RVCT Revision Completion Instructions

For convenience when reviewing RVCT instructions, please refer to the revised RVCT .pdf for the proposed format of the corresponding variable.

RVCT QUESTION LIST

1. **Date Reported**
2. **Date Submitted**
3. **Case Numbers**
4. Reporting Address for Case Counting
5. **Count Status**
6. **Date Counted**
7. **Previous Diagnosis of TB Disease**

8. **Date of Birth**
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19. Smear/Pathology/Cytology of Tissue and Other Body Fluids
20. **Culture of Tissue and Other Body Fluids**
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40. Initial Drug Susceptibility Results
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42. Moved
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44. Reason Therapy Stopped or Never Started
45. **Reason Therapy Extended >12 Months**
46. Type of Outpatient Health Care Provider
47. Directly Observed Therapy (DOT)
48. Final Drug Susceptibility Testing
49. Final Drug Susceptibility Results

Instructions

It is strongly recommended that the RVCT form be completed by a health care provider and maintained in the TB patient's medical record. Data entry may be done by clerical staff; however clerical staff without a strong medical background should not abstract medical information. If the reporting area has their own TB case reporting form and it is used to complete or populate the RVCT variables, the staff should closely review the RVCT variable format and instructions to assure that variables from their form match the RVCT.

The RVCT must be completed for all verified cases of TB that are to be included in the reporting area's annual morbidity count. CDC also recommends the use of RVCT forms for the collection of data on:

1. Transfer TB cases (e.g., TB cases counted in another state or country).
2. TB cases that have completed therapy and recur within 12 months of completing therapy. The pre-recurrence RVCT state case number (Question 3) for such cases should be entered as the "Linking State Case Number" with "Recurrence" as the reason and "Verified Case: Recurrent TB within 12 months" must be selected for the variable, "Count Status" - Question 5.

Note: Throughout this document, the term "state" is used to refer to the reporting jurisdiction, though not all jurisdictions are states.

1 Date Reported

The month-day-year reported is the month, day, and year that a health department (e.g., local, county, state) first suspected that the patient might have TB. When a private health care provider suspects the patient may have TB and notifies the local or county health department, the "date reported" is the date the health department received the report from the private health care provider. If the patient has had a previous diagnosis of tuberculosis, month-day-year reported applies to the current TB episode. If the day is unknown, enter "99" as a default value.

Brief summary of events and sequence for "**Date Reported**", "**Date Submitted**", and "**Date Counted**": Often, an RVCT will initially be created by a local or county health department since it is at this level when a patient is first suspected to have TB and will determine "date reported." When a private health care provider suspects the patient may have TB and notifies the local or county health department, the "date reported" is the date the health department received the report from the private health care provider. The RVCT will then usually be submitted to the reporting area (e.g., state health department), and this date is referred to as the "date submitted." In most reporting areas (e.g., state), the state health department has count authority and reviews the RVCT to determine whether or not to officially count the TB patient as a TB case ("date counted"). However, a few states have granted local or county health departments count authority and in these states, the local or country health departments will determine the "date counted" (see "**Date Submitted**" and "**Date Counted**").

2 Date Submitted

Indicate the date the RVCT form was submitted to or completed by the reporting area (e.g., state health department). If the day is unknown, enter "99" as a default value.

See **"Date Reported"** for a brief summary of events and time sequence for "Date Reported", "Date Submitted", and "Date Counted."

3 Case Numbers

Both the state case number and the city/county case numbers are 15 alphanumeric characters in length. The **state case number** is the official identification number for the case. If additional communication is required about a record between CDC and a reporting area, this number is used to identify the record. The **state case number** is also commonly known as the "RVCT number." The **city/county case number** should also be listed if it exists. Every case reported, whether from a city/county or state surveillance system, must have a unique case number for identification purposes. A **city/county case number** may not be assigned to more than one case during a calendar year. Similarly, a **state case number** may not be assigned to more than one case during a calendar year. However, a single case may be assigned identical city/county and state case numbers.

NOTE:	**Case numbers must not include personal identifiers**. In order to maintain patient confidentiality, do not use names (neither patient nor provider), initials, social security numbers, addresses, phone numbers, or other information that could potentially identify a patient. Case numbers are transferred to CDC, and therefore must not include personal identifying information.

Case Number FORMAT: Case numbers should be assigned as follows:

a. The first four characters are the four-digit year in which the case is reported (e.g., 2005). Year reported is used rather than year counted since there may be a lag between when states or city/county areas first suspected that the patient might have TB. Also, year counted would not apply if Count Status, Question 5, is a noncountable case.
b. The fifth and sixth characters are the two-letter alpha abbreviation of the state or area reporting this case (e.g., CA for California). This abbreviation is also known as the state code.
c. The seventh through fifteenth characters are the locally assigned nine-digit alphanumeric locally assigned RVCT identification number.

For the purposes of linking RVCT forms, up to two RVCT State Case Numbers may be entered on the form under **"Linking State Case Number."** Also enter the **"Reason"** why linking is desired by entering the single-digit code, where **"1"** is for "Recurrence" or "Previous diagnosis of TB"; **"2"** is for "Epidemiologically linked case" such as a source case or contact to another case; and "**3**" is for "Case transferred from another area."

Example 1: If you are completing a "recurrence" RVCT for a TB case who completed therapy but recurred within 12 months after completing therapy, you must enter the RVCT state case number of the pre-recurrence TB case and enter "1" as the reason code, so that both RVCT forms can be linked.

Example 2: If you have identified the source case for the TB case for whom you are filling out the RVCT and the RVCT state case number of the source case is available, enter the RVCT state case number of the source case under "Linking State Case Number", and enter "2" as the reason code.

Example 3: if you are managing a TB case counted by another program area, enter the RVCT state case number from the transferring jurisdiction and enter "3" as the reason code.

4 Reporting Address for Case Counting

Indicate the city, county, and zip code of the patient's residence at the time of diagnosis. Also indicate if the patient lives within the city limits. To the extent possible, the address for case counting should represent the home address (whether permanent or temporary) of the patient. Recommendations for counting reported tuberculosis cases are outlined in the appendix of the "Reported Tuberculosis in the United States" which is published annually by the CDC.

Follow these guidelines within a reporting area:

a. If a person is diagnosed in the community that they consider their home, he or she should be included in the morbidity count for that area, and the city, county, and zip code of residence should be entered in this field.

b. If a newly diagnosed patient is an out-of-area resident who will return to his or her home for treatment, they should be included in the morbidity count of their home area, and the city, county, and zip code of their home area should be entered in this field.

   For example, a patient in a community only for hospitalization and diagnosis is not considered a case in that community, but rather in the area in which he or she resides. Communication between health departments may be necessary to decide which jurisdiction will count the case. Immigrants (i.e., resident aliens living in the U.S.), migrants, U.S. military personnel, and other transient individuals should be counted in the community in which they reside at the time of diagnosis. The city, county, and zip code of residence at the time of diagnosis should be entered in this field. If a foreign visitor is diagnosed with TB in the U.S., is receiving antituberculosis drug therapy, and has been, or plans to remain in the country for at least 90 days, the case should be counted in the area of current residence, and the city, county, and zip code of his or her current residence should be entered in this field. Persons arriving in the U.S. who were diagnosed with TB before arriving here should not be counted as a case of TB in the U.S. Such cases are considered to have occurred in another country, even if therapy is continued or completed in the U.S.

c. Patients who are residents of correctional facilities (e.g., local, state, federal, military) should be counted in the area in which the correctional facility is located, and the city, county and zip code of the facility should be entered in this field.

d. Patients who are residents of long term care facilities at the time of diagnosis should be counted in the area in which the facility is located, and the city, county and zip code of the facility should be entered in this field.

e. Homeless persons or others without any fixed residence should be counted in the community in which they are living at the time of diagnosis (e.g., the locality of the shelter in which the patient was living). Enter the city, county and zip code of that locality.

5 Count Status

In addition to completing an RVCT form for all counted TB cases, reporting areas are recommended to complete an RVCT form for TB patients counted by another reporting area whom they are medically managing or providing resources to (e.g., medications), even though these cases cannot be counted towards their annual morbidity count. Moreover, this variable will allow capture of RVCT information for cases who completed therapy and recurred within 12 months after completing therapy, who are not counted towards the annual morbidity count since the recurrence occurred within 12 months. For CDC guidelines on counting TB cases, please refer to the appendix in "Recommendations for Counting Reported TB Cases", located in the annual TB report published by CDC.

Check **"Count as a TB case"** if the patient was officially counted as a TB case by the person with count authority (usually state health department).

If the patient was not counted as a TB case by the person with count authority, check the most appropriate reason why the verified TB case was not counted.

- For TB cases who were counted by another area within the US, such as a county, or state (e.g., transfer in), select **"Verified Case: Counted by another US area (e.g. county, state)".** Typically, such TB patients have already completed their diagnostic work-up and are on anti-TB medications.

- For TB cases who were counted by another country, select "**Verified Case: TB treatment initiated in another country**." It may be hard to verify if TB patients were counted in another country; typically, such TB patients have already completed their diagnostic work-up and are on anti-TB medications. If "**Verified Case: TB treatment initiated in another country**", enter the country to complete **"*Specify:* _____."**

If completing a new RVCT form for a TB patient who had a recurrence of TB within 12 months after completing therapy, select **"Verified Case: Recurrent TB within 12 months."** By completing a new RVCT form, both RVCT forms can be linked and information can be collected on the recurrence episode. The recurrence RVCT form will not be counted in the morbidity count for that reporting area, but still can be counted when measuring burden for a reporting area. This will also permit analysis of important information on relapsing TB cases. For patients who recur after 12 months of having completed therapy, do not select **"Verified Case: Recurrent TB within 12 months"** since these patients are considered, for surveillance purposes, to have a separate TB episode and should be counted as a new case and a new RVCT form should be completed with "**Count as a TB case**" selected.

6 Date Counted

The **"Date Counted"** is the month, day, and year that the health department responsible for counting TB cases (usually the state health department) verified the case as TB and included it in the official TB case count. If the day is unknown, enter "99" as a default value. Cases for which bacteriologic results are pending or for which verification of disease is questioned for any other reason should be counted only after they are determined to be verified TB cases. This could mean that a case that was reported in one year may not be counted until the following year. For example, if a patient is reported to the health department in December 2005, but bacteriologic or clinical evidence of TB is not available until January 2006, the case should be counted in January 2006 (when TB disease was verified), not in December 2005.

See **"Date Reported"** for a brief summary and time sequence for "Date Reported", "Date Submitted", and "Date Counted."

7 Previous Diagnosis of TB Disease

Check "**Y**es" if the patient has had a previous diagnosis of TB disease. A previous diagnosis of latent TB infection (i.e., LTBI) should not be entered. A patient is considered to have had a previous diagnosis of TB disease if he had verified disease in the past, had completed therapy or was lost to supervision for more than 12 consecutive months, and now has verified disease again. Often, TB disease is confused with latent TB infection (LTBI) and LTBI should not be coded as previous TB disease. Therefore, documentation of the previous episode of TB disease is important. Written documentation of the previous episode of TB diseases is ideal. However, if the TB disease episode occurred years ago, or in another location (e.g., country) obtaining written documentation can be difficult. Therefore, when written documentation is not available, reliable verbal documentation of a previous episode of TB disease is acceptable (e.g., medications taken, length of medication, sputum smear examination results).

- If "**Yes**", provide the year in which the patient's previous episode of TB disease was diagnosed. For example, if the patient was diagnosed with TB disease in 1985, was reported to have completed therapy or was lost to supervision in 1986, and is found to have verified disease again in 2005, enter "1985" in the boxes provided. If the patient had more than one previous episode of TB disease, enter the year of the most recent previous episode. If the patient had a previous episode of TB which was recorded as a TB case for U.S. national surveillance, for the purposes of linking RVCT forms, contact the state in which the patient was counted for the most recent previous diagnosis and enter the most recent previous RVCT state case number for this case under **"Linking State Case Number."** Also enter the **"Reason"** why linking is desired as "Recurrence" or "Previous diagnosis of TB".

Check "**N**o" if the patient has not had a previous diagnosis of TB disease.

8 Date of Birth

Indicate the month, day, and year of birth for the TB patient. For example: 04/26/1968. A complete date of birth is required. Partial dates are acceptable ONLY for patients where date of birth is truly unknown. For example, certain societies or cultures throughout the world do not document the day, month, or sometimes, even the year of birth. In such cases, enter "99" for either the day and/or month, and enter the year of birth. If the month, day, and year of birth are not all known, enter "99/99/9999" on the form.

9 Sex at Birth

Check the appropriate box for the biological sex of the TB patient – "**Male**" or "**Female**".

10 Ethnicity

The answer to this question should be based on the individual's self identity or self reporting. Indicate the ethnicity that the person considers themselves to be – select one.

Check **"Hispanic or Latino"** if the patient considers themselves to be of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin'" can be used in addition to "Hispanic or Latino."

Check **"Not Hispanic or Latino"** if the patient does not consider themselves to be "Hispanic or Latino."

11 Race

The answer to this question should be based on the individual's self identity or self reporting. Patients shall be offered the option of selecting one or more racial designations. Indicate the race that the person considers themselves to be – select one or more.

Check **"American Indian or Alaska Native"** if a person has origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.

Check **"Asian"** if a person has origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

If **"Asian",** complete **"*Specify:* _____."**

Check **"Black or African American"** if a person has origins in any of the black racial groups of Africa.

Check **"Native Hawaiian or Other Pacific Islander"** if a person has origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

If **"Native Hawaiian or Other Pacific Islander,"** complete **"*Specify:* _____."**

Check **"White"** if a person has origins in any of the original peoples of Europe, the Middle East, or North Africa.

12 Country of Birth

Ask the patient in which country they were born and then enter the corresponding country to complete ***"Specify _____".*** . Please follow the important instructions below for defining country of birth:

a. If the patient was born in one of the 50 United States or born abroad of a U.S. citizen parent (e.g., born on a military installation), select "United States" as the country of birth.

b. For this question, U.S. Territories, U.S. Island Areas, and U.S. Outlying Areas (e.g., American Samoa, Federated States of Micronesia, Guam, Republic of the Marshall Islands, Commonwealth of the Northern Mariana Islands, Republic of Palau, Puerto Rico, U.S. Virgin Islands) should be considered as distinct areas and their specific names should be entered.

13 Month-Year Arrived in U.S.

For patients who were **NOT** born in one of the 50 United States or **NOT** born abroad of a U.S. citizen parent, enter the month and year the patient first arrived in the U.S.

For patients born in one of the U.S. Territories, U.S. Island Areas, and U.S. Outlying Areas (e.g., American Samoa, Federated States of Micronesia, Guam, Republic of the Marshall Islands, Commonwealth of the Northern Mariana Islands, Republic of Palau, Puerto Rico, U.S. Virgin Islands), enter the month and year the patient first arrived in the U.S., only if the country of birth is different from the jurisdiction (i.e., U.S. Territories, U.S. Island Areas, and U.S. Outlying Areas) reporting the case to the CDC (e.g., the country of birth is Federated States of Micronesia, but Guam is reporting the case).

If, after arriving in the U.S., the patient frequently travels internationally, then enter the month and year when the patient first arrived in the U.S. If only the year of arrival is known, enter "99" for the month and enter the 4-digit year. For example, if the patient arrived in 1963, but the month cannot be determined, enter "99" for the month and "1963" for the year of arrival. If both the month and year of arrival are not known, enter "99" for the month and "9999" for the year of arrival.

14 Pediatric TB Patients (<15 years old)

To better capture important information about pediatric TB patients (<15 years old), this variable will request information on country of birth for primary guardian(s) of the pediatric case and whether the pediatric TB patient lived outside the U.S. for an uninterrupted period of more than 2 months.

For all pediatric TB patients (<15 years old), please ask:

A. Whether the pediatric TB patient **"lived outside the U.S. for an uninterrupted period of more than 2 months."** For **multiple "lived outside the U.S. for an uninterrupted period of more than 2 months"** episodes, complete the question for up to three most recent countries. For this question, "lived" is defined as the place where a person lives or sleeps most of the time or the place the person considers to be their usual home during the stated time period. Although it may be difficult to determine the exact amount of time that a person lived outside the U.S. for an uninterrupted period, indicate "**Yes**" and the country code(s) if time period is believed to be >= 8 weeks.
   - Check **"Yes"**, if the pediatric TB patient lived outside the U.S. for an uninterrupted period of more than 2 months and enter the countries. If the patient lived in more than one country, enter up to three countries in which the patient lived for more than 2 uninterrupted months most recently.
   - Check **"No"**, if the pediatric TB patient did not live outside the U.S. for an uninterrupted period of more than 2 months.
   - Check **"Unknown"**, if it is unknown whether the pediatric TB patient lived outside the U.S. for an uninterrupted period of more than 2 months.

B. Enter **"country of birth for the primary guardian(s)"** (e.g., mother, father, foster parent, grandparent) of the pediatric TB patient and enter the appropriate countries for up to two parents or primary guardians. Country of birth is defined as:
   - If the person was born in one of the 50 United States or born abroad of a U.S. citizen parent (e.g., born on a military installation), select "United States" as the country of birth.
   - For this question, U.S. Territories, U.S. Island Areas, and U.S. Outlying Areas (e.g., American Samoa, Federated States of Micronesia, Guam, Republic of the Marshall Islands, Commonwealth of the Northern Mariana Islands, Republic of Palau, Puerto Rico, U.S. Virgin Islands) should be considered distinct areas and their specific names should be entered.

15 Status at TB Diagnosis

Check **"Alive"** if the patient was alive at the time of TB diagnosis. Patients whose TB was suspected and who were started on at least two antituberculosis drugs prior to the day of death should be classified as alive at the time of TB diagnosis even though the TB case may not be verified and counted until after death.

Check "**Dead"** if the patient was deceased at the time the investigation of possible TB disease was initiated. Patients who were only on one antituberculosis drug prior to the day of death because TB disease was not suspected, and who were then diagnosed with TB disease after death are classified as dead at the time of TB diagnosis. For example, if a person who was taking isoniazid as preventive therapy for latent TB infection dies, and is found after death to have had TB disease, this person should be classified as **"Dead"** at TB diagnosis.

- If **"Dead"** (e.g., those patients that were classified as "dead" at the time of TB diagnosis), enter the date (month, day, year) that the patient died. For example: 01/17/2005. If the day is unknown, enter '99' on the form (e.g., 01/99/2005).
- If **"Dead"** (e.g., those patients that were classified as **"Dead"** at the time of TB diagnosis) determine whether TB disease was a cause of death (e.g., underlying cause of death, immediate cause of death, a significant condition contributing to death) and check the corresponding box (e.g., **"Yes"**, **"No"**, **"Unknown"**). Ideally, written documentation of the cause of death (e.g., death certificate, autopsy report, medical records) is recommended. If TB is listed on the death certificate as either the immediate cause, an underlying cause, or other significant condition contributing to death, then check **"Yes"** for "If DEAD, was TB a cause of death." However, a reliable verbal source (e.g., a health care provider) will be accepted.

16 Site of TB Disease

NOTE:	If there is evidence that more than one organ or disease site involved, then check all appropriate sites of disease in Question 16 "Site of Disease." If the initial chest radiograph is reported "miliary TB" or as showing a "miliary" or "bilateral micronodular" pattern, indicate this finding on Question 22, "Initial Chest Radiograph or Other Imaging Study."

Check the boxes corresponding to the site(s) of TB disease (select all that apply). **"Lymphatic: Intrathoracic"** includes hilar, bronchial, mediastinal, peritracheal, and other lymph nodes within the thorax.

If the site of TB disease is **"Other"**, enter the anatomic code(s) in the boxes provided (see Appendix V). Up to three **"Other"** anatomic codes can be entered. In Appendix V, the anatomic codes for **"Other"** are marked with an asterisk (*). Select only from those items marked with an asterisk (*). Anatomic codes without an asterisk (*) are parts of organ systems corresponding to Site of TB Disease.

17 Sputum Smear

For the purpose of this question, sputum includes spontaneous and induced sputum. *Do not include* the results of microscopic examination of pulmonary secretions obtained by tracheal suction, bronchoscopy procedures (e.g., bronchial washing, scrapings, biopsies), or gastric aspiration (see Smear/Pathology/Cytology of Tissue and Other Body Fluids – Question 19). Timing of sputum smears for the purpose of this question should be during the diagnostic work-up stage or shortly thereafter. Specimens collected after the patient has been on treatment for a while (e.g., 2-3 weeks) should not be recorded using this variable. If an initial sputum specimen was collected, and the results were unknown and "unknown" was entered as a response to this question, but the results subsequently became known, update this variable with the results.

Check **"Positive"** if several sputum examinations were done, and if any one is positive for acid-fast organisms (i.e., AFB).

Check **"Negative"** if the results of all examinations (or the only examination) were negative.

Check **"Not done"** if a sputum smear examination is known not to have been done.

Check **"U**nknown" if it is not known if a sputum smear examination was performed, or if the results are not known for a reason other than pending results (e.g., result was lost or specimen contaminated, and no other specimens can be obtained).

If the sputum smear was **"Positive"** or **"Negative",** indicate the date (month, day, year) the sputum specimen was collected. If several sputum examinations were done and one or more sputum examinations were **"Positive"** for acid-fast organisms, enter the date the first positive sputum examination was collected. If several sputum examinations were done and all were **"Negative"** for acid-fast organisms, enter the date the first negative sputum examination was collected.

18 Sputum Culture

For the purpose of this question, sputum includes spontaneous and induced sputum. *Do not include* the culture results of pulmonary secretions obtained by tracheal suction, bronchoscopy procedures (e.g., bronchial washing, scrapings, biopsies), or gastric aspiration (see "Culture of Tissue and Other Body Fluids – Question 20). Timing of sputum cultures for the purpose of this question should be during the diagnostic work-up stage or shortly thereafter. Specimens collected after the patient has been on treatment for a while (e.g., 2-3 weeks) should not be recorded using this variable. If an initial sputum specimen was collected, and the results were unknown and "unknown" was entered as a response to this question, but the results subsequently became known, update this variable with the results.

Check **"Positive"** if a sputum culture result was positive for *M. tuberculosis* (*Mycobacterium tuberculosis*) complex. If several sputum cultures were done, check **"Positive"** if any one is positive for *M. tuberculosis* complex.

Check **"Negative"** if the results of all sputum cultures (or the only sputum culture) were negative for *M. tuberculosis* complex.

Check **"Not done"** if a sputum culture is known not to have been done.

Check **"Unknown"** if it is not known if a sputum culture was performed, or if the results are not known for a reason other than pending results (e.g., result was lost or specimen contaminated, and no other specimens can be obtained).

If the sputum culture was "**Positive**" or "**Negative**", indicate the date (month, day, year) the sputum specimen was collected. If several sputum cultures were done and one or more sputum cultures were "Positive" for *M. tuberculosis* complex, enter the date the first positive sputum culture was collected. If several sputum cultures were done and all the sputum cultures were "Negative" for *M. tuberculosis* complex, enter the date the first negative sputum culture was collected. For the first sputum culture reported to be positive for *M. tuberculosis* (*Mycobacterium tuberculosis*) complex, enter "**Date Result Reported"** for the month, day, year the result is reported by the laboratory. This date should be reflected on the laboratory report as the date the report is released or made available.

Select the "**Reporting Laboratory Type"** that best describes the reporting laboratory. **"**Public health laboratory" is defined as any **laboratory** associated with local and state health departments. **"**Commercial laboratory" **is defined as any laboratory** that charges a fee for each specimen processed or test performed. **"**Other" includes hospital laboratories and laboratories associated with federal public health agencies (i.e., Center for Disease Control and Prevention, federal government Veteran's Administration, Indian Health Services (IHS), Tribal Health Department, and Bureau of Prison).

19 Smear/Pathology/Cytology of Tissue and Other Body Fluids

NOTE: For the purpose of this question, tissue and other body fluids does not include sputum. Examples of tissue and other body fluids include tracheal aspirate, bronchial washing or lavage, urine, bone marrow, lymph node, cerebral spinal fluid, lung, or pleura which are collected from various procedures (e.g., bronchoscopy, biopsy, gastric aspiration, pleural fluid aspiration). Results from sputum smear examinations and sputum cultures should be entered using "Sputum Smear" – Question 17 and "Sputum Culture" – Question 18.

Timing of smear or pathologic/cytologic examinations for the purpose of this question should be during the diagnostic work-up stage or shortly thereafter. Specimens collected after the patient has been on treatment for a while (e.g., 2-3 weeks) should not be recorded using this variable. If an initial specimen was collected, and the results were unknown and "unknown" was entered as a response to this question, but the results subsequently became known, update this variable with the results. If there is more than one "positive" smear/pathologic/cytologic specimen, choose the specimen which shows the strongest support for TB disease.

Check **"Positive"** if any tissue or body fluid other than sputum (e.g., tracheal aspirate, bronchial washing, urine, bone marrow, lymph node, cerebral spinal fluid, lung, pleura) collected from procedures (e.g., bronchoscopy, biopsy, gastric aspiration, pleural fluid aspiration) was either:

a. positive for acid-fast organisms (i.e., AFB) during a smear examination, or
b. showed granulomas, granulomatous inflammation, or other pathologic or histologic findings consistent with TB disease during a pathologic/cytologic examination (e.g., such findings would be listed on the pathology or cytology report).

Check **"Negative"** if all smear or pathologic/cytologic examinations of tissue or body fluid were negative for acid-fast organisms (via smear examination) or showed no evidence of granulomas, granulomatous inflammation, or other pathologic or histologic findings consistent with TB disease during a pathologic/cytologic examination (e.g., such findings would be listed on the pathology or cytology report).

For "**Positive**" or "**Negative**" results, enter the following information.

a. the date (month, day, year) the specimen was collected
b. select the appropriate anatomic code from the Anatomic Code list (see Appendix V), and enter the code in the boxes provided

   NOTE: If tissue or body fluid specimens from different anatomic sites were collected, enter the results for appropriate specimen (e.g., specimen providing the strongest support for TB diagnosis).
c. select the type of examination performed *(select all that apply)*.

Check **"Not done"** if such examinations (e.g., smear, pathology/cytology) of tissue or body fluids are known not to have been done.

Check **"Unknown"** if it is not known if such examinations (e.g., smear, pathology/cytology) of tissue or body fluids were performed or if the results are not known for a reason other than pending results (e.g. result was lost or specimen contaminated, and no other specimens can be obtained).

20 Culture of Tissue and Other Body Fluids

NOTE: For the purpose of this question, tissue and other body fluids does not include sputum. Examples of tissue and other body fluids include tracheal aspirate, bronchial washing or lavage, urine, bone marrow, lymph node, cerebral spinal fluid, lung, or pleura which are collected from various procedures (e.g., bronchoscopy, biopsy, gastric aspiration, pleural fluid aspiration). Results from sputum smear examinations and sputum cultures should be entered using questions "Sputum Smear" – Question 17 and "Sputum Culture" – Question 18.

Timing of cultures for the purpose of this question should be during the diagnostic work-up stage or shortly thereafter. Specimens collected after the patient has been on treatment for a while (e.g., 2-3 weeks) should not be recorded using this variable. If an initial specimen was collected, and the results were unknown and "unknown" was entered as a response to this question, but the results subsequently became known, update this variable with the results. If there is more than one "positive" culture of tissue and other body fluids specimen, choose the specimen which shows the strongest support for TB disease.

Check **"Positive"** if any tissue or body fluid, other than sputum (e.g., tracheal aspirate, bronchial washing, urine, bone marrow, lymph node, cerebral spinal fluid, lung, pleura) collected from procedures (e.g., bronchoscopy, biopsy, gastric aspiration, pleural fluid aspiration) was positive for *M. tuberculosis* complex.

Check **"Negative"** if all tissue or fluid cultures, other than sputum cultures, were negative for *M. tuberculosis* complex and enter:

.

For "**Positive**" or "**Negative**" results, enter the following information.

a. the date (month, day, year) the specimen was collected
b. select the appropriate anatomic code from the Anatomic Code list (see Appendix V), and enter the code in the boxes provided

NOTE: If tissue or body fluid specimens from different anatomic sites were collected, enter the results for appropriate specimen (e.g., specimen providing the strongest support for TB diagnosis).

Check **"Not done"** if tissue or body fluid cultures are known not to have been done.

Check **"Unknown"** if it is not known if tissue or body fluid cultures were performed or if the results are not known for a reason other than pending results (e.g., result was lost or specimen contaminated, and no other specimens can be obtained).

For the first sputum culture reported to be positive for *M. tuberculosis* (*Mycobacterium tuberculosis*) complex, enter "**Date Result Reported"** for the month, day, year the result is reported by the laboratory. This date should be reflected on the laboratory report as the date the report is released or made available. Select the "**Reporting Laboratory Type"** that best describes the reporting laboratory. **"**Public health laboratory" is defined as any laboratories associated with local and state health departments. **"**Commercial laboratory" **is defined as any laboratory** that charges a fee for each specimen processed or test performed. **"**Other" includes hospital laboratories and laboratories associated with federal public health agencies (i.e., Center for Disease Control and Prevention, federal government Veteran's Administration, Indian Health Services (IHS), Tribal Health Department, and Bureau of Prison).

21 Nucleic Acid Amplification Test

For the purpose of this question, results from a nucleic acid amplification (NAA) test will be accepted only if the test is approved by the Food and Drug Administration (FDA).

Check **"Positive"**, if the NAA test was positive for *M. tuberculosis* complex. If several NAA tests were done and one or more were **"Positive"**, enter the results for the first positive NAA test.
Check **"Negative"**, if all NAA test were negative for *M. tuberculosis* complex.
Check **"Indeterminate"**, if the NAA test yielded indeterminate results (e.g., inconclusive, inhibitory).
Check **"Not Done"**, if an NAA test was not performed.
Check **"Unknown"**, if it was not known whether an NAA test was performed.

If the NAA test is **"Positive"** or **"Negative"** using currently approved practice guidelines enter,

a. the date (month, day, year) the specimen was collected
b. the type of specimen on which NAA testing was performed. **If it was a sputum specimen, check** "Sputum." **If it was not a sputum specimen,** select the appropriate anatomic code from the Anatomic Code list (see Appendix V), and enter the code in the boxes provided. If the specimen type was unknown, leave the boxes blank.

For the first NAA test reported to be positive for *M. tuberculosis* (*Mycobacterium tuberculosis*) complex, enter "**Date Result Reported"** for the month, day, year the result is reported by the laboratory. This date should be reflected on the laboratory report as the date the report is released or made available.

Select the "**Reporting Laboratory Type"** that best describes the reporting laboratory. **"**Public health laboratory" is defined as any laboratory associated with local and state health departments. **"**Commercial laboratory" **is defined as any laboratory** that charges a fee for each specimen processed or test performed. **"**Other" includes hospital laboratories and laboratories associated with federal public health agencies (i.e., Center for Disease Control and Prevention, federal government Veteran's Administration, Indian Health Services (IHS), Tribal Health Department, and Bureau of Prison).

22 Initial Chest Radiograph and Other Chest Imaging Study

This variable collects information on both initial chest radiograph and chest CT scan, if conducted.

A. Initial Chest Radiograph

Indicate the result of the initial chest radiograph(s) taken during the diagnostic evaluation for tuberculosis as either "**Normal**", "**Abnormal**", "**Not done**", or "**Unknown**."

Check **"Normal"** if the initial chest radiograph(s) showed no abnormalities consistent with TB and was normal.

Check **"Abnormal"**, if the initial chest radiograph(s) showed any abnormalities (e.g., hilar adenopathy, infiltrate(s), cavity, scarring) associated with TB and,

a. indicate if any of the initial chest radiograph(s) obtained showed evidence of one or more cavities by checking **"Yes"**, **"No"**, or **"Unknown"**,
b. indicate if any of the initial chest radiograph(s) obtained showed evidence of "miliary" disease (e.g., "miliary" TB or "miliary or "bilateral micronodular" pattern) by checking **"Yes"**, **"No"**, or **"Unknown."**

Check **"Not done"** if an initial chest radiograph is known not to have been done.

Check **"Unknown"** if it is not know if an initial chest radiograph was done, or if the result of the initial chest radiograph is unknown.

B. Initial Chest CT Scan or Other Chest Imaging Study

Indicate the result of the initial chest CT scan or other chest imaging study taken during the diagnostic evaluation for tuberculosis as either "**Normal**", "**Abnormal**", "**Not done**", or "**Unknown**."

Check **"Normal"** if the initial chest CT scan or other chest imaging study showed no abnormalities consistent with TB and was normal.

Check **"Abnormal"**, if the initial chest CT scan or other chest imaging study showed any abnormalities (e.g., hilar adenopathy, infiltrate(s), cavity, scarring) associated with TB and,

c. indicate if any of the initial chest CT scan obtained showed evidence of one or more cavities by checking **"Yes"**, **"No"**, or **"Unknown"**,
d. indicate if any of the initial chest CT scan obtained showed evidence of "miliary" disease (e.g., "miliary" TB or "miliary or "bilateral micronodular" pattern) by checking **"Yes"**, **"No"**, or **"Unknown."**

Check **"Not done"** if an initial chest CT scan or other chest imaging study is known not to have been done.

Check **"Unknown"** if it is not know if an initial chest CT scan or other chest imaging study was done, or if the result of the initial chest CT scan is unknown.

23 Tuberculin (Mantoux) Skin Test at Diagnosis

Indicate the result of the Mantoux (tuberculin, PPD, 5TU) test performed during the diagnostic TB disease evaluation which follows currently accepted guidelines (Appendix IX)

NOTE:	If skin testing was not performed during the current diagnostic evaluation because the patient has a history of a past ***positive*** tuberculin skin test, **AND** the previous positive test is documented in the medical record, the previous positive test result may be reported in this field. Patient self-report of a previous positive PPD is not acceptable. A history of a previous ***negative*** tuberculin skin test, whether documented or not, and a patient self-report of a negative previous or current skin test are also not acceptable.

Check **"Positive"** if the patient is probably infected with *M. tuberculosis* and meets the criteria for a positive tuberculin skin test (see Appendix IX).
Check **"Negative"** if the tuberculin skin test did not meet current criteria for a positive test and was negative, as defined in Appendix IX.
Check **"Not done"** if the tuberculin skin test (TST) was not performed or if a patient states he/she had a positive TST in the past and it cannot be documented, and now the patient refuses to have a new TST placed.
Check **"Unknown"** if it is not known whether the tuberculin skin test was performed, or if the results are not known.

For **"Positive"** or **"Negative"** tuberculin skin tests (TST), indicate:

1) the **"Date Tuberculin Skin Test (TST) Placed."** The complete date (month, day, year) should be entered. However, if the "day" or "month" portion of the date is unknown, "99" may be entered in the "day" or "month" field.
2) the **"Millimeters (mm) of Induration"** in the boxes provided. If the available skin test result indicates only that the result was "positive" or "negative," but does not give the millimeters of induration, indicate whether the test is recorded as "positive" or "negative" and code the millimeters of induration as "99."

24 Interferon Gamma Release Assay for *Mycobacterium tuberculosis* at Diagnosis

Interferon gamma release assays (IGRA) are blood tests for detecting *Mycobacterium tuberculosis* infection.[1] For this variable, indicate the result of an IGRA test performed during the diagnostic TB disease evaluation.

Check **"Positive"** if any IGRA test result was interpreted as *M. tuberculosis* infection is likely..

Check **"Negative"** if all IGRA test results were interpreted as *M. tuberculosis* infection is unlikely.
Check **"Indeterminate"** if the IGRA test results could not be determined to be positive or negative.
Check **"Not done"** if interferon gamma release assay for *M. tuberculosis* was not performed.

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[1]Surveillance appendices referred to in this instructions document include:

Appendix SUR IX
Criteria for a Positive Tuberculin Skin Test

Please refer to the ATS/CDC Statement entitled "Targeted Tuberculin Skin Testing and Treatment of Latent TB Infection," available at http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf. Table 7 presents criteria for tuberculin positivity, by risk group.

Appendix SUR V
Anatomic Codes

Note: Only codes marked with an asterisk (*) should be used when a site of disease is **Other.**

Dermal System

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

Hematopoietic System

04* Bone marrow
05* Spleen
06* Blood

Lymphatic System

07 Lymph node

Musculoskeletal System

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

Respiratory System

18* Nose
19* Accessory Sinus

Check **"Unknown"** if it is not known whether interferon gamma release assay for *M. tuberculosis* was performed, or if the results are not known.

If any interferon gamma release assay for *M. tuberculosis* was conducted indicate:

1) the date the blood sample was collected (**"Date Collected"**). The complete date (month, day, year) should be entered. However, if the "day" portion of the date is unknown, "99" may be entered in the "day" field. If more than one test was conducted, and one or more test results were "Positive," enter the date the first positive IGRA blood sample was collected. If one or more IGRA tests were done and all the results were negative, enter the date the first negative IGRA blood sample was collected. If all test results were indeterminate, enter the date the first indeterminate result was reported.

20* Nasopharynx
21* Epiglottis and larynx
22* Trachea
23 Bronchus
24 Bronchiole
25 Lung
26 Pleura
27 Upper respiratory fluids
28 Bronchial fluid
29 Pleural fluid

Cardiovascular System

30* Pericardium
31* Heart
32* Cardiac valve
33 Pericardial fluid
34* Blood vessel

Gastrointestinal System

35* Mouth
36* Lip
37* Tongue
38* Tooth, gum and supporting structures of the tooth
39* Salivary gland
40* Liver
41* Gallbladder
42* Extrahepatic bile duct
43* Pancreas
44 Saliva
45 Bile and pancreatic fluid
46* Pharynx, oropharynx, and hypopharynx
47* Tonsils and adenoids
48* Esophagus
49* Stomach
50* Small intestine - duodenum
51* Small intestine - jejunum & ileum
52* Appendix
53* Colon
54* Rectum
55* Anus

2) specify the type of blood test performed ("***Specify*** _____"). If more than one test was conducted, list the test type corresponding to the blood sample result entered.

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56 Gastric aspirate
57 Gastrointestinal contents (feces)
58 Omentum and peritoneum
59 Peritoneal fluid

Urogenital System

60 Kidney
61 Renal pelvis
62 Ureter
63 Urinary bladder
64 Urethra
65 Penis
66 Prostrate and seminal vesicle
67 Testis
68 Epididymis, vas deferens, spermatic cord and scrotum
69 Urine
70 Male genital fluids
71 Vulva, labia, clitoris, and Bartholin's gland
72 Vagina
73 Uterus
74 Cervix
75 Endometrium
76 Myometrium
77 Fallopian tube, broad ligament, parametrium, and parovarian region
78 Ovary
79 Female genital fluids

Fetal Structures

80* Placenta, umbilical cord, and implantation site
81* Fetus and embryo

Endocrine System

82* Pituitary gland
83* Adrenal gland
84* Thyroid or parathyroid gland(s)
85* Thymus

Neurological System

86 CSF (Cerebral spinal fluid)
87 Meninges, dural sinus, choroid plexus
88* Brain
89* Spinal cord

25 Primary Reason Evaluated for TB Disease

Indicate the single primary or initial reason why the TB patient was evaluated for TB disease (*select one choice only*). The definition of "primary or initial" for the purpose of this question is the situation or reason that led to the initial suspicion that the patient may have TB disease. If a TB patient was referred, but the reason is unknown, an attempt should be made to identify that reason.

Check **"TB Symptoms"**, if the patient was evaluated for TB disease due to signs and symptoms consistent with TB (e.g., prolonged or persistent cough, fever, lymphadenopathy, night sweats, weight loss). For example, if a TB patient seeks medical care due to TB symptoms, then "TB symptoms" should be the primary reason the TB patient was evaluated for TB disease. If however, a TB patient was initially encountered via a contact investigation, and during the contact investigation the TB patient was also noted to have TB symptoms, "contact investigation" should be chosen as the primary reason the TB patient was evaluated for TB disease. Please refer to the additional examples described below.

Check **"Abnormal Chest Radiograph"**, if the patient had an incidental chest radiograph consistent with TB disease. The reason for taking the chest radiograph should be independent of the other choices listed in the question and should not have been done to rule out TB disease. For example, if the chest radiograph was taken as a result of a workup for TB disease due to a positive tuberculin skin test obtained during targeted testing, select "targeted testing." However, if a chest radiograph was taken as part of preoperative testing, where there was no suspicion of TB disease, then select "abnormal chest radiograph."

Check **"Contact Investigation"**, if the patient was diagnosed with TB disease as a result of a contact investigation or source case finding.

Check **"Targeted Testing"**, if the patient was evaluated for TB disease due to a positive tuberculin skin test or positive interferon gamma release assay administered because the patient was specifically considered at high risk for TB (e.g., persons from areas of the world with high rates of TB)[2] or as part of a targeted testing screening program. For the purpose of this question, targeted testing should not be selected if another more appropriate reason exists, such as contact investigation, immigration medical examination, or employment/ administrative testing, or health care worker status– see other choices.

Check **"Health Care Worker"** if the patient was evaluated for TB disease due to a positive tuberculin skin test administered because the patient was a health care worker. "Health care worker" refers to all paid and unpaid persons working in healthcare settings who have the potential for exposure to *M. tuberculosis*. These may include but are not limited to physicians, nurses, aides, dental workers, technicians, staff in laboratories and morgues, emergency medical personnel, students, part-time staff, temporary and contract staff, and persons not involved directly in patient care but potentially at risk for occupational exposure (e.g., volunteers, outreach workers, dietary, housekeeping, maintenance, clerical, and janitorial staff). Also included are persons who deliver health care in the community (e.g., public health nurse, visiting nurse, outreach worker).

90* Cranial, spinal and peripheral nerve
91* Eye and ear appendages
92* Ear and mastoid cells

Other

93 Pus
94* Other
95 Multiple Sites
99 Unknown

[2]

Check **"Employment/Administrative Testing"**, if the patient was diagnosed with TB disease during a routine employment physical examination, employment tuberculin skin testing requirement, or primary or secondary school program for routine tuberculin skin testing. This category reflects an administrative requirement (e.g., a tuberculin skin testing program applied to all 5th graders in a school or to all job applicants) rather than targeted testing of a select group of individuals considered at high risk. If skin testing was performed because the individual was considered at high risk, check "Targeted testing" or other more appropriate category such as "Health care worker." If employment was health care related, check "Health care worker" rather than "Employment/administrative testing."

Check **"Immigration Medical Exam"**, if the patient underwent a medical examination as part of the immigration application process and was found to have TB disease. A medical examination is mandatory for specific persons seeking admission to the U.S. (e.g., immigrants, refugees, asylees). These medical examinations may occur overseas or in the U.S. depending on the situation. In addition, some persons applying for nonimmigrant visas or special status (e.g., parolees) for temporary admission to the U.S. may be required to have a medical examination.

Check **"Incidental Lab Result"**, if incidental specimen is positive for acid fast bacilli (AFB) or an incidental culture is positive for *Mycobacterium tuberculosis* (e.g., when the specimen was tested for AFB or cultured for TB without suspicion of TB disease or when TB disease was not considered a possible diagnosis, such as during a bronchoscopy or autopsy, organ donation, hospitalization or analysis for other disease].

Check **"Unknown"** if the reason why the TB patient was evaluated for TB disease is unknown. This includes patients who are referrals and the reason for referral is unknown.

26 HIV Status at Time of Diagnosis

CDC recommends that **ALL** TB cases receive HIV counseling, testing, and referral at the time of TB diagnostic evaluation or TB diagnosis. Refer to the CDC public health surveillance definition for HIV infection.

HIV status is **"Negative"** if the patient has had a documented negative HIV test at the time of TB diagnostic evaluation or at TB diagnosis. Undocumented patient history that an HIV test result was negative is not acceptable. Such patients should be offered the opportunity to be tested for HIV. In addition, if a patient has had a negative test in the past, regardless of when the HIV test was performed, the patient should be offered HIV counseling and testing at the time of TB diagnostic evaluation or TB diagnosis. If the patient had received HIV counseling and testing a short period before the TB diagnostic evaluation or TB diagnosis (e.g., a few months) and the documented results were negative for HIV infection, and the patient has absolutely no risk for HIV, then these HIV test results may be used for this question. The length of time prior to TB diagnosis for which a negative HIV test result may be accepted should be based on clinical judgment of patient risk, not to exceed one year.

HIV status is **"Positive"** if one of the following is applicable:

1. the patient is tested for HIV and the laboratory result is interpreted as positive according to published criteria.[3]
2. the patient has a documented medical history of a previous positive HIV test, or a documented previous diagnosis of HIV infection or AIDS.

If **"Positive"**, list the **"State HIV/AIDS Patient Number"** and/or **"City/County HIV/AIDS Patient Number."** HIV/AIDS Patient Numbers can be obtained from the state or local HIV/AIDS surveillance program.

HIV status is **"Indeterminate"** if the patient has had a documented indeterminate HIV test at the time of TB diagnostic evaluation or TB diagnosis. Undocumented patient history is not acceptable.

HIV status is **"Refused"** if the patient was offered the test at the time of the TB diagnostic evaluation or TB diagnosis, but declined to be tested.

HIV status is **"Not offered"** if the patient was not offered the test at the time of the TB diagnostic evaluation or TB diagnosis.

HIV status is **"Test done, results unknown"** if the patient had a HIV test at the time of the TB diagnostic evaluation or TB diagnosis and the results are not known to the TB program.

HIV status is **"Unknown"** if it is not known if the patient has had an HIV test, was ever offered a test, or was referred for HIV counseling and testing (e.g., anonymous testing center, private testing center), but it is unknown whether the HIV counseling and testing was done.

3

27 Homeless Within Past Year

Check **"No"** if the patient was not homeless during the 12 months prior to the time when the TB diagnostic evaluation was performed.

Check **"Yes"** if the patient was homeless at any time during the 12 months prior to the time when the TB diagnostic evaluation was performed.

Check "**Unknown**" if it is not known whether the patient was homeless during the 12 months prior to the time when the TB diagnostic evaluation was performed.

A **homeless** person may be defined as:

1. An individual who lacks a fixed, regular, and adequate nighttime residence; and
2. An individual who has a primary nighttime residence that is:
    a. A supervised publicly or privately operated shelter designed to provide temporary living accommodations, including welfare hotels, congregate shelters, and transitional housing for the mentally ill; or
    b. An institution that provides a temporary residence for individuals intended to be institutionalized; or
    c. A public or private place not designated for, or ordinarily used as, a regular sleeping accommodation for human beings.

A **homeless** person may also be defined as a person who has no home (e.g., is not paying rent, does not own a home, and is not steadily living with relatives or friends). Another definition is a person who lacks customary and regular access to a conventional dwelling or residence. Included as homeless are persons who live on streets or in nonresidential buildings. Also included are residents of homeless shelters, shelters for battered women, welfare hotels, and single room occupancy (SRO) hotels. In the rural setting, where there are usually few shelters, a homeless person often will live on the street or with relatives in substandard housing. Being homeless does not refer to a person who is imprisoned or in a correctional facility. There are many definitions for homeless (National Coalition for the Homeless).

28 Resident of Correctional Facility at Time of Diagnosis

NOTE:	Any questions regarding classification of a specific correctional facility as federal, state, local, juvenile, or other should be referred to the department of corrections within the state.

Check **"No"** if the patient was not an inmate when the TB diagnostic evaluation was performed.

Check **"Unknown"** if it is not known if the patient was an inmate when the TB diagnostic evaluation was performed.

Check **"Yes"** if the patient was an inmate of a correctional facility at the time when the TB diagnostic evaluation was performed.

If **"Yes"**, indicate the type of facility [4] (*select one*). If the TB patient was a resident of more than one facility when the diagnostic evaluation was performed, select the facility where the majority of the TB diagnostic evaluation was performed.

- A **"Federal Prison"** is a confinement facility administered by a federal agency. For the purpose of this question, privately operated federal correctional facilities are included in "federal prison."
- A **"State Prison"** is a confinement facility administered by a state agency. For the purpose of this question, privately operated state correctional facilities are included in "state prison."
- A **"Local Jail"** is a confinement facility usually administered by a local law enforcement agency, intended for adults but sometimes also containing juveniles, which holds persons detained pending adjudication and/or persons committed after adjudication for sentences of usually a year or less. Temporary holding facilities, or lockups, that do not hold persons after being formally charged in court are excluded. Both city and county jails are included in this category. Federal and state prisoners who are boarded at local jails should be reported as residents of the local jail. For the purpose of this question, privately operated local correctional facilities are included in "local jail."
- A **"Juvenile Correctional Facility"**[5] is a public or private residential facility, including juvenile detention centers, reception and diagnostic centers, ranches, camps, farms, boot camp, residential treatment centers, and halfway houses or group homes. The juveniles served by these facilities include those charged or adjudicated as delinquents; non-delinquent/non-criminal offender (e.g., runaways, truants, incorrigibles, curfew violators); and those committed or detained for treatment of abuse, dependency, neglect, or other reasons. Juveniles who are boarded at federal or state prisons or local jails should be reported as residents of the sites at which they are boarded.
- **"Other Correctional Facility"** includes ICE Detention Centers, Indian reservation facilities (e.g., tribal jails), military stockades and jails, federal Park Police facilities, police lockups (temporary-holding facilities for persons who have not been formally charged in court), or other correctional facilities that are not included in the other choices and is not "Unknown."
- **"Unknown"** if the patient was an inmate when the TB diagnostic evaluation was performed, but the type of correctional facility is not known.

If "**Y**es", indicate ("**Yes**" or "**No**") whether the patient was under the custody of Immigration and Customs Enforcement (ICE) at the time of diagnosis. Persons in ICE custody can be housed in stand alone ICE Detention Centers or other correctional facilities (e.g., federal or state prison, local jail) when a stand-alone ICE Detention Center is not available.

4

5

29 Resident of Long-Term Care Facility at Time of Diagnosis

NOTE:	The state licensing agency for long-term care facilities can assist in determining under which of these categories a facility is classified.

Check **"No"** if the patient was not a resident of a long-term care facility when the TB diagnostic evaluation was performed.

Check **"Unknown"** if it is not known if the patient was a resident of a long-term care facility when the TB diagnostic evaluation was performed.

Check **"Yes"** if the patient was a resident of a long-term care facility at the time the TB diagnostic evaluation was performed.

If **"Yes"**, indicate the type of facility (*select one*). If the TB patient was a resident of more than one facility when the diagnostic evaluation was performed, select the facility where the majority of the TB diagnostic evaluation was performed.

- A **"Nursing Home"** is defined as a freestanding facility having 3 or more beds that provides nursing care services (e.g., nursing or medical care and/or supervision over medications that may be self-administered). Facilities may be certified by Medicare or Medicaid, or not certified but licensed by the State as a nursing home (e.g., skilled nursing facility, intermediate care facility, nursing care unit of a retirement center).
- A **"Hospital-based Facility"** is defined as a nursing home that is a distinct unit of hospital, with 3 or more beds, that is either physically attached or if not attached, managed by a hospital. Facilities may be certified by Medicare or Medicaid, or licensed by the State.
- A **"Residential Facility"** having 3 or more beds is classified as a residential facility (e.g., congregate residential setting) if it meets both of the following criteria: 1) was not classified as a nursing home or hospital-based facility as described above, and 2) provides personal care or supervision to its residents, not nursing care services, in addition to room and board (e.g., help with bathing, dressing, eating, walking, shopping). Included under residential facilities are assisted living facilities, homes for mentally retarded or developmentally disabled persons, board and care homes (e.g., residential care homes, group homes, homes for the aged, family care homes, adult foster care homes, personal care homes, adult congregate living facilities, residential community care facilities, domiciliary care homes).
- A **"Mental Health Residential Facility"** is defined as a mental health residential facility that provides 24-hour care in a hospital or residential treatment or supportive setting. This includes state and local mental hospitals, private psychiatric hospitals, non-federal general hospitals with separate psychiatric services, Department of Veterans Affairs (VA) medical centers, residential treatment centers (RTC's) for emotionally disturbed children, and multi-service mental health organizations with residential treatment programs. *Excluded* are other federal psychiatric facilities, such as those of the Department of Defense, Bureau of Prisons, Public Health Service, and Indian Health Service. Also excluded are Indian reservation facilities that are not federal.
- A **"Alcohol or Drug Treatment Facility"** includes only long-term rehabilitation/residential facilities designated for treatment of 30 days or longer. *Excluded* are all ambulatory or outpatient facilities, detoxification units, and facilities designated for less than 30 days of treatment. The state alcohol and drug treatment agency can assist in determining if a facility is considered residential. The National Survey of Substance Abuse Treatment Services (N-SSATS) and the Substance Abuse and Mental Health Services Administration (SAMHSA)[6] are useful references.
- **"Other Long-term Care Facility"** includes facilities not mentioned above that are designated for treatment of 30 days or longer and is not "Unknown."
- **"Unknown"** if the patient was a resident of a long-term care facility, but the type of facility is unknown.

[6]

30 Primary Occupation within the Past Year

Within the past 12 months from the diagnostic TB evaluation, select the primary occupation of the patient (*select one*). If more than one occupation options is applicable to the patient, choose the occupation which the patient performed for the longest period of time within the past 12 months (i.e. the patient's primary occupation). For example, if the patient was a health care worker and a student (e.g. taking night classes), then the patient's primary occupation would be classified as "**Health Care Worker**."

Check **"Health Care Worker"** if the patient was an all-paid or unpaid person working in healthcare settings with potential for exposure to *M. tuberculosis*. These may include but are not limited to physicians, nurses, aides, dental workers, technicians, staff in laboratories and morgues, emergency medical personnel, students, part-time staff, temporary and contract staff, and persons not involved directly in patient care but potentially at risk for occupational exposure (e.g., volunteers, outreach workers, dietary, housekeeping, maintenance, clerical, and janitorial staff). Also included are persons who deliver health care in the community (e.g., public health nurse, visiting nurse, outreach worker).

Check **"Correctional Facility Employee"** if the patient was any person who has worked in a correctional facility. The facility may be a federal or state prison, local jail, juvenile correctional facility, ICE (Detention Center, or other correctional facility (see correctional facility, Question 28).

Check **"Migrant/Seasonal Worker"** if the patient was any individual who is required to be absent from a permanent place of residence for the purpose of seeking employment or who may vary their employment for the purpose of remaining employed while maintaining a permanent place of residence [e.g., migratory agricultural worker, seasonal agricultural worker, migrant factory worker, migrant construction worker, migrant service industry worker, migrant sporting worker (e.g., horse racing, dog racing)].

Check **"Other Occupation"** if the patient was any person who has been regularly employed for pay or income at any occupation that is not included in the above choices within the 12 months before the TB diagnostic evaluation.

Check "**Retired**" if the patient was any person who was retired within the 12 months before the TB diagnostic evaluation was performed.

Check **"Unemployed"** if the patient was not employed during the past 12 months prior to the diagnostic TB evaluation. This should not include persons who are ineligible for employment such as infants, children, students, housewives, retirees, and persons receiving permanent disability benefits or persons who were institutionalized - such individuals should be included in the appropriate occupation option such as "**Retired**" or "**Not Eligible for Employment**". "**Unemployed**" should be checked if the person was unemployed for the majority of the prior 12 month period; shorter time frames, such as 1 week of unemployment in the past 12 months such not be coded as "Unemployed."

Check "**Not Eligible for Employment**" **"** if the patient was not employed for reasons other than unemployment within the 12 months before the TB diagnostic evaluation, such as infants, children, students, homemakers (e.g., housewife, househusband), and persons receiving permanent disability benefits or persons who were institutionalized.

Check **"Unknown"** if the employment status during the 12 months prior to the diagnostic TB evaluation of the patient was unknown.

31 Injecting Drug Use Within the Past Year

Check **"No"** if the patient has not injected drugs within the past 12 months.

Check **"Yes"** if it is known that the patient injected drugs within the past 12 months.

Check **"Unknown"** if it is not known if the patient injected drugs within the past 12 months.

The purpose for collecting this information is to assess the patient's ability to adhere to antituberculosis drug therapy. The intent of this question is not to require a detailed systematic interview of each patient, but to identify those patients whose drug use might interfere with their ability to complete antituberculosis drug therapy. Use of medically unsupervised injecting drugs within the past year should be sought as an indicator of recent activity (e.g., when did the patient last inject drugs). If, during the course of TB treatment, information is obtained concerning this variable, please update this variable.

Medical documentation or other indices of a history of enrollment in a drug treatment program (e.g., methadone detoxification, methadone maintenance, outpatient drug free, residential or inpatient, halfway house, prison or jail treatment, narcotics anonymous, cocaine anonymous, or other self help), medical or laboratory documentation of injecting drug use (e.g., urine testing, if done), or physical evidence (e.g., needle tracks) may be useful in answering this question. Since the patient interview for injecting drug use is often negative initially, it may be necessary to inquire of the patient at multiple visits.

Injecting drug use involves the use of hypodermic needles and syringes for injection of drugs not prescribed by a health care provider. Route of administration may be intravenous, subcutaneous (e.g., skin popping), or intramuscular. Drugs injected may include heroin or other opiates (e.g., Demerol, Dilaudid, Morphine, opium), cocaine, heroin and cocaine (e.g., speedball), methamphetamines, amphetamines or other stimulants (e.g., Ritalin), phencyclidine (e.g., PCP, Angel Dust), lysergic acid diethylamide (e.g., LSD) or other hallucinogens, barbiturates, steroids or other hormones, Fentanyl, MDMA (e.g., Ecstasy), other drugs or unknown drugs.

32 Non-injecting Drug Use Within the Past Year

Check **"No"** if the patient did not use non-injecting drugs within the past 12 months.

Check **"Yes"** if it is known that the patient used non-injecting drugs within the past 12 months.

Check **"Unknown"** if it is not known whether the patient used non-injecting drugs within the past 12 months.

The purpose for collecting this information is to assess the patient's ability to adhere to antituberculosis drug therapy. The intent of this question is not to require a detailed systematic interview of each patient but to identify those patients whose drug use might interfere with their ability to complete antituberculosis drug therapy. Use of non-injecting drugs or illicit drugs within the past year should be sought as an indicator of recent activity (e.g., when did the patient last use non-injecting drugs). If, during the course of TB treatment, information is obtained concerning this variable, please update this variable.

A history of enrollment in a drug treatment program (e.g., outpatient drug free, residential or inpatient, halfway house, prison or jail treatment, cocaine anonymous, or other self help), as well as medical or laboratory documentation of drug use (e.g., urine toxicology), may be useful in answering this question. Since the patient interview for non-injecting drug use is often negative initially, it may be necessary to inquire of the patient at multiple visits.

NOTE:	Alcohol is *not* included as a drug in this question (see "Excess Alcohol Use within Past Year" - Question 33).

Non-injecting drug use involves the use of licensed or prescription drugs or illegal drugs that were not injected and were not prescribed for the patient by a health care provider. The drugs may be ingested, inhaled, sniffed, or smoked. Non-injected drugs may include: heroin or other opiates (e.g., Demerol, Percocet, Codeine, Dilaudid, MS Contin, non-prescription methadone), cocaine (e.g., snorting), crack (e.g., smoking cocaine), ingested amphetamines (e.g., speed, uppers, bennies), Xanax, Ativan, Valium or other benzodiazepams, phencyclidine (e.g., PCP), ketamine, LSD, or other hallucinogens, barbiturates, marijuana (e.g., pot, weed, grass, reefers), hashish, THC, inhalants (e.g., nitrous oxide [whippets], poppers, rush, huff, