify	previously the evaluation was not	Specify the reason for "Not Completed", in the form's comments section (Section F).

Did Not Initiate Evaluation

A domestic evaluation for TB has not been started for the arriving immigrant or refugee because of one of the following reasons.

Data Item	Description	Comments
Not Located		The health department is responsible for determining when all resources have been exhausted in search of the patient
Moved within U.S. transfer made:	Although the patient was located, an evaluation was not initiated because he or she relocated to another jurisdiction.	Initial jurisdiction is able to transfer the patient's record to the secondary jurisdiction in EDN.

Data Item	Description	Comments
Lost to Follow-Up	· ·	Initial jurisdiction cannot provide locating information.
Moved outside U.S.		
Refused Evaluation		
Died		
Unknown	The evaluation was not started for unknown reasons	
Other, specify	An evaluation was NOT initiated for reasons other than those stated above.	Other reasons should be specified in the comments section.

D3. Diagnosis

The diagnosis section of the worksheet collects information on the patient's domestic TB diagnosis.

D3. Diagnosis	Class 0 - No TB exposure, not infected	Class 1 - TB exposure, no evidence of infection
	Class 2 - TB infection, no disease	Class 3 - TB, TB disease
	Class 4 - TB, inactive disease	Pulmonary Extra-pulmonary Both sites

Classification of Persons Exposed to and/or Infected with <i>M. tuberculosis</i>	Description	Comments
Class 0	No TB exposure	Negative reaction to tuberculin skin test or IGRA No history of exposure
Class 1: TB exposure, no evidence of infection	Exposure to TB but not latent TB infection	Negative reaction to tuberculin skin test or IGRA No evidence of infection. History of exposure to tuberculosis but negative reaction to the tuberculin skin test
Class 2: TB infection, no disease	Latent TB Infection (LTBI)	Positive reaction to the tuberculin skin test Negative microscopy/bacteriology results No clinical or radiographic evidence of tuberculosis
Class 3: TB, active disease	Active TB disease	Clinically active tuberculosis Person must have clinical and/or radiologic evidence of tuberculosis Established most definitively by isolation of <i>M. tuberculosis</i> In absence for a positive culture for <i>M. tuberculosis</i> , persons in this class must have a positive reaction to the tuberculin test Class 3 is further defined as pulmonary or extrapulmonary, in both sites on the follow-up form.

Exposed to and/or Infected with <i>M. tuberculosis</i>		Comments
Class 4: Tuberculosis, inactive disease	diséase	History of previous episode(s) of tuberculosis or abnormal stable radiographic findings Positive reaction to tuberculin skin test Negative microscopy/bacteriology No clinical and/or radiographic evidence of current disease

Source:

The CDC Prevention Guidelines Database Archive at

Note:

The Class 5 TB Suspect category is intentionally left out of EDN TB follow-up reporting. The goal is to capture the complete follow-up: diagnostic, disposition, and treatment. Allowing Class 5 TB suspect as an end-point would not allow CDC to collect information on treatment.

D4. Report of a Verified Case of Tuberculosis (RVCT)

D If diagnosed with TB disea	se, RVCT Reported	D5. RVCT#:	RVCT # unknown

Data Item	Description	Instructions/Comment
RVCT Reported	tuberculosis to CDC ' '- An unmarked check box means that the patient was <u>not</u> reported as a verified case of tuberculosis to CDC	Complete this only if the patient has active tuberculosis
	' - A marked check box means that the patient <u>was</u> reported as a verified case of tuberculosis to CDC	
RVCT#	Indicates the RVCT# assigned to the patient	Complete this only if the patient was reported to the RVCT
RVCT # Unknown	Indicates that the patient was reported to the RVCT; however, the RVCT# is unknown An unmarked check box means the RVCT number is known A marked check box means the RVCT number is unknown	

Section E. Introduction

Section E collects information on domestic TB treatment. Section E should be filled out only if treatment was recommended for a person with a Class 2, 3, or 4 classifications.

