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.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Disease Control and Prevention



January 7, 2014

Version 1.0

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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 followup 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 followup-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.

Digital Certificates: 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.

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 Folle	ow-Up Wo	ksheet		L	ast reviewed: 6/21/2013
A1. Name (Last. First. Middle):	A2. Alien #:		A3, Vi	isa type:	A4. Initial U.S	
A5. Age: A8. Gender:	A7. DOB:		A8. TE	B Class:		
A9.Country of examination:		4	10.Count	try of birth:		
A11a. Address:		A	12. a. Sp	oonsor agency nan	ne:	
A11b. Phone:			b. Pl	hone(s):		
A11c. Other:			c. Ar	ddress:		
B. Jurisdictional Information						
B1. Arrival jurisdiction:			B2. Curre	ent jurisdiction:		
C. U.S. Evaluation						
C1. Date of Initial U.S. medical evaluation:						
Mantoux Tuberculin Skin Tes					mma Release As	
C2a. Was a TST administered? Yes	No Unk			IGRA administere		No Unknown
If YES, C2b. TST placement date:/_	_/			3b. Date collected		Date unknown
Placement dat	e unknown		С	3c. IGRA brand:	QuantiFERON	T-SPOT
C2c. TST mm:	Unknown			[Other (specify	je –
C2d. TST interpretation:	ositive Ne	egative	c	3d. Result: Po	ositive Negat	ive Indeterminate
Π·	nknown			П In	valid 🗍 Unkno	wn
C2e. History of Previous Positive TST		c	3e. Histor	ry of previous posit	tive IGRA	
U.S Review of Pre-Immigration C	KR		U.	S. Domestic CXR	1	Comparison
C4. Pre-immigration CXR available?		C7. U.S.	domestic	CXR done?		C11. U.S. domestic
Yes No Not Verifiable		∏ _{Yes}	No	Unknown		CXR comparison to pre-immigration CXR:
C5. U.S. interpretation of pre-immigration	NP-			of U.S. CXR:		
Normal	over.			of U.S. CXR:	· · · · · ·	Stable
Abnormal (must select one below):		Nor		JI 0.3. CAR.		Worsening
Not consistent with active TE						Improving
		Abn		ust select one belo		Unknown
Non-cavitary, consistent with	тв	ļĻ		nsistent with active		_
Cavitary, consistent with TB				avitary, consistent v		
Poor Quality			_	ry, consistent with	тв	
Unknown			nown			
C6. Other pre-immigration CXR abnormalitie		C10. U.S	. domesti	c CXR abnormaliti	es:	
Volume loss Infiltrate Granulor	na(ta)	Volur	ne loss	Infiltrate	Granuloma(ta)	
Adenopathy Other (specify)		Aden	opathy	Other (specify))	
U.S. Review of Pre-Immigration Treatment						
C12a. Completed treatment pre-immigration		No		Arrived on treatme		
IT YES, Treated for TB disease				Yes No		
C12b. Treatment start date://		te unknowr	1	YES, TB disea	se LTBI	
C12c. Treatment end date: ///						
C12d. Treatment reported by: Treatment documented on DS forms C14: Pre-Immigration treatment concerns?						
				Yes No		
Patient reported treatment co panel physician examination	mpletion <u>at</u> or t	etore	11	YES,		
Both-documented on DS form	ns & patient ren	orted		Treatment du	ration too short	
				Incorrect trea	tment regimen	
C12e. Standard TB treatment regimen w	as administered	17		Other, please	specify:	
Yes No Unable to verify				_		
			1			

Alien #	EDN TB Follo	w-Up Worksheet (Cont)	Last reviewed: 6/21/2013
C15. U.S. Microscopy	/Bacteriology* Sputa collected	in U.S.? Yes No *Cover	t all mouth regardless of sputs collection method.
# Date Collected	AFB Smear	Sputum Culture	Drug Susceptibility Testing
1 _/_/	Positive Negative Not Done Unknown	NTM MTB Complex Contaminated Negative Not Done Unknown	MDR-TB Mono-RIF Mono-INH Other DR No DR Not Done
2 _/_/	Positive Negative Not Done Unknown	NTM MTB Complex Contaminated Negative Not Done Unknown	MDR-TB Mono-RIF Mono-INH Other DR No DR Not Done
3 _/_/	Positive Negative Not Done Unknown	NTM MTB Complex Contaminated Negative Not Done Unknown	MDR-TB Mono-RIF Mono-INH Other DR No DR Not Done
D. Evaluation Disposi	tion		
D1. Evaluation disposi	ition date://		
D2. Evaluation disposi Completed ev. If evaluation was treatment recomm Yes LT Ac D3. Diagnosis	aluation Initiated Ev completed, was nended? Not Locate No Lost to Fol	ow-Up Moved outside U.S. valuation Died Other, specify	Did not initiate evaluation
DO. Diagnosis	Class 2 - TB infection, no disease	Class 3 - TB, TB disea	
	Class 4 - TB. inactive disease		
D If diagnosed with 7		D5. RVCT#:	RVCT # unknown
E. U.S. Treatment		55.14401 8.	
Died Unknown If YES: To dise E3. U.S. tr If NO, sp Pat Pat Die Die If Jreatment a	c	U.S. Other (specify)	ed to:
G. Screen Site Inform	ation		
Provider's Name:			
Clinic Name:			
Telephone 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 (Last, First, Middle):		A2. Alien #:	A3. Visa type:	isa 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 agen	ncy name:		
A11b. Phone:		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)



- 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-Immigration 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 preimmigration 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
/f 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
C10. U.S. domestic CXR abnormalities:
Volume loss Infiltrate Granuloma(ta)
Adenopathy Other (specify)

- 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*

Alie	en #		EDN TB Follo	w-Up Work	sheet (Cont)		Last	reviewed: 6/21/2013
C1	5. U.S. Microscopy	/Bacteriology*	Sputa collected	in U.S.?	Yes	No *Cover	s all results regardless of sput	a collection method.
#	Date Collected	AFB \$	Smear		Sputum Cu	ulture	Drug Susce	ptibility Testing
1	/	Positive	Negative	NTM Contar	minated	MTB Complex Negative Unknown	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done
2	//	Positive	Negative	NTM Contai Not Do	minated	MTB Complex Negative Unknown	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done
3		Positive	Negative	NTM Contai	minated	MTB Complex Negative Unknown	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	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.

- 1. 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.
- 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 <u>5</u> 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 <u>EDNhelpdesk@cdc.gov</u> for more information.

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

Introduction

Section A of the tuberculosis follow-up worksheet contains alien demographic information. This section is **prepopulated 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.

	Description	Instructions/Comments
Name (Last, First, Middle)	Complete name	The system will automatically
		populate this field.
Alien #	Unique identification number assigned by the	The system will automatically
	U.S. Department of State.	populate this field.
Visa Type	Visa classification as determined by the	The system will automatically
	Department of State. Visa types are explained	populate this field.
	in Table 2 on the next page.	
Initial Entry Date	The date arrived in the U.S., as documented	The system will automatically
	by CDC Quarantine Stations or U.S. Bureau of	populate this field.
	Citizenship agents.	
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.,		The system will automatically
m, f)		populate this field.
DOB (mm/dd/yyyy)		The system will automatically
		populate this field.

	Description (continued)	Instructions/Comments
TB Class	TB classification as determined by the	The system will automatically populate
	overseas panel physician.	this field.
Class Condition	Condition of public health significance	The system will automatically populate
	as determined by the panel physician.	this field.
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 agency's contact information.	The system will automatically populate this field. Refugees often have a sponsoring agency; immigrants do <u>not</u> .

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.
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.

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 substancerelated 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. 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:

	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		Alien #	EDN TB Follo	w-Up Worksheet (Cont)	Last reviewed: 6/21/2013
C1. Date of Initial U.S. medical evaluation://	-	C15. U.S. Microscopy/Bact			*Covers all results regardless of sputa collection method.
Mantoux Tuberculin Skin Test (TST)	Interferon-Gamma Release Assay (IGRA)	# Date Collected	AFB Smear	Sputum Culture	Drug Susceptibility Testing
C2a. Was a TST administered? Yes No Unknown #YES, C2b. TST placement date:/ Placement date unknown C2c. TST mm: Unknown	C3a. Was IGRA administered? Yes No Unknown #YES, C3b. Date collected:/_/ C3c. IGRA brand: QuantiFERON♥ T-SPOT Other (specify):		Positive Negative Not Done Unknown	NTM MTB Co Contaminated Negative Not Done Unknown	Mono-INH Other DR
C2d. TST interpretation: Positive Negativ Unknown C2e. History of Previous Positive TST		2 _/_/	Positive Negative	NTM MTB Co Contaminated Negative Not Done Unknow	e Mono-INH Other DR
Yes No Not Verifiable	U.S. Domestic CXR Comparison U.S. domestic CXR done? C11. U.S. domestic CXR comparison to pre-immigration CXR:	3 _/_/ □	Positive Negative	NTM MTB Co Contaminated Negative Not Done Unknow	e Mono-INH Other DR
Normal C9. Abnormal (must select one below):	KES, C8. Date of U.S. CXR: Interpretation of U.S. CXR: Normal Abnormal (must select one below):				
	Volume loss Infiltrate Granuloma(ta) Adenopathy Other (specify)				
C12a. Completed treatment pre-immigration? Yes No I/YES, Treated for TB disease Treated for LTBI C12b. Treatment start date: _/ Start date unkl C12c. Treatment and date: _/ End date unkl C12d. Treatment documented on DS forms Patient reported treatment completion <u>at</u> or <u>before</u> panel physician examination Both-documented on DS forms & patient reported Unknown C12e. Standard TB treatment regimen was administered? Yes No Unable to verify	known Image: Start date Image: Start date nown Image: Start date Image: Start date C13a. Start date: Image: Start date Image: Start date C14: Pre-Immigration treatment concerns? Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date Image: Start date				

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

	Description	Instructions/Comments
Date of Initiate U.S. Medical		Indicate the date the domestic
Evaluation (mm/dd/yyyy)		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 <u>not the</u>
		date when the health department
		first contacted the immigrant or
		refugee.

C2. 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:	/	
	Placem	ent date unknown	
	C2c. TST mm:	Unknown	
	C2d. TST interpretation:	Positive Negative	
		Unknown	
C2e. His	story of Previous Positive TS	т	

	Description	Instructions/Comments
Was a TST administered? - Yes, No, Unknown	 Inquiry as to whether an 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) TST mm	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. Indicate the millimeters of induration for the TST.
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.

|--|

C3. Interferon Gamma Release Assay (IGRA)

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

	Description	Instructions/Comments
Was IGRA administered? – Yes,	Inquiry of whether an IGRA was	Indicate whether an IGRA was
No, Unknown	administered post-U.S. arrival	administered during the domestic
	during domestic screening for TB.	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		Indicate the date the IGRA was
(e.g., 01/01/2010)		administered during domestic
ICDA Brand Overstiff DON T		screening for TB.
IGRA Brand – QuantiFERON, T-		Indicate the specific brand of IGRA
SPOT, Other (specify)		administered. If the specific brand is not on the provided list, select
		"Other, specify" and indicate the
		brand.
Result – Positive, Negative,	The result of the IGRA test	Indicate the result of the IGRA test
Indeterminate, Invalid, Unknown	 'Positive' – means that it is 	administered during domestic
	probable that the person is	screening for TB.
	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 M. tuberculosis.	

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)			

	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.
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 overseas CXR. If a U.S. physician interprets the overseas CXR as	If the U.S. clinician indicated abnormalities in the overseas CXR, please indicate one.

	abnormal, indicate type of abnormality(-ies) reported. Check all that apply.	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 <i>If YES,</i> 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

	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 "unknown".
Date of U.S. CXR (mm/dd/yyyy)		If no chest X-ray was taken in the 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.
Abnormal – Not consistent with active TB, Noncavitary, consistent with TB, Cavitary, consistent with	The U.S clinician's interpretation of abnormalities found on the <u>domestic</u> CXR. If a U.S. clinician	Please select one of the abnormalities.
ТВ	 interprets the <u>domestic</u> 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 	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	Please list other abnormalities	If other abnormalities are present,
Abnormalities – Volume Loss,	found on the <u>domestic</u> CXR by the	please indicate them.
Infilitrate, Granuloma(ta),	U.S. clinician. Check all that apply.	
Adenopathy, Other (Specify)		If no CXR is available, leave this
		section blank. Please specify other
		abnormalities found, such as miliary,
		in the comments section. Do not
		transcribe what was reported on the
		overseas medical evaluation to
		complete this section.



