TB CASE REPORT & DATA ENTRY MANUAL
TB Case Report and Data Entry Manual
TB PROGRAM, OHA
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Introduction to TB Case Reporting in Orpheus

Tuberculosis (TB) is a nationally notifiable disease, and reporting is required by law in Oregon. Local Public Health Authorities (LPHAs) must report suspected or confirmed TB cases to the Oregon Health Authority TB Program (TB-OHA) using Orpheus—the Oregon Public Health Epidemiologists' User System.

Paper reports are not accepted.

Orpheus is the system used by TB-OHA to collect and manage data on TB cases and contacts. This data supports statewide TB control and prevention efforts. De-identified surveillance data is also submitted from Orpheus to the <u>Division of Tuberculosis Elimination (DTBE)</u> at the Centers for Disease Control and Prevention (CDC).

Purpose of This Manual

This manual provides step-by-step instructions for reporting TB disease cases in Orpheus, including:

- How and when to open a new case record
- How to enter required data
- Guidance on verification status and documentation
- How to close a case record
- How to enter contact investigation data and outcomes

For detailed definitions of data fields, refer to the <u>Report of Verified Case of Tuberculosis Instruction Manual</u> available at the CDC <u>Division of Tuberculosis Elimination</u>.

⚠ These instructions are intended to support complete, accurate and valid data entry in Orpheus. They do not replace expert medical judgment or CDC clinical guidelines for TB diagnosis and management. For clinical questions, please contact TB-OHA directly.

Reporting Timeline

All suspected or confirmed TB cases must be reported in Orpheus within five (5) business days of the LPHA receiving the initial report.

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PART 1. THE TB CASE REPORT: OVERVIEW

All reportable TB disease data is stored in Orpheus, the Oregon Public Health Epidemiology User System. Local Public Health Authorities (LPHAs) are required to notify the Oregon Health Authority (OHA) of any confirmed or presumptive TB disease reported within their jurisdiction within five working days.

Reporting Pathways

Reports of confirmed or presumptive TB may reach state or local public health authorities through various channels. Depending on the source and method of reporting, the information may be directed to either the LPHA or the OHA TB Program (TB-OHA). Common reporting pathways include:

- A physician calling the LPHA or TB-OHA
- A clinical laboratory sending a faxed report to the LPHA or TB-OHA
- An electronic laboratory report (ELR) submitted to TB-OHA via Orpheus

Responsibility for Case Record Creation in Orpheus

Responsibility for creating a case record in Orpheus depends on how the report is received:

- LPHA receives the report (via phone or faxed/lab report):
 The LPHA is responsible for creating the case record in Orpheus, regardless of whether TB disease is presumptive or confirmed.
- **TB-OHA receives the report** (via phone or lab report):
 A TB Epidemiologist will create the case record in Orpheus and notify the LPHA.
 The LPHA is responsible for entering data.
- ELR is received in Orpheus:
 TB-OHA will create the case record and inform the LPHA. The LPHA is responsible for entering data.

When to Create a Report in Orpheus

An LPHA should create a report in Orpheus within five business days when any of the following criteria are met:

- A patient has a positive rapid diagnostic nucleic acid amplification test (e.g., GeneXpert MTB/RIF) or positive culture for *Mycobacterium tuberculosis* or *Mycobacterium tuberculosis complex*
- A pathology report indicates findings consistent with tuberculosis
- A patient is started on empiric multidrug therapy for TB

How to Report Confirmed TB disease

- 1. Open a TB case record in Orpheus
 - Refer to "Verification Status", below
- 2. Complete patient demographic information
- 3. Fill out the following tabs in their entirety, based on information available at the time:
 - Admin (specifically, Local epi)
 - Labs
 - Clinical
 - Treatment (start date, height, weight, and drug regimen)
 - Risks
 - Follow-up
- 4. As soon as possible, enter information for medical case review
 - Patient height, weight, treatment start date, and treatment regimen
- 5. Attach supporting documents to Docs tab, including:
 - Radiology reports
 - Pathology reports
 - Lab reports from labs other than OSPHL
- SPHL lab reports are received as ELRs and processed by TB-OHA. These do not need to be attached by the LPHA
- Short Contact data entry is covered in Section 4 of this guide.

How to Report Unconfirmed TB Disease

- 1. Open a TB case record in Orpheus
 - Refer to "Verification Status". below
- 2. Complete patient demographic information
- 3. Fill out the following tabs in their entirety, based on information available at the time:
 - Admin (specifically, Local epi)
 - Labs
 - Treatment (start date, height, weight, and drug regimen)
- 4. As soon as possible, enter information for medical case review
 - Patient height, weight, treatment start date, and treatment regimen
- 5. Attach supporting documents to Docs tab, including:
 - Radiology reports
 - Pathology reports
 - Lab reports from labs other than OSPHL

SPHL lab reports are received as ELRs and processed by TB-OHA. These do not need to be attached by the LPHA.

Verification Status

- Lab-confirmed at time of report:
 Choose Verification Status "Confirmed"
- Treatment started but not lab-confirmed:
 Choose Verification Status "Unconfirmed, started Tx"
- Neither confirmed nor on treatment:
 Choose Verification Status "Presumptive"
 Data collection and entry for presumptive TB disease is not required until confirmation or start of treatment.

If TB-OHA Receives a Confirmed Lab Report (ELR or Fax)

- The TB Epidemiologist will:
 - Open the case record in Orpheus
 - · Enter verification status, lab results, and demographic data
 - Notify the LPHA via case note and email
- The LPHA case manager should complete the remaining tabs within five business days (See How to Report Confirmed TB Disease, above).