E. U.S. Treatment
E1. U.S. treatment initiated: Yes No Unknown
If NO, specify the reason:
Patient declined against medical advice Lost to follow-up Moved within U.S, tranferred to:
Died Moved outside the U.S. Other (specify)
Unknown
If YES: TB disease LTBI
E2. Treatment start date://
E3. U.S. treatment completed: Yes No Unknown
If NO, specify the reason:
Patient stopped against medical advice Lost to follow-up Adverse effect
Provider decision Moved outside the U.S. Moved within U.S, tranferred to:
Died Unknown Other (specify)
If treatment was completed, E4. Treatment completion date://
If treatment was iniated but NOT completed, E5. Treatment end date://

Data Item	Description	Instructions/Comments
U.S. Treatment Initiated		If yes is indicated, please continue on to the "If YES" portion of section

Data Item	Description	Instructions/Comments
If No, specify reason: Patient declined against medical advice, Lost to follow-up, Moved within U.S., transferred to:, Died, Moved outside the U.S., Other(specify), Unknown	Treatment was not initiated for the patient for one of the following reasons: Patient declined against medical advice Lost to follow-up – means that the patient did not report for TB treatment, and subsequent attempts to contact the patient have failed Moved within United States, transferred to: -means the patient moved to another jurisdiction Died Moved outside the U.S Unknown Other, specify – means the patient did not initiate treatment for reasons other than specified above	
If Yes,	If treatment was initiated, indicate whether it was started for LTBI or active TB disease	
Treatment Start Date (mm/dd/yyyy)		
Treatment Completed	Indicates whether U.S. treatment was completed .	

Data Item	Description	Instructions/Comments
If No, specify reason	Indicates reasons for not completing treatment. Patient stopped against medical advice Lost to follow-up Adverse effect – means treatment was permanently stopped because of an adverse event due to anti-TB medications Provider decision – means that treatment was stopped by the provider for reasons other than adverse effects Moved within United States, transferred to jurisdiction before treatment could be completed Moved outside the U.S Died Unknown – means that treatment was not completed for reasons other than treatment was not completed for reasons other than those listed above	
U.S. Treatment Completion Date		Complete only if treatment was completed
U.S. Treatment End Date		Complete only if treatment was not completed

Section F: Comments

Section F. Introduction

Section F is the comments section of the TB follow-up worksheet. Please include any important medical or patient outcome information or clarifications that could not be captured in other sections of the worksheet here.

F. Comments	

Data Item	Description	Instructions/Comments
Comments	Comments section.	Use this section to provide more information on responses indicated 'other, please specify.' If additional room is needed, information can be written or typed on a second form and attached to the worksheet.

Section G: Screen Site Information

Section G. Introduction

Section G contains information about where the immigrant or refugee was evaluated. EDN does not collect the physician's signature.

G. Screen Site Information
Provider's Name:
Clinic Name:
Telephone Number:

Data Item	Description	Instructions/Comments
Provider's Name	The name of the provider who	
	performed U.S. medical evaluation.	
Clinic Name	The name of the clinic where the	
	patient was evaluated.	
Telephone Number	Clinic phone number.	

Appendix A: Country Codes

Birth	Country Name	Region
Country		
AF	AFGHANISTAN	Near East
AL	ALBANIA	Eastern Europe
AG	ALGERIA	North Africa
AQ	AMERICAN SAMOA	Pacific
AN	ANDORRA	Western Europe
AO	ANGOLA	Southern Africa
AV	ANGUILLA	Caribbean
AY	ANTARCTICA	Pacific
AL	ANTIGUA AND BURBUDA	Caribbean
AG	ARGENTINA	South America
AQ	ARMENIA	USSR/Former Soviet Union
AN	ASHMORE AND CARTIER ISL	Pacific
AO	AUSTRALIA	Austral Asia
AV	AUSTRIA	Western Europe
AY	AZERBAIJAN	USSR/Former Soviet Union
AC	BAHAMAS, THE	Caribbean
AR	BAHRAIN	Middle East
AM	BAKER ISLAND	Pacific
AT	BANGLADESH	Central Asia
AS	BARBADOS	Caribbean
AU	BASSAS DA INDIA	Southern Africa
AJ	BELARUS	USSR/Former Soviet Union
BF	BELGIUM	Western Europe
BA	BELIZE	Central America
BN	BENIN	West Africa
FQ	BERMUDA	North America
BG	BHUTAN	Central Asia
BB	BOLIVIA	South America
BS	BOSNIA AND HERCEGOVINA	Eastern Europe
BC	BOTSWANA	Southern Africa
BV	BOUVET ISLAND	Southern Africa
BR	BRAZIL	South America
IO	BRITISH INDIAN OCEAN TERRITORY	Southern Africa
VI	BRITISH VIRGIN ISLANDS	Caribbean
BX	BRUNEI	East Asia
BU	BULGARIA	Eastern Europe
UV	BURKINA FASO	West Africa
MM	BURMA	East Asia
BM	BURMA, MYANMAR	East Asia
BY	BURUNDI	Central Africa
CB	CAMBODIA	East Asia
CM	CAMEROON	Central Africa
CA	CANADA	North America
	0, 1, 1, 1, 1	1 total / amonoa

Birth Country	Country Name	Region
CV	CAPE VERDE	West Africa
CJ	CAYMAN ISLANDS	Caribbean
CT	CENTRAL AFRICAN REPUBLIC	Central Africa
CD	CHAD	Central Africa
CI	CHILE	South America
CH	CHINA	East Asia
KT	CHRISTMAS ISLAND	Pacific
IP	CLIPPERTON ISLAND	Latin America
CK	COCOS (KEELING) ISLANDS	Pacific
CO	COLOMBIA	South America
CN	COMOROS	Southern Africa
CF	CONGO	Central Africa
CW	COOK ISLANDS	Pacific
CR	CORAL SEA ISLANDS	Pacific
CS	COSTA RICA	Central America
IV	COTE D'IVOIRE	West Africa
HR	CROATIA	Eastern Europe
CU	CUBA	Caribbean
CY	CYPRUS	Middle East
EZ	CZECH REPUBLIC	Eastern Europe
CZ	CZECHOSLOVAKIA (OLD)	Eastern Europe
CG	DEMOCRATIC REPUBLIC OF THE CONGO	Central Africa
DA	DENMARK	Western Europe
DJ	DJIBOUTI	East Africa
DO	DOMINICA	Caribbean
DR	DOMINICAN REPUBLIC	Caribbean
EC	ECUADOR	South America
EG	EGYPT	North Africa
ES	EL SALVADOR	Central America
EK	EQUATORIAL GUINEA	Central Africa
ER	ERITREA	East Africa
EN	ESTONIA	USSR/Former Soviet Union
ET	ETHIOPIA	East Africa
EU	EUROPA ISLAND	Southern Africa
FK	FALKLAND (IS MALVINAS)	South America
FO	FAROE ISLANDS	Western Europe
FM	FED STATES MICRONESIA	Pacific
FJ	FIJI	Pacific
FI	FINLAND	Western Europe
FR	FRANCE	Western Europe
FG	FRENCH GUIANA	South America
FP	FRENCH POLYNESIA	Pacific
GB	GABON	Central Africa
GA	GAMBIA, THE	West Africa
GZ	GAZA STRIP	Middle East
GG	GEORGIA	USSR/Former Soviet Union
GM	GERMANY	Western Europe

Country Name	Region
GHANA	West Africa
GIBRALTAR	Western Europe
GLORIOSO ISLANDS	Southern Africa
GREECE	Eastern Europe
GREENLAND	Western Europe
GRENADA	Caribbean
GUADELOUPE	Caribbean
GUAM	Pacific
GUATEMALA	Central America
GUERNSEY	Western Europe
GUINEA	West Africa
GUINEA-BISSAU	West Africa
GUYANA	South America
HAITI	Caribbean
HEARD ISLAND & MCDONALD ISLANDS	South Africa
HONDURAS	Central America
HONG KONG	East Asia
HOWLAND ISLAND	Pacific
HUNGARY	Eastern Europe
ICELAND	Western Europe
INDIA	Central Asia
INDONESIA	East Asia
IRAN	Near Asia
IRAQ	Middle East
IRELAND	Western Europe
ISRAEL	Middle East
ITALY	Western Europe
JAMAICA	Caribbean
JAN MAYEN	Western Europe
	East Asia
	Pacific
JERSEY	Western Europe
	Middle East
	Pacific
	Middle East
	Southern Africa
	USSR/Former Soviet Union
	East Africa
	Pacific
	Pacific
	East Asia
,	East Asia
,	Middle East
	USSR/Former Soviet Union
	East Asia
	USSR/Former Soviet Union
	Middle East
	GHANA GIBRALTAR GLORIOSO ISLANDS GREECE GREENLAND GRENADA GUADELOUPE GUAM GUATEMALA GUERNSEY GUINEA GUINEA-BISSAU GUYANA HAITI HEARD ISLAND & MCDONALD ISLANDS HONDURAS HONG KONG HOWLAND ISLAND HUNGARY ICELAND INDIA IRAQ IRELAND ISRAEL ITALY JAMAICA JAN MAYEN JAPAN JARVIS ISLAND

Country Name	Region
LESOTHO	Southern Africa
LIBERIA	West Africa
LIBYA	North Africa
LIECHTENSTEIN	Western Europe
LITHUANIA	USSR/Former Soviet Union
LUXEMBOURG	Western Europe
MACAU	East Asia
MACEDONIA	Eastern Europe
MADAGASCAR	South Africa
MALAWI	Central Africa
MALAYSIA	East Asia
MALDIVES	Central Asia
MALI	West Africa
MALTA	Western Europe
MAN, ISLE OF	Western Europe
MARSHALL ISLANDS	Pacific
MARTINIQUE	Caribbean
MAURITANIA	West Africa
MAURITIUS	Southern Africa
MAYOTTE	Southern Africa
MEXICO	Central America
MIDWAY ISLAND	Pacific
	USSR/Former Soviet Union
	Western Europe
MONGOLIA	Central Asia
MONTENEGRO	Eastern Europe
MONTSERRAT	Caribbean
MOROCCO	North Africa
MOZAMBIQUE	Southern Africa
NAMIBIA	Southern Africa
NAURU	Pacific
NAVASSA ISLAND	Caribbean
NEPAL	Central Asia
NETHERLANDS	Western Europe
NETHERLANDS ANTILLES	Caribbean
NEW CALEDONIA	Australasia
NEW ZEALAND	Australasia
NICARAGUA	Central America
NIGER	West Africa
NIGERIA	West Africa
NIUE	Pacific
NORFOLK ISLAND	Pacific
NORTHERN MARIANA ISLANDS	Pacific
NORWAY	Western Europe
OMAN	Middle East
PAKISTAN	Near Asia
PALMYRA ATOLL	Pacific
	LESOTHO LIBERIA LIBYA LIECHTENSTEIN LITHUANIA LUXEMBOURG MACAU MACEDONIA MADAGASCAR MALAWI MALAYSIA MALI MALI MALTA MAN, ISLE OF MARSHALL ISLANDS MARTINIQUE MAURITANIA MAVOTTE MEXICO MIDWAY ISLAND MONACO MONGOLIA MONTENEGRO MONTSERRAT MOROCCO MOZAMBIQUE NAMIBIA NAURU NAVASSA ISLAND NEPAL NETHERLANDS NETHERLANDS NETHERLANDS NIGER NIGERIA NIUE NORFOLK ISLAND NORWAY OMAN PAKISTAN NORWAY OMAN PAKISTAN

Birth Country	Country Name	Region
PM	PANAMA	Central America
PP	PAPUA NEW GUINEA	Australasia Asia
PF	PARACEL ISLANDS	East Asia
PA	PARAGUAY	South America
PE	PERU	South America
RP	PHILIPPINES	Pacific
PC	PITCAIRN ISLANDS	Pacific
PL	POLAND	Eastern Europe
PO	PORTUGAL	Western Europe
PT	PORTUGUESE TIMOR	Pacific
RQ	PUERTO RICO	Caribbean
QA	QATAR	Middle East
RE	REUNION	South Africa
RO	ROMANIA	Eastern Europe
RS	RUSSIA	USSR/Former Soviet Union
RW	RWANDA	Central Africa
SX	S. GEORGIA/S.SANDWICH ISLANDS	Latin America
SM	SAN MARINO	Western Europe
TP	SAO TOME AND PRINCIPE	Central Africa
SA	SAUDI ARABIA	Middle East
SG	SENEGAL	West Africa
SR	SERBIA	Eastern Europe
SE	SEYCHELLES	Southern Africa
SL	SIERRA LEONE	West Africa
SN	SINGAPORE	East Asia
LO	SLOVAK REPUBLIC	Eastern Europe
SI	SLOVENIA	Eastern Europe
BP	SOLOMON ISLANDS	Pacific
SO	SOMALIA	East Africa
SF	SOUTH AFRICA	Southern Africa
FS	SOUTHERN OCEAN & ANTARCTIC LANDS	East Asia
SP	SPAIN	Western Europe
PG	SPRATLY ISLANDS	East Asia
CE	SRI LANKA	Central Asia
ST	ST LUCIA	Caribbean
SH	ST. HELENA	Southern Africa
SC	ST. KITTS AND NEVIS	Caribbean
SB	ST. PIERRE AND MIQUELON	North America
VC	ST. VINCENT/GRENADINES	Caribbean
SU	SUDAN	North Africa
NS	SURINAME	South America
SV	SVALBARD	Western Europe
WZ	SWAZILAND	Southern Africa
SW	SWEDEN	Western Europe
SZ	SWITZERLAND	Western Europe
SY	SYRIA	Middle East
TW	TAIWAN	East Asia

Birth Country	Country Name	Region
TI	TAJIKISTAN	USSR/Former Soviet Union
TZ	TANZANIA, UNITED REPUBLIC OF	East Africa
TH	THAILAND	East Asia
TO	TOGO	West Africa
TL	TOKELAU	Pacific
TN	TONGA	Pacific
TD	TRINIDAD AND TOBAGO	Caribbean
TE	TROMELIN ISLAND	Southern Africa
PS	TRUST TERR OF PACIFIC	Pacific
TS	TUNISIA	North Africa
TU	TURKEY	Near Asia
TX	TURKMENISTAN	USSR/Former Soviet Union
TK	TURKS AND CAICOS ISLANDS	Caribbean
TV	TUVALU	Pacific
UM	U.S. MINOR OUTLYING ISLANDS	Pacific
UR	U.S.S.R. (OLD)	USSR/Former Soviet Union
UG	UGANDA	Central Africa
UP	UKRAINE	USSR/Former Soviet Union
TC	UNITED ARAB EMIRATES	Middle East
UK	UNITED KINGDOM	Western Europe
ZZ	UNKNOWN	Uncertain
UY	URUGUAY	South America
US	USA	North America
UZ	UZBEKISTAN	Eastern Europe
NH	VANUATU	Pacific
VT	VATICAN CITY	Western Europe
VE	VENEZUELA	South America
VM	VIETNAM	East Asia
VQ	VIRGIN ISLANDS	Caribbean
WQ	WAKE ISLAND	Pacific
WF	WALLIS AND FUTUNA	Pacific
WE	WEST BANK	Middle East
WI	WESTERN SAHARA	North Africa
WS	WESTERN SAMOA	Pacific
YM	YEMEN	Middle East
YU	YUGOSLAVIA (OLD)	Eastern Europe
ZA	ZAMBIA	Southern Africa
ZI	ZIMBABWE	Southern Africa

Appendix B: TB Worksheet Glossary

Term	Definition
Acid-fast bacilli (AFB)	Microorganisms that, when stained, retain color even after they have been washed in an acid solution; may be detected under a microscope in a stained smear. <i>M. tuberculosis</i> is the most common AFB and this is a quick way to determine if the person has TB infection.
Active TB disease	An illness caused by bacteria called <i>Mycobacterium tuberculosis</i> , in which tuberculosis (TB) bacteria are multiplying and attacking parts of the body, most commonly the lungs. A person with active TB disease is capable of spreading the disease to others if the TB bacteria are active in the lungs or throat. The symptoms of active TB include weakness, weight loss, fever, no appetite, chills, and sweating at night. Other symptoms may include a bad cough, pain in the chest, and coughing up blood.
Cavity	A hollow space within the lung, visible on a chest X-ray or CT scan
Culture	To grow organisms on media (substances containing nutrients) so that they or the product of this process can be identified
Diagnostic evaluation	An evaluation used to diagnose TB disease; includes a medical history, a chest X-ray, the collection of specimens for bacteriologic examination, and possibly a tuberculin skin test or an interferon-gamma release assay such as the QuantiFERON®-TB Gold Test
Drug-resistant TB	TB caused by organisms that are able to grow in the presence of particular drug; TB that is resistant to at least one first-line ant tuberculosis drug
Extra pulmonary TB	TB disease that occurs in places other than the lungs, such as the lymph nodes, the pleura, the brain, the kidneys, or the bones; most types of extra pulmonary TB are not infectious
Interferon-gamma (IFN-γ)	Protein that is normally produced by the body in response to infection
Interferon-gamma release assay (IGRA)	A type of blood test that measures a person's immune reactivity to <i>M. tuberculosis</i> by measuring release of IFN- γ. In the U.S., QuantiFERON®-TB Gold, QuantiFERON®-TB Gold In-Tube, and T-SPOT® are examples of this kind of test.
Latent TB infection (LTBI)	Refers to the condition when a person is infected with tubercle bacilli, but TB disease has not developed. Persons with LTBI do not have TB disease symptoms, and they cannot spread TB germs to others. Persons with LTBI usually have a positive result to the Mantoux tuberculin skin test or an interferon-gamma release assay.
LTBI treatment	Medication that is given to people who have latent TB infection to prevent them from developing TB disease
Mantoux Tuberculin skin test (TST)	A method of testing for TB infection; a needle and syringe are used to inject 0.1 mL of 5 tuberculin units of liquid tuberculin between the layers of the skin (intradermally), usually on the forearm; the reaction to this test, a palpable swollen area (induration), is measured 48 to 72 hours after the injection and is interpreted as positive or negative depending on the size of the reaction and the patient's risk factors for TB

Term	Definition
	Resistant to at least the drugs isoniazid and rifampin, MDR TB is more
	difficult to treat than drug- susceptible TB
	One of the organisms that causes TB in humans, and sometimes called
	the tubercle bacillus; belongs to a group of bacteria called mycobacteria
Mycobacterium tuberculosis	A group of closely related mycobacteria that can cause active TB
complex	(e.g., M. tuberculosis, M. bovis, and M. africanum). Most TB in the
	United States is caused by <i>M. tuberculosis.</i>
	TB disease that occurs in the lungs, typically causing a cough and an
	abnormal chest X-ray. Pulmonary TB is usually infectious if untreated.
	Most TB cases reported in the United States are pulmonary TB.
Report of Verified Case of	The national tuberculosis (TB) surveillance data reporting form. All
Tuberculosis (RVCT)	jurisdictions report these data to CDC on each newly reported case of
	TB. The results are used for determining the TB morbidity case rates for
	the United States, U.S. territories, U.S. island areas and U.S. outlying
	areas.
	A specimen that has been smeared onto a glass slide, stained, washing
	in an acid solution, and then placed under the microscope for
	examination; used to detect acid-fast bacilli in a specimen
Specimen	A sample collected from a person for testing
Sputum	Phlegm from deep in the lungs, collected in a sterile container for
	processing and examination
Susceptibility	An organism's ability to be killed by a particular drug

Appendix C: Privacy Act System Notice 09-20-0103

System name: Alien Tuberculosis Follow-up Program. HHS/CDC/NCEZID.

Security classification: None.

<u>System location</u>: Office of the Director, Division of Global Migration and Quarantine, National Center for Emerging and Zoonotic Infectious Diseases, Corporate Square, Bldg. 10, Rm. 1209, Centers for Disease Control and Prevention.

<u>Categories of individuals covered by the system</u>: Immigrants and refugees with tuberculosis.

<u>Categories of records in the system</u>: Medical history.

<u>Authority for maintenance of the system</u>: Public Health Service Act, Section 325, "Examination of Aliens" (42 U.S.C. 252); and the Immigration and Nationality Act, Section 212(g), "Application for Waiver of Grounds of Inadmissibility" (8 U.S.C. 1182(g)).

<u>Purpose(s)</u>: To provide a record system for the surveillance and periodic medical evaluation of immigrant aliens with tuberculosis.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: Disclosure may be made to state health departments, city health departments or the courts, private physicians, or other health care facilities that will provide medical care for the immigrant alien. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual. In the event of litigation where the defendant is: (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Department of Justice has agreed to represent such employee, for example, in defending a claim against the Public Health Service based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, disclosure may be made to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected. Records may be disclosed by CDC in connection with public health activities to the Social Security Administration for sources of locating information to accomplish the research or program purposes for which the records were collected. CDC is authorized to share information on aliens with the Social Security Administration to determine eligibility for benefits, pursuant to Section 1631 (e) of the Social Security Act as amended by Public Law 103-296, or as otherwise provided for in the Social Security Act.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage: Card files and computer tapes/disks and printouts.

Retrievability: Records are retrieved by name, Alien Registration Number, and by year of birth.

Safeguards:

- 1. <u>Authorized Users</u>: A database security package is implemented on CDC's mainframe computer to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of the Centers for Disease Control and Prevention (CDC), or its contractors, as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected.
- 2. <u>Physical Safeguards</u>: Access to the CDC Clifton Road facility where the mainframe computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric keypad) system. Access to the data entry area is also controlled by a cardkey system. The hard copy records are kept in locked cabinets in locked rooms. The local fire department is located nearby. The computer room is protected by an automatic sprinkler system, automatic sensors (e.g., water, heat, smoke, etc.) are installed, and portable fire extinguishers are located throughout the computer room. The system is backed up on a nightly basis with copies of the files stored off site in a secure fireproof safe. The 24-hour guard service in buildings provides personnel screening of visitors. Electronic anti-intrusion devices are in effect at the Federal Records Center.
- Procedural Safeguards: Protection for computerized records both on the mainframe and the CIO Local Area Network (LAN) includes programmed verification of valid user identification code and password prior to logging on to the system, mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily backup procedures, and a Vault Management System for secure off-site storage is available for backup tapes. To avoid inadvertent data disclosure, "degaussing" is performed to ensure that all data are removed from Privacy Act computer tapes and/or other magnetic media. Additional safeguards may be built into the program by the system analyst as warranted by the sensitivity of the data. CDC and contractor employees who maintain records are instructed to check with the system manager prior to making disclosures of data. When individually identified data are being used in a room, admittance at either CDC or contractor sites is restricted to specifically authorized personnel. Privacy Act provisions are included in contracts, and the CDC Project Director, contract officers and project officers oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to CDC or destroyed, as specified by the contract.
- 4. <u>Implementation Guidelines</u>: The safeguards outlined above are developed in accordance with Chapter 45- 13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual; and Part 6, "Automated Information System Security," of the HHS Information Resources Management Manual. FRC safeguards are in compliance with GSA Federal Property Management Regulations, Subchapter B-- Archives and Records. Data maintained in CDC Atlanta's Processing Center are in compliance with OMB Circular A-130, Appendix III. Security is provided for information collection, processing, transmission, storage, and dissemination in general support systems and major applications. The CIO LAN currently operates under Novell Netware v 4.11 and is in compliance with "CDC & ATSDR Security Standards for Novell File Servers."

<u>Retention and disposal</u>: Card files are maintained in the agency for two years and are destroyed by paper recycling process after 2 years. Computer files are maintained for 4 years at CDC. Records are destroyed by erasing tape after 4 years.

Notification procedure: An individual may learn if a record exists about himself or herself by contacting the system manager at the address above. Requesters in person must provide driver's license or other positive identification. Individuals who do not appear in person must either: (1) submit a notarized request to verify their identity; or (2) certify that they are the individuals they claim to be and that they understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act subject to a \$5,000 fine. An individual who requests notification of or access to medical records shall, at the time the request is made, designate in writing a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion. A parent or guardian who requests notification of, or access to, a child's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child by means of a birth certificate or court order, as well as verify that he or she is who he or she claims to be. The following information must be provided when requesting notification: (1) full name; (2) the approximate date and place of the study, if known; and (3) nature of the questionnaire or study in which the requester participated.

<u>Record access procedures</u>: Same as notification procedures. Requesters should also reasonably specify the record contents being sought. An accounting of disclosures that have been made on the record, if any, may be requested.

<u>Contesting record procedures</u>: Contact the official at the address specified under System Manager above, reasonably identify the record and specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

<u>Record source categories</u>: Information obtained from alien's visa medical documents at port of entry by Quarantine Inspectors.

Systems exempted from certain provisions of the act: None.