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

	Description	Instructions/Comment(s)
Completed treatment pre-	Indicate whether TB treatment was	If treatment for LTBI or active TB
immigration? – Yes (Treated for	completed overseas before U.S.	disease was completed pre-
TB disease, Treated for LTBI), No	arrival.	immigration, please indicate "Yes"
		and whether the person was treated
		for LTBI or active TB disease.
If you		Fill out data itama C12h - C12a anhuif
If yes,		Fill out data items C12b – C12e only if
		TB treatment was <u>completed</u> pre-
Treatment start data		immigration.
Treatment start date		Indicate the date the TB treatment
		was started. If the treatment start
Treatment end date		date is "unknown," check that box Indicate the date the TB treatment
freatment end date		was ended. If the treatment end date
Treatment Departed Dy		is "unknown," check that box Indicate how the overseas treatment
Treatment Reported By		
U.S. Review of TB Disease	Indicates whether overseas	was reported. If no overseas treatment was
0.5. Review of TB Disease		
	treatment was reviewed by U.S. clinician. Also determines whether	recommended or documented, skip
		C14-C17 and go to section D.
	treatment was documented by the	
	panel physician on DS forms, was	
	reported by the patient, or was	
Autor days Treatment	reported by both.	
Arrived on Treatment	Indicates if the patient arrived on	
	treatment from overseas.	
Completed Treatment Overseas	Indicates whether treatment was	

	completed overseas.	
Overseas Treatment Concerns	Indicates whether the U.S. clinician	If there are concerns, the U.S.
	has concerns regarding the treatment	clinician should provide comments in
	regimen prescribed by the overseas	section F.
	panel physician.	

Alie	en #		EDN TB Follo	w-Up Worksheet (Co	ont)	Last reviewed: 6/21/2013		
C1	5. U.S. Microscopy	/Bacteriology*	Sputa collected	in U.S.? Yes	No *Covers	No *Covers all results regardless of sputa collection method.		
#	Date Collected	AFB Sn	near	ear Sputum Culture		Drug Susceptibility Testing		
1	/	Positive	Negative	NTM Contaminated Not Done	MTB Complex Negative Unknown	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done	
2		Positive	Negative	NTM Contaminated Not Done	MTB Complex Negative Unknown	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done	
3		Positive	Negative	NTM Contaminated Not Done	MTB Complex Negative Unknown	MDR-TB Mono-INH No DR	Mono-RIF Other DR Not Done	

	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.	Examples of specimen sources include the following: sputum and bronchial washing.		
Date (mm/dd/yyyy)	Date of specimen collection.			
AFB Smear Result				
Not Done, Positive,				
Negative, Unknown			_	
Culture Result Not Done, NTM,		Not Done	Culture not performed	
Negative,		NTM	Non-tuberculosis	
Contaminated, MTB			mycobacteria	
Complex, Unknown		Negative	Results were negative	
			for growth of	
			mycobacteria	
		Contaminated	Sputum culture test for	
			AFB is known to have	
			been contaminated	
	Description (continued)	Instructions/0	Comments (continued)	
---	-------------------------	----------------	---	
Culture Result <i>(continued)</i> Not Done, NTM, Negative, Contaminated, MTB Complex, Unknown		MTB	Culture results are positive for growth of <i>Mycobacterium</i> <i>tuberculosis</i> complex (<i>M.</i> <i>tuberculosis, M. bovis, M.</i> <i>africanum</i>)	
		Unknown	If it is NOT known if a sputum smear was performed, or the results are NOT known for a reason other than 'pending results'	
Drug Resistance (DR) Not Done, Mono-Rif, No DR, MDR-TB, Mono-INH, Other DR		Mono-Rif	Any specimen cultures resistant only to Rifampin. Specimen cultures resistant to Rifampin and another drug (except Isoniazid) would be noted under "Other Resistance)	
		No DR	Pansusceptible	
		MDR-TB	Multiple drug-resistant tuberculosis	
		Mono-INH	Any specimen cultures resistant only to Isoniazid (regardless of concentration level of resistance). Specimen cultures resistant to Isonizaid and another drug (except Rifampin) would be noted under 'Other Resistance'	
		Other DR	Resistance to drugs or a drug combination not listed above. Please record the resistant pattern in Section F: Comments	

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 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	Lost to Follow-Up Moved outside U.S.
LTBI	Refused Evaluation Died
Active TB	Unknown Other, specify
D3. Diagnosis Class 0 - No TB e	xposure, not infected Class 1 - TB exposure, no evidence of infection
Class 2 - TB infec	tion, no disease Class 3 - TB, TB disease
Class 4 - TB, inac	tive disease Pulmonary Extra-pulmonary Both sites
D If diagnosed with TB disease, RV	/CT 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.

D. Evaluation Disposition	
D1. Evaluation disposition date:/	_/
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	Lost to Follow-Up Moved outside U.S.
LTBI	Refused Evaluation Died
Active TB	Unknown Other, specify

Domestic TB Follow-Up Evaluation End Points

	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.

	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:.

	Description	Comments
Not Located	Indicate 'not located' only for evaluations that	Only indicate not located for evaluations
	not have been started	that not have been started.
Lost to Follow-up	The person failed to return to complete the	Initial jurisdiction CANNOT provide
	evaluation.	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 States;	The patient moved to another EDN jurisdiction	Initial jurisdiction is able to transfer the
transferred to:	before an evaluation could be completed.	patient's record to the secondary jurisdiction in EDN.
Died		
Other, specify	For reasons other than those stated previously the evaluation was not completed.	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.

	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	Although the patient was located, an	Initial jurisdiction is able to transfer the
made:	evaluation was not initiated because he or she	patient's record to the secondary
	relocated to another jurisdiction.	jurisdiction in EDN.
Lost to Follow-Up	The patient was located but failed to report for	Initial jurisdiction cannot provide locating
	initial TB screening at the clinic, and	information.
	subsequent attempts to contact have failed.	
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	Description	Comments
and/or Infected with <i>M. tuberculosis</i>		
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.

Classification of Persons Exposed to and/or Infected with <i>M. tuberculosis</i>	Description (continued)	Comments (continued)
Class 4: Tuberculosis, inactive disease	Old, healed, inactive TB disease	 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:

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 disease,	RVCT Reported D5. RVCT #:	RVCT # unknown
	Description	Instructions/Comment
RVCT Reported	 Indicates whether the patient with active TB disease was reported as a verified case of tuberculosis to CDC '□' - An unmarked check box means that the patient was not reported as a verified case of tuberculosis to CDC '□' - A marked check box means that the patient <u>was</u> reported as a verified case of tuberculosis to CDC 	Complete this only if the patient has active tuberculosis
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 <u>known</u> '■' – A marked check box means the RVCT number is <u>unknown</u> 	

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://

	Description	Instructions/Comments
U.S. Treatment Initiated		If yes is indicated, please continue
		on to the "If YES" portion of section
If No, specify reason:	Treatment was not initiated for the	
Patient declined against medical	patient for one of the following	
advice, Lost to follow-up, Moved	reasons:	
within U.S., transferred to:, Died,	Patient declined against medical	
Moved outside the U.S.,	advice	
Other(specify), Unknown	• 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.	
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 <u>not</u> completed for unknown reasons Other, specify – means that 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 <u>not</u> 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		

	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. 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:	

	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	Country Name	Region
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
AC	ANTIGUA AND BARBUDA	Caribbean
AR	ARGENTINA	South America
AM	ARMENIA	USSR/Former Soviet Union
AT	ASHMORE AND CARTIER ISL	Pacific
AS	AUSTRALIA	Austral Asia
AU	AUSTRIA	Western Europe
AJ	AZERBAIJAN	USSR/Former Soviet Union
BF	BAHAMAS, THE	Caribbean
BA	BAHRAIN	Middle East
FQ	BAKER ISLAND	Pacific
BG	BANGLADESH	Central Asia
BB	BARBADOS	Caribbean
BS	BASSAS DA INDIA	Southern Africa
во	BELARUS	USSR/Former Soviet Union
BE	BELGIUM	Western Europe
BH	BELIZE	Central America
BN	BENIN	West Africa
BD	BERMUDA	North America
ВТ	BHUTAN	Central Asia
BL	BOLIVIA	South America
ВК	BOSNIA AND HERCEGOVINA	Eastern Europe
BC	BOTSWANA	Southern Africa
BV	BOUVET ISLAND	Southern Africa
BR	BRAZIL	South America
Ю	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
СВ	CAMBODIA	East Asia

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

Central Africa North America West Africa Caribbean Central Africa

GZ	GAZA STRIP
GG	GEORGIA
GM	GERMANY
GH	GHANA
GI	GIBRALTAR
GO	GLORIOSO ISLANDS
GR	GREECE
GL	GREENLAND
GJ	GRENADA
GP	GUADELOUPE
GQ	GUAM
GT	GUATEMALA
GK	GUERNSEY
GV	GUINEA
PU	GUINEA-BISSAU
GY	GUYANA
HA	HAITI
HM	HEARD ISLAND & MCDONALD ISLANDS
НО	HONDURAS
НК	HONG KONG
HQ	HOWLAND ISLAND
HU	HUNGARY
IC	ICELAND
IN	INDIA
ID	INDONESIA
IR	IRAN
IZ	IRAQ
EI	IRELAND
IS	ISRAEL
IT	ITALY
JM	JAMAICA
JN	JAN MAYEN
JA	JAPAN
DQ	JARVIS ISLAND
JE	JERSEY
JS	JERUSALEM
JQ	JOHNSTON ATOLL
JO	JORDAN
JU	JUAN DE NOVA ISLAND
KZ	KAZAKHSTAN
KE	KENYA
KQ	KINGMAN REEF
KR	KIRIBATI
KN	KOREA, DEMOCRATIC PEOPLE'S REPUBLIC
KS	KOREA, REPUBLIC OF
KU	KUWAIT
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Middle East

Caribbean Caribbean Pacific

East Asia Pacific

Caribbean

East Asia Pacific

East Africa Pacific Pacific East Asia East Asia Middle East

Western Europe

Western Europe Middle East Pacific Middle East Southern Africa

USSR/Former Soviet Union

Eastern Europe Western Europe **Central Asia** East Asia Near Asia Middle East Western Europe Middle East Western Europe

Central America Western Europe West Africa West Africa South America Caribbean South Africa Central America

Western Europe West Africa Western Europe Southern Africa Eastern Europe Western Europe

USSR/Former Soviet Union

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KG	KYRGYZSTAN
LA	LAOS
LG	LATVIA
LE	LEBANON
LT	LESOTHO
LI	LIBERIA
LY	LIBYA
LS	LIECHTENSTEIN
LH	
LU	LUXEMBOURG
MC	MACAU
МК	MACEDONIA
MA	MADAGASCAR
MI	MALAWI
MY	MALAYSIA
MV	MALDIVES
ML	MALI
MT	MALTA
IM	MAN, ISLE OF
RM	MARSHALL ISLANDS
MB	MARTINIQUE
MR	MAURITANIA
MP	MAURITIUS
MF	MAYOTTE
MX	MEXICO
MQ	MIDWAY ISLAND
MD	MOLDOVA
MN	MONACO
MG	MONGOLIA
MW	MONTENEGRO
MH	MONTSERRAT
MO	MOROCCO
MZ	MOZAMBIQUE
WA	NAMIBIA
NR	NAURU
BQ	NAVASSA ISLAND
NP	NEPAL
NL	NETHERLANDS
NT	NETHERLANDS ANTILLES
NC	NEW CALEDONIA
NZ	NEW ZEALAND
NU	NICARAGUA
NG	NIGER
NI	NIGERIA
NE	NIUE
NF	NORFOLK ISLAND

USSR/Former Soviet Union East Asia USSR/Former Soviet Union Middle East Southern Africa West Africa North Africa Western Europe USSR/Former Soviet Union Western Europe East Asia Eastern Europe South Africa Central Africa East Asia **Central Asia** West Africa Western Europe Western Europe Pacific Caribbean West Africa Southern Africa Southern Africa Central America Pacific USSR/Former Soviet Union Western Europe **Central Asia** Eastern Europe Caribbean North Africa Southern Africa Southern Africa Pacific Caribbean **Central Asia** Western Europe Caribbean Australasia Australasia **Central America** West Africa West Africa Pacific Pacific

CQ	NORTHERN MARIANA ISLANDS	Pacific
NO	NORWAY	Western Europe
MU	OMAN	Middle East
PK	PAKISTAN	Near Asia
LQ	PALMYRA ATOLL	Pacific
PM	PANAMA	Central America
РР	PAPUA NEW GUINEA	Australasia Asia
PF	PARACEL ISLANDS	East Asia
РА	PARAGUAY	South America
PE	PERU	South America
RP	PHILIPPINES	Pacific
PC	PITCAIRN ISLANDS	Pacific
PL	POLAND	Eastern Europe
РО	PORTUGAL	Western Europe
РТ	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
ТР	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
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| P a g e

SV	SVALBARD
WZ	SWAZILAND
SW	SWEDEN
SZ	SWITZERLAND
SY	SYRIA
TW	TAIWAN
ті	TAJIKISTAN
TZ	TANZANIA, UNITED REPUBLIC OF
ТН	THAILAND
то	TOGO
TL	TOKELAU
TN	TONGA
TD	TRINIDAD AND TOBAGO
TE	TROMFLIN ISLAND
PS	TRUST TERR OF PACIFIC
TS	TUNISIA
TU	TURKEY
ТХ	TURKMENISTAN
ТК	TURKS AND CAICOS ISLANDS
TV	TUVALU
UM	U.S. MINOR OUTLYING ISLANDS
UR	U.S.S.R. (OLD)
UG	UGANDA
UP	UKRAINE
тс	
UK	UNITED KINGDOM
ZZ	UNKNOWN
UY	URUGUAY
US	USA
UZ	UZBEKISTAN
NH	VANUATU
VT	VATICAN CITY
VE	VENEZUELA
VM	
VQ	VIRGIN ISLANDS
WQ	WAKE ISLAND
WF	WALLIS AND FUTUNA
WE	WEST BANK
WI	WESTERN SAHARA
WS	WESTERN SAMOA
YM	YEMEN
YU	YUGOSLAVIA (OLD)
ZA	ZAMBIA
ZI	ZIMBABWE

Western Europe Southern Africa Western Europe Western Europe Middle East East Asia USSR/Former Soviet Union East Africa East Asia West Africa Pacific Pacific Caribbean Southern Africa Pacific North Africa Near Asia USSR/Former Soviet Union Caribbean Pacific Pacific USSR/Former Soviet Union Central Africa USSR/Former Soviet Union Middle East Western Europe Uncertain South America North America Eastern Europe Pacific Western Europe South America East Asia Caribbean Pacific Pacific Middle East North Africa Pacific Middle East Eastern Europe Southern Africa 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 Mycobacterium
	tuberculosis, 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 antituberculosis drug
Extrapulmonary 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 extrapulmonary
	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
	ТВ
Multidrug-resistant TB (MDR TB)	Resistant to at least the drugs isoniazid and rifampin,
	MDR TB is more difficult to treat than drug-
	susceptible TB
Mycobacterium tuberculosis	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 complex	A group of closely related mycobacteria that can
	cause active TB (e.g., <i>M. tuberculosis</i> , <i>M. bovis</i> , and
	<i>M. africanum</i>). Most TB in the United States is caused
	by M. tuberculosis.
Pulmonary TB	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 Tuberculosis (RVCT)	The national tuberculosis (TB) surveillance data
	reporting form. All 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.
Smear	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.

Categories of individuals covered by the system: Immigrants and refugees with tuberculosis.

Categories of records in the system: 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

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.

<u>Retrievability</u>: 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.

3. <u>Procedural Safeguards</u>: 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.

<u>Notification procedure</u>: 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.