Case Confirmation

Once TB disease is confirmed (either at time of report or later):

- The TB Epidemiologist assigns a case number and count date
- LPHA staff should:
 - Attach relevant documentation (e.g., radiology reports, case notes, non-OSPHL lab reports) to the Docs tab
 - Enter treatment start date, initial drug regimen, and patient height and weight
- The TB Epidemiologist may follow up with the LPHA to complete missing information

☼ Only OHA staff have permission to edit TB ELRs. The TB Epidemiologist processes and attaches ELRs to the Labs tab and will enter relevant information on other tabs.

Case Medical Review

All new TB patients — whether confirmed or started on empiric treatment — are reviewed by TB-OHA at the start of treatment. The following information is required for review and should be entered as soon as possible:

Treatment start date

- Initial drug regimen
- Patient height and weight

Any changes to treatment suggested by the State Infectious Disease medical consultant will be communicated to the LPHA case manager.

If TB is Ruled Out

If TB disease is ruled out or determined not to be TB, the LPHA case manager or TB Epidemiologist should:

- Change the case status to "No case"
- Add a case note in Orpheus explaining the change

Data Quality Assurance (QA)

- The TB Epidemiologist conducts QA reviews of Orpheus case records and contact records to ensure completeness and accuracy.
- Based on QA review, the epidemiologist may request the LPHA to:
 - Complete missing data
 - Correct errors

© Quality data ensures compliance with CDC reporting and supports local surveillance.

Case Record Closure

- When treatment is complete, the LPHA enters closure information in the Treatment tab, including:
 - Date treatment stopped
 - Reason treatment was stopped (Closure reason)
 - Directly Observed Therapy (DOT) status

 Other final or missing case record data (See Case Record Closure in Section 3)

PART 2. TB DISASE REPORTING IN ORPHEUS

Required Information for TB Disease Reporting

When creating a TB case record in Orpheus, the following information and tabs must be completed:

- Demographic information
- Admin Tab
- Labs Tab
- Clinical Tab
- Treatment Tab
- Risks Tab
- Follow-Up Tab
- ◇ Detailed instructions for case record creation and data entry are outlined in the sections below.

Creating the Case Record

Steps to Create a New Case Record

From the Orpheus home page, click on + to create a new case record. A pop-up window will appear. Complete the following fields:

Field	Instructions
Disease	Select TB from the dropdown.
TB Disease Status	Choose from: • Confirmed

Field	Instructions
	 Unconfirmed, started tx Presumptive (See page <u>Verification Status</u> for guidance on assigning status.)
Name	Enter the patient's first and last name.
Date of Birth	Enter date of birth.
Sex	Enter current sex.
Institution of Residence	Enter only if applicable (e.g., patient resides in a correctional facility, long-term care facility, or shelter). Not required for a private residence.
Address	Enter residence address (permanent or temporary). County will auto-populate based on Zip code.

Once all fields are complete, click "Create Case."

- Orpheus will search for existing person records using name and DOB.
- If an exact match appears: Click "Create Case" [1] next to the correct match to link the TB case record to the existing person record.
- If no match or an inexact match is found, click "Ignore Matches Create Person and Case." [2]



 \Re If no potential matches are found, the new case window will appear without displaying any potential matches.

Demographic Information Panel

Enter demographic information in the central panel of the TB module. All fields **above** the "STATE USE ONLY" section are **required**.

- ♦ Choose from the drop-down options. Do **not** overwrite dropdowns with free text.
- ♦ Do **not** enter anything in "STATE USE ONLY" fields.

Required Fields

Field	Instructions
Orpheus Case ID	Auto-generated
Name, Disease, Status, DOB, Age, Sex, Address	Auto-populated from the New Case Investigation window at time of case record creation.
Status	Choose from drop-down options. See <u>Verification Status</u>
Verification	Entered by OHA
Deceased	Enter "No" if alive at diagnosis. If patient dies during treatment, update with date and cause of death

Field	Instructions
Current Sex & SOGI	"Current Sex" auto-populates from case creation window. SOGI data is required by state statute. See Equity & Inclusion Division website for guidance
Pregnancy	If current sex is female (regardless of age), select Yes/No/Unknown. Enter estimated due date if known
Race (REALD)	Required by state statute. Ask the patient to self-identify. Do not guess. Use checkboxes and/or free text. See Equity & Inclusion Division website for guidance
Worksite, Occupation, Industry	Worksite is the name or location of employer Occupation is the general type of occupation from the past 12 months. Choose from drop- down and do not overwrite. Industry will be filled by TB Epidemiologist
Housing at Diagnosis and Past Year	Choose housing status at diagnosis and the most severe housing status in the year before diagnosis. See housing status definitions below.

Housing Status Definitions

- Homeless: Living in places not meant for human habitation (e.g., car, park, shelter). Also considered "literally homeless"
- **Unstably Housed**: Frequent moves, overcrowding, "couch surfing," eviction, or at risk of losing housing

• **Stably Housed**: Secure, consistent housing not at risk of loss

Housing status questions are also asked on the **Risks** tab in slightly different ways. Both sets of housing questions are required for different reporting purposes.

Address & Phone Number

- Auto-populated if entered during case record creation
- Confirm address and LPHA jurisdiction
- If jurisdiction appears incorrect, contact the TB Epidemiologist
- Enter address and phone number manually if not previously entered

State Use Only Fields

- Completed by OHA
- Includes count date, TB case number, and count status
- If the case is not counted in Oregon, the Count Status field will contain an explanatory entry

Admin Tab: Administration

Report Dates

Date received by LHD and Date reported to state are auto-generated.
 LHD completion date and State completion date are entered at case record closure.

Case EPIs

Role	Details
State Epi	Always assigned to the State TB Epidemiologist (currently Kiley Ariail)
Local Epi	Defaults to the person who created the case record. The LPHA should change to the case manager responsible for the TB patient

Dupdate the **Local Epi** if the case manager changes.

Moved Out of State

At time of move or at case record closure, if the patient moves out of state during treatment:

- Select Yes
- Specify where (e.g., out of state, out of U.S.)
- Enter the state or country moved to
 - Mark "Out of US-Transnational Referral if referral information is sent to the receiving country, e.g., through Cure-TB for transfers to Mexico.

Related Cases

- · Completed by OHA only
- Used to link epi-linked cases or multiple TB episodes in the same person

Treating Provider

Optional

• Click "+ **Provider**" to search and select the treating provider

Lab Summary Tab: Laboratory Results

General Instructions

- Complete all fields on the Labs tab (except State only: Genotyping).
- Enter "Not done" if a test was not performed.
- Leave fields blank if results are pending. Do not enter "Unknown".
- **Do not overwrite** drop-down options.

TST/IGRA at Diagnosis

Category	Instructions
TST (Tuberculin Skin Test)	 Enter date placed, result, and induration in mm (if positive) Previous results may be entered if done within 1 year prior to diagnosis If not placed, select "Not Done"
IGRA (Interferon Gamma Release Assay)	 QuantiFERON or T-Spot Enter date drawn and result Previous results may be entered if done within 1 year prior to diagnosis If not drawn, select "Not Done"

Chest Imaging at Diagnosis

Category	Instructions
Imaging Type	-Enter date of chest X-ray and/or CT scanIf not done, enter "Not done"
Result Options	 Normal: No abnormalities consistent with TB Abnormal: TB-associated abnormalities Unknown: Imaging done, result unknown Not Done: No imaging performed
If Abnormal	Select descriptor if either Chest X-ray or CT is abnormal: - Cavitary: Cavitary findings - Miliary: Miliary findings - Both: Cavitary and miliary - Neither: Abnormal but neither cavitary nor miliary

Sputum Bacteriology

Category	Sputum Smear	Sputum Culture
Result Options	- Positive: Any positive sputum AFB smear. Indicate smear level 1+ (rare), 2+ (few), 3+ (moderate) or 4+ (many) Negative: All sputum AFB smears negative - Not Done: No sputum AFB smear performed - Unknown: Sputum AFB	 Positive: Any sputum culture positive for <i>M. tuberculosis</i> or <i>M. tuberculosis</i> complex Negative: All sputum cultures negative Not Done: No sputum culture performed Unknown: Sputum culture result unknown or lost

Category	Sputum Smear	Sputum Culture
	smear result unknown or results lost	
Instructions	 If multiple sputum AFB smears are collected, enter collection date & result of first positive smear result reported If all are negative, enter collection date of first negative smear result reported Update if pending/unknown results become available 	 If multiple cultures, enter collection date & result of first positive culture result reported If all negative, enter collection date of first negative culture result reported Update if pending/unknown results become available
Collection Date	 Enter collection date of first positive specimen (see above) If no positives, enter collection date of first negative specimen 	 Enter collection date of first positive specimen (see above) If no positives, enter collection date of first negative specimen
Result Date	 Enter date first positive result was reported If all negative, enter date of first negative result 	 Enter date first positive result was reported If all negative, enter date of first negative result
Culture Conversion	N/A	 Required if initial sputum culture is positive Enter "Yes" if conversion documented, with collection/result date Enter "No" if not documented and select reason from dropdown Sputum culture conversion date is defined as the date of specimen collection for the first negative

Category	Sputum Smear	Sputum Culture
		culture result after which there are no subsequent positive results.

Nucleic Acid Amplification Testing (NAAT)

Category	Instructions
Definition	NAAT refers to rapid diagnostic tests (e.g., GeneXpert, PCR) performed on primary clinical specimens . Tests to identify organisms in culture isolates are not considered NAAT for reporting.
Result Options	 - Positive: Any positive result - Negative: At least one negative and no positives - Indeterminate: All results are indeterminate - Not Done: NAAT not performed - Unknown: NAAT status unknown or results lost
Collection Date	 Positive: Collection date of first positive NAAT result Negative: If no positives, collection date of first negative NAAT result
Result Date	 Positive: Date first positive result was reported Negative/Indeterminate: Date first such result was reported
Specimen Source	Select from dropdown. Do not overwrite. Contact TB Epidemiologist if unsure.

Tissue/Fluid Smear, Pathology, or Cytology (Non-Sputum)

Category	Instructions
Definition	This section includes lab results (AFB smear, pathology, or cytology) from non-sputum specimens (e.g., bronchial fluid, tracheal aspirate, lymph node, pleural fluid, CSF, etc.). Only include specimens collected during diagnostic workup or within 2 weeks of treatment start.
Result Options	 - Positive: Any specimen shows AFB or pathology deemed consistent with TB (e.g., granulomas) - Negative: All specimens show no findings consistent with TB disease - Not Done: No smear/pathology/cytology performed - Unknown: Status unknown or results lost/contaminated
Collection Date	 Positive: Collection date of first positive specimen Negative: If all negative, collection date of first negative specimen
Specimen Source	Select from dropdown. Do not overwrite. Contact TB Epidemiologist if unsure.
Exam Type	Select the type of exam that corresponds to the result: - Smear - Pathology/Cytology - Both
Reporting Rule	A positive result supersedes a negative. If results are discrepant , select the positive exam type. If both are positive or both are negative, select "Both."

Culture of Tissue & Other Body Fluids (Non-Sputum)

Category	Instructions
Definition	Includes cultures from non-sputum specimens such as Bronchial cells/fluid, tracheal aspirate, lymph node, lung tissue or fluid, pleural fluid, cerebrospinal fluid (CSF), etc. ① Only include specimens collected during diagnostic workup or within 2 weeks of treatment start.
Result Options	 - Positive: Any specimen is culture-positive for <i>M. tuberculosis</i> or <i>M. tuberculosis complex</i> - Negative: All specimens are culture-negative - Not Done: No culture performed - Unknown: Status unknown or results lost/contaminated If results were initially pending but later become available, update the record.
Collection Date	 Positive: Collection date of first positive specimen Negative: If all negative, collection date of first negative specimen
Specimen Source	 Select from dropdown Do not overwrite Contact TB Epidemiologist if unsure

Notes Box

Use the **Notes Box** to record any additional details related to:

- Tests performed
- Tissue or fluid specimens
- Result clarifications

The notes box is optional but helpful for documenting context or nuances not captured in structured fields.

Labs Tab Overview

The Labs tab displays a summary of diagnostic laboratory results at diagnosis, including those received electronically and those entered manually.

Electronic Lab Reports (ELRs)

- ELRs are displayed after review and processing by the **TB Epidemiologist**.
- Only OHA staff can process TB ELRs.
- Processed ELRs will appear automatically in this tab.

Manual Entry of Lab Reports

When to Use	Use to enter lab reports received via fax or other (non-ELR) methods.
Steps	 1. Click the "+" button to open the lab entry window. 2. Complete the following fields: Laboratory Name Specimen Collection Date Report Date Specimen Type (select from dropdown) Test Type Result Interpretation

[♦] Use dropdown menus where available. Do **not** overwrite dropdown options. Consult the TB Epidemiologist for clarification if needed.

Clinical Tab

General Instructions

- Complete all fields on the Clinical tab.
- Use dropdown menus where available.
- Do not overwrite dropdown options.

Symptomatic at Initial Evaluation

Field	Instructions
Symptomatic	Indicate by selecting "Y" or "N" whether the TB patient was symptomatic at the time of initial evaluation.
Symptom Onset Date	If symptomatic, enter the date symptoms began (if known, an estimate is ok).

Reason for TB Evaluation

Drop-down Option	Definition
TB Symptoms	Patient sought care for symptoms consistent with TB (e.g., cough, fever, night sweats, weight loss, lymphadenopathy). Includes atypical symptoms.
Contact Investigation	Patient was evaluated as part of a contact investigation.

Drop-down Option	Definition
Targeted Testing	Patient was tested due to high-risk status (e.g., country of origin, high-risk group).
Employment/Admin Screening	Patient was evaluated for employment or administrative purposes.
Health Care Worker Screening	Patient was tested for employment in a healthcare setting.
Immigration	Case patient was evaluated as an immigrant/refugee (e.g., B-waiver, status adjuster).
Incidental Abnormal CXR/CT or Lab	TB was not initially clinically suspected; abnormalities were found during unrelated clinical evaluation (e.g., bronchoscopy, autopsy).
Unknown	Reason for evaluation is not known.
Other	Select if none of the above apply. Enter explanation in the pop-up box.

- Use dropdowns only. Do **not** overwrite options.
- ♦ Most often, "TB Symptoms" applies.

Clinical Questions

Click the "? Ask Clinical Questions" button to open the clinical questions pop-up. Mark Yes, No, or Unknown for each symptom. Enter explanatory notes if desired.

- Cough Enter duration
- Fever
- Night Sweats
- **Hemoptysis** (bloody sputum)
- Weight Loss Enter amount lost
- **Other Symptoms** Enter additional symptoms (e.g., lymphadenopathy, chest pain, fatigue)

Site(s) of Disease

Field	Instructions
Primary Site	Check the most appropriate primary site(s) of disease. Contact the TB Epidemiologist if unsure which site to select.
Other Site	If site of disease not listed among primary sites, select from the dropdown in the "Other" field. Contact the TB Epidemiologist if unsure which site to select.

◇ Do not overwrite dropdown options.

HIV Test Result at Diagnosis

Field(s)	Instructions
HIV Test Result at diagnosis	Required for all case patients, regardless of age or risk. Enter result, test date, and specimen type (blood or saliva). Either a blood test or rapid test is acceptable. A test obtained within 1 year of diagnosis is acceptable.
If HIV test result positive	Additional required fields will appear: - CD4 Specimen Date: most recent - CD4 Count: most recent - HIV Case ID (entered by TB Epidemiologist)

Treatment Tab

General Instructions

- Enter all applicable fields.
- Use dropdown menus where available.
- Do not overwrite dropdown options.
- Enter initial treatment regimen only. Do not update if regimen changes after 2 weeks of treatment.

Treatment Details

Field	Instructions
Treatment Start Date	Enter the date the patient started multi-drug therapy.
Height & Weight	Enter the patient's height and weight at time of diagnosis. Check <90% Ideal Body Weight if appropriate.
Expected Length of Treatment	Enter the expected length of treatment if known using free text. An estimate is fine. This field is not required but helps the TB Epidemiologist know when to check for updates on treatment completion.

[♦] **Note:** Date stopped, closure, treatment extension, DOT, DOT weeks, and Provider(s) will be entered when the case patient completes treatment.

Initial Drug Regimen

Field	Instructions
Initial Drug Regimen	The standard 4-drug RIPE regimen is auto-populated in the dropdown boxes.

Field	Instructions
Dosage	Enter the dosage as numbers only.
Dose Frequency	Enter the dose frequency.
Regimen Notes	Enter initial drug treatment/initiation phase regimen only. Do not change these values if the regimen changes later.

- ♦ If the case patient is taking an alternative initial regimen:
 - If the patient is being treated as if they have multi-drug-resistant TB, regardless
 of drug susceptibility results, choose "Yes" under "Treated as MDR."
 - Click + to reveal a new drug dropdown field.
 - Choose the drug from the dropdown list.
 - Do **not** overwrite dropdown options.
 - To remove a drug, click **X** at the end of the drug row.
- ♦ If the patient is **not** started on the initial 4-drug RIPE regimen, specify a reason.
- Note: Remaining fields will be entered when the case patient completes treatment.

Drug Susceptibility Tab

- Drug susceptibility results are entered by the OHA TB Epidemiologist.
- No action is required on this tab by local staff.

Risks Tab

General Instructions

- Risk questions directly affect TB program funding.
- In general, "Unknown" is not an acceptable response if a patient is alive and able to be interviewed. If a patient has died, a proxy interviewee should be asked these questions if possible.
- If fields are marked "Unknown," the TB Epidemiologist will follow up to request completion.
- Enter answers to risk questions by clicking the ? Ask Risk Questions button and answering the questions in the pop-up boxes.
- Guidance for answering each question is included on the Orpheus question interface.

Risk Questions & Instructions

Risk Factor	Instructions
Previous diagnosis of TB Disease	Select "Yes" if patient has a previous diagnosis of TB disease, regardless of treatment. Otherwise, choose "No", "Refused", or "Unknown". Add explanatory notes if needed.
Previous treatment for LTBI	Same guidance as above.
Occupation History	Indicate if the patient has ever worked as a health care worker, correctional facility employee, migrant/seasonal worker, or none.
Homeless in past year	Select "Yes" if patient indicates they have experienced homelessness in the year leading up to diagnosis. Homeless is defined as lacking a fixed, regular, and adequate nighttime residence. Includes shelters, public

Risk Factor	Instructions
	spaces, or unstable housing (e.g., couch surfing). Otherwise, choose "No", "Refused", or "Unknown".
History of homelessness	Same definition as above, but applies to any time in the past before the year leading up to diagnosis.
Resident of correctional facility at diagnosis	Select Yes if the patient was living in a correctional facility at diagnosis. Includes prisons, jails, juvenile facilities, immigration detention, tribal jails, etc. Otherwise, choose "No", "Refused", or "Unknown".
History of incarceration	Select Yes if the patient has ever lived in a correctional facility. Otherwise, choose "No", "Refused", or "Unknown".
Resident of long- term care facility at diagnosis	Select Yes if at time of diagnosis patient lived in a nursing home, SNF, hospital-based or residential mental health or substance use treatment facility. Does not include assisted living. Otherwise, choose "No", "Refused", or "Unknown".
Alcohol use in past year	Select Yes, if patient indicates heavy alcohol use, defined as binge drinking on 5+ days in the month before diagnosis. Binge = 4+ drinks (women) or 5+ drinks (men) in ~2 hours. Otherwise, choose "No", "Refused", or "Unknown".
Intravenous drug use in past year	Select Yes if patient used non-prescribed drugs via IV, subcutaneous, or intramuscular routes. Otherwise, choose "No", "Refused", or "Unknown".
Non-Intravenous drug use in past year	Select Yes if patient used marijuana (medicinal or recreational), misuse of prescription drugs, or other non-injecting drug use (ingested, inhaled, sniffed, or smoked). Otherwise, choose "No", "Refused", or "Unknown".

Risk Factor	Instructions
Smoking (Tobacco)	Select from options: Current everyday smoker, Current some day smoker, Former smoker, Never smoker, Smoker (current status unknown), or Unknown if ever smoked.
TB Risks	Select all that apply: Contact of MDR TB patient, Contact of infectious TB patient, Missed contact, Incomplete LTBI therapy, TNF-alpha antagonist therapy, Post-organ transplant, Diabetes, End-stage renal disease, Immunosuppression (non-HIV). If none, select "None." If other, select "Other/specify" and add details in Notes.
Diabetes (if applicable)	If Diabetes is selected above, enter: A1c collection date, A1c value (%), and fasting blood glucose (mg/dL). The most recent collection date is desirable. If these results are not available, arrange for testing.
Viral Hepatitis	Select "Yes", "No", "Refused", or "Unknown".

Follow-Up Tab

General Instructions

• Enter answers to follow-up questions by clicking the ? Ask Follow-Up Questions button and completing the pop-up boxes.

Residence Outside the United States

Field	Instructions
Residence outside the U.S.	If the patient has ever lived for 2 or more months uninterrupted outside the 50 United States, enter Yes .

[♦] This question will **almost always be "Yes"** if the patient was born outside the U.S. and immigrated at age **2 months or older**.

PART 3. CLOSING A CASE RECORD

Required Tabs for Case record Closure

When treatment is complete, close the case record by completing information in the following tabs:

- Treatment
- Central Static Pane
- Admin

Closure Tab: Treatment

Field	Instructions
Treatment Stop Date	Enter the date the patient last ingested medication for treatment of TB disease or suspected TB.
Closure Reason	Select reason treatment stopped from dropdown options. Do not overwrite options. • Completed therapy: Patient completed course of treatment as prescribed. • Lost: Patient could not be located prior to end of treatment (e.g., the case patient moved to an unknown or known location and could not be located). This selection does not apply to

Field	Instructions
	patients who move outside the U.S. and cannot be followed up; see "Other". • Uncooperative/refused: Patient refused to complete treatment and stopped taking medications. • Adverse treatment event: Treatment was permanently stopped because of an adverse event caused by anti-TB medications. If the case patient died due to an adverse treatment event: • Closure reason = "Died" • Deceased = "Yes" in Central Panel • Reason for death = "Related to Treatment" • Not TB: Diagnostic evaluation did not support a diagnosis of TB (e.g., M. avium was isolated from a clinical specimen). • Died: Case patient was alive at diagnosis but died before the start or completion of treatment. • Dying: Treatment was stopped prior to imminent death. • Other: Treatment was discontinued for a known reason not included in the above choices and is not unknown. A case patient who moved out of state and the receiving state never followed up would fall into this category, as would case patients who move internationally and are lost to follow-up due to international relocation. • Unknown: Reason for treatment stop unknown.
Treatment Extension	This field is required if treatment lasted more than 12 months. Select from dropdown. Do not overwrite options. Rifampin resistance Adverse drug reaction Non-adherence Failure of treatment Clinically indicated – other reasons Other
Provider Type	Enter the type(s) of medical provider(s) who provided treatment. Choose all that apply.
Administration Type	Select treatment observation type from dropdown. Do not overwrite options. Choose all that apply. • DOT (Directly observed therapy, in person)

Field	Instructions	
	EDOT (Electronic DOT, via video call or other)Self-Administered	

Closure: Central Panel

If Closure Reason is "Died," enter the following:

Field	Instructions		
Deceased	Select "Yes"		
Date of Death	Enter date		
Cause of Death	 Select from dropdown. Options include Related to TB disease Related to TB therapy Unrelated to TB disease Unknown 		

Closure Tab: Admin

Completion Date

Field	Instructions	
LHD Completion Date	Enter the date the case record was closed and record completed by the Local Public Health Authority.	
State Completion Date	The State Completion Date will be entered by the TB Epidemiologist after final record review.	

Moved During Treatment

Field	Instructions
Moved Out of State	Enter "No" if the case patient did not move or moved within Oregon. Enter "Yes" if the case patient moved to another state or country. If "Yes," select one: • Out of state – Enter name of state or U.S. territory • Out of the U.S. – Enter country name and check "Out of US– Transnational Referral" if referral made to destination jurisdiction.

PART 4. ENTERING CONTACTS IN ORPHEUS

Three Essential Points

Required Data Entry:

LPHAs must enter contact investigation information directly into the *Contact Investigation* tab in Orpheus. Submission of the TB Contact Investigation Form to the TB-OHA is **not required**.

Optional Use of the TB Contact Investigation Form:

LPHAs may use the TB Contact Investigation Form to:

- 1. Prioritize follow-up of contacts
- 2. Track evaluation and treatment of contacts

Use of the TB Contact Investigation Form is **optional**. Submission of the form does not substitute for entry of contacts in Orpheus. The form is available on the TB-OHA website: <u>TB Contact Investigation</u> Form (PDF)

Guidance and Support:

These data entry instructions do **not** replace clinical or public health guidelines for TB diagnosis, treatment, or control. For comprehensive guidance, refer to the CDC's <u>Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis (MMWR, December 16, 2005, Vol. 54, No. RR-15).</u>

For technical assistance or consultation, contact the TB Program at the Oregon Health Authority (OHA).

Contact Investigation Data Entry

Types of Information in the Contacts Tab

- Case Patient Infectiousness Information
- Data Submission Dates
- Contact Demographics
- Contact Risks
- Contact Medical Evaluation
- Contact Treatment and Final Status

Contacts Tab

The Contacts tab has three distinct areas:

- Top: A case-specific area ("Case Information" and "Infectious Period")
- Middle: A clickable list of contacts
- Bottom: A contact-specific detail screen with seven tabs

Case Patient-Specific Information: Contact Investigation Need

The State TB epidemiologist assigns a Contact Investigation Need (CI Need) level, visible at the top of the Contacts tab.

Contact Investigation Need Levels

- **High**: Sputum-smear positive and/or cavitary/laryngeal disease. Initiate contact investigation within 72 hours.
- Medium: Sputum-smear negative, culture-positive pulmonary/laryngeal disease.
 Initiate within 72 hours.
- **Low**: Sputum-smear and culture negative pulmonary/pleural disease. Investigation recommended; notify OHA if not feasible.
- **None**: Pulmonary involvement ruled out. No contact investigation needed.

Infectious Period

Start Date

Estimate as 3 months before symptom onset or first positive TB finding (whichever is earlier). Positive findings include:

- Positive AFB smear
- Positive NAAT
- Positive culture for MTB
- Abnormal CXR consistent with TB
- Initiation of TB treatment

End Date

Estimate as when the patient has been released from home/community isolation.

Note: End date is estimated for contact investigation purposes only. Clinical home or hospital isolation decisions may differ. For more information, see the following resources or contact the OHA TB Program:

- <u>Tuberculosis Investigative Guidelines</u>, see page 8 and 11.
- CDC Self-Study Module 8: Contact Investigations for Tuberculosis
- <u>Guidelines for the Investigation of Contacts to Persons with Infectious</u>
 Tuberculosis

No Contacts

If no contacts were identified, document the reason:

- No contacts identified despite effort
- Contact follow-up not done
- Contacts same as another case patient (include Orpheus Case ID in Contact Notes tab)

Checkbox

Check No Contacts box if no contacts were identified for any reason.

Adding Contacts

- Contacts may be added manually. If a large contact investigation (e.g., school or workplace), contacts can be entered onto the Contact Investigation Upload Form (Excel).
- To obtain the Contact Investigation Upload Form, or for upload support, contact the TB epidemiologist at 503-487-7031.

Manual Entry of Contacts

- 1. Click the **+Contact** button in the header above the contact list.
- 2. Enter demographic and contact info and click **Create Contact**.
- 3. Orpheus will search for matches (see page <u>13</u>).
 - If an exact match appears: click Link this Contact
 - If no match: click Ignore Match, Create New Person

Contact Demographics Tab

Contact Address

If not pre-filled or if address needs correction, click the Address field to open the Address card.

- If the contact resides with the case patient, click Copy Case Address
- Otherwise, enter or update residence address and click Save Changes

Age & Sex

Enter Date of Birth, age, and sex if not pre-filled.

Race & Ethnicity

Select from dropdowns. Do not overwrite dropdown values.

Date of Last Exposure

Important for determining timing of tests and for contact investigation quality assurance.

- Last exposure may be the same as the end of infectious period entered above. If so, this field may be left blank.
- If exposure is ongoing (e.g., household contact to an infectious patient), check "Ongoing exposure".

Contact Risks Tab:

Risk Level

Contact risk is categorized as either **high** or **low** based on the contact's exposure to the case patient and their individual exposure or medical risk factors. Risk level is automatically assigned when contact exposure risk factors are selected.

High Risk of Infection typically indicates that the contact either had significant exposure to the case patient or has a medical condition that increases their likelihood of developing TB disease after infection.

For example:

- A household contact is considered high risk due to prolonged exposure.
- A contact with HIV may have had less exposure but still be at high risk due to increased susceptibility to TB infection and disease.

Note: Contacts initially classified as "Low" may be reclassified as "High" if the investigation reveals a high level of infectiousness or evidence of transmission (e.g., >10% latent infection rate in evaluated contacts or identification of secondary active case patients).

Exposure Risk Factor Definitions

Exposure Risk Factors

Select all that apply:

- Household
 - Contact lives in the same residence as the case patient.
- Age <5
 - Contact is under 5 years old. Young children are more likely to develop TB disease after infection. Start window treatment after chest X-ray rules out active disease. Consult the TB-OHA.
- HIV/AIDS
 - Contact is HIV-positive or has AIDS. Consider window treatment or full LTBI treatment. HIV significantly increases the risk of TB disease progression.

CXR Consistent with Inactive TB

Fibrosis or calcified nodules may indicate prior TB.

Note: A single CXR cannot confirm inactivity. If no prior imaging is available, collect sputum for culture. Once active TB is ruled out, these contacts are high priority for LTBI treatment.

Congregate Setting

Exposure occurred in a shared setting (e.g., school, correctional facility, shelter, nursing home, workplace).

- If you believe the contact is low risk despite exposure in a congregate setting, check "Other Low Risk" and specify the setting.
- Consult the TB-OHA for assistance. Onsite or technical support is available.

Exceeds Exposure Limits

Contact is otherwise healthy (age ≥5) but had significant exposure. Examples include but are not limited to:

- Close friend
- Coworker sharing an office
- Daily carpool member

Reference Exposure Limits (for guidance only):

- ≥ 4 cumulative hours in a small, poorly ventilated space (e.g., car)
- ≥ 8 cumulative hours in a small, well-ventilated space (e.g., apartment)
- ≥ 12 cumulative hours in a large space (e.g., classroom)
- ≥ 50 cumulative hours in a large open area (e.g., auditorium)

Other Medical Risk Factors

Contact has a significant medical condition other than HIV/AIDS. Examples include, but are not limited to:

- Use of immunosuppressive agents (e.g., chemotherapy, transplant medications, TNF-alpha antagonists)
- Prednisone >15 mg/day for >4 weeks
- Silicosis, uncontrolled diabetes, gastrectomy, jejunoileal bypass

Note: Contacts on prednisone or TNF-alpha inhibitors (e.g., Enbrel, Remicade, Humira) should receive prophylactic window treatment. Consider treatment for all contacts with significant medical risks.

Other

Use this category if the contact has a risk factor not listed above. Specify the risk factor in the space provided.

No Risk

Contact has no known exposure or risk factors.

Other Low Risk

Contact had limited exposure and no medical risks. Specify the setting. Example: A student in a school investigation with minimal exposure and no risk factors.

Note: Contact the TB-OHA for help determining risk level if needed.

Contact Evaluation Tab:

Symptomatic

Check "Symptomatic" if the contact is showing signs and symptoms of TB such as:

- Cough
- Fever
- Night sweats
- Hemoptysis
- Weight loss

If the contact is symptomatic, initiate a workup for TB disease.

Note: Consult with TB-OHA if needed.

Prior Positive TST/QFT

Check "Prior Positive TST/QFT" if a prior positive TB screening result is documented.

Note: Contacts with prior positive TST/QFT should, at minimum, be screened for symptoms. A chest X-ray is recommended for contacts with medical risks or symptoms, or if the case patient is highly infectious (e.g., during an outbreak). Consider offering LTBI treatment to prior positives who have not completed therapy.

History of Prior TB or LTBI

If the contact has a history of TB or LTBI and you believe adequate prior treatment was completed, check the "Prior Treatment" box. Enter details, if known, in the Prior Test/Treatment Notes field.

To assess adequacy of prior treatment, consider asking:

- Where were you treated?
- What drugs did you receive? How many different drugs? How many pills each day? What size and color were the pills/capsules?
- How long were you on treatment?
- Did you take medications daily? Every pill?
- Did you miss medication sometimes? How often?
- Did health care workers observe you taking your medications?
- Note: Contacts with prior treatment should, at a minimum, be screened for symptoms. A chest X-ray is recommended for contacts with medical risks or symptoms, or if the case patient is highly infectious (e.g., during an outbreak).
- Note: The "New LTBI" and "Eval Complete" boxes will auto-populate based on values entered in the evaluation tab.

1st Round Test (<8 week test)

Enter the results of the first round TST or IGRA. First round TST or IGRA is performed less than 8 weeks after last known exposure. Use the Last Exposed date on the Demographics tab to calculate. If this field is not populated, use the Infectious Period End date in the case patient information area.

- In general, an IGRA is preferred over a TST
- An IGRA may be either a QuantiFERON (QFT) or T-spot test
- Enter date TST was placed or date blood was drawn for IGRA, result in mm (for TST) or qualitative result for IGRA (Positive, Negative, Indeterminate)

2nd Round Test (=>8 week test)

Enter the results of the second round TST or IGRA. Second round TST or IGRA is performed at 8 weeks or more since first-round test, or at 8 weeks or more after last exposure.

Use this section for:

- Follow-up tests done 8 or more weeks after the first round test
- Single tests administered more than 8 weeks after last exposure

Chest X-ray

If a chest X-ray is completed, enter the date, results and facility.

Contacts Treatment/Final Status Tab:

Complete treatment information for all contacts for whom LTBI treatment has been initiated. This includes:

- Contacts newly diagnosed with LTBI
- Contacts receiving window treatment
- Contacts with documented prior positive TST or IGRA
- Immunocompromised individuals receiving full preventive therapy (regardless of TST or IGRA result)

Treatment Start Date

Enter the date LTBI treatment began.

Treatment Stop Date

Enter the date LTBI treatment ended

Treatment Regimen

Select the treatment regimen from the dropdown menu. Do not overwrite the options. Available choices include:

- INH daily 6 months
- INH daily 9 months
- INH biweekly DOT 6 months
- INH biweekly DOT 9 months
- RIF daily 4 months
- INH + Rifapentine 12 weeks
- Window Prophylaxis
- Other (specify)

If the regimen is not listed, select "Other" and describe it in the "Other Regimen" field.

Final Status

Select the contact's final status after evaluation and/or treatment is complete. Use the dropdown menu and do not overwrite the options:

- Active TB Diagnosed
- Died
- Moved

If the contact resides in or moved out of Oregon, complete and upload to the Docs tab an Interjurisdictional Transfer Notification. Leave the TB Epidemiologist a note. The TB Epidemiologist will forward the IJN to the receiving jurisdiction for follow-up and evaluation. Contact the TB Epidemiologist for additional guidance.

- Refused Treatment
- Lost to Follow-up
- Provider Decision Toxicity
- Provider Decision Other
- Refused Evaluation
- Completed LTBI Treatment

Treatment or Other Comments

Use this text box to document:

- Treatment complications
- Incomplete evaluations
- Explanations for "Provider Decision Other"
- Any other relevant contact-specific notes

Contacts Notes Tab:

Use the Notes tab to create notes specific to a contact. This may include:

- · Details about evaluation findings
- Documentation of attempts to locate or follow up with the contact
- · Reminders for subsequent testing

Note: Do not enter contact-specific notes in the Case Notes tab.

Contacts Links Tab:

The Links tab displays other Orpheus case patient or contact records associated with the current contact's person record.

Contacts Docs Tab:

The contacts Docs tab is a convenient place to upload and store documents related to the specific contact. Documents including Protected Health Information (PHI) are acceptable. Examples include:

- Interjurisdictional Notifications
- Chart notes
- Radiology reports

APPENDIX 1: DATA ENTRY TIMELINE FOR TB CASES AND CONTACTS

	What	When	How	What Else
Se	Case report: Initial confirmed or presumptive*	Open case in Orpheus within 5 business days if: -medication is started for TB disease or - NAAT or culture is MTB positive or - pathology report is consistent with TB	Create case record and complete required data elements in Orpheus (see Case Report and Data Entry Manual)	Attach to Orpheus case record initial lab reports (if not from OSPHL), pathology, and CXR reports
TB Disease Cases	Verification update**	Update Orpheus case record within one week if: - NAAT or culture is MTB positive or - 2 months treatment completed if clinical case	Complete Orpheus data elements required for verification (see Case Report and Data Entry Manual)	Attach to Orpheus case record verification lab reports (if not from OSPHL)
18T	Completion of treatment update	Update Orpheus case record within one week if: -TB medications are stopped or - Lab results are negative for TB and TB disease is ruled out	Complete Orpheus data elements required for closure (see Case Report and Data Entry Manual)	Attach to Orpheus case record final CXR (if indicated and available)
	Initial report	Within 4 weeks or after 1st round test		
Contact Investigation	Update	In 8 weeks or after 2nd round test (include CXR & treatment start data for LTBI)	Complete in Orpheus Data elements for each contact	For assistance with contact data entry, call TB Program at
Co	Completion	After all contacts on treatment for LTBI are completed, treatment is stopped, or contact lost to follow-up		971-673-0160.

^{*}Case Report and Data Entry Manual is located on the TB-OHA website under Program Forms at http://healthoregon.org/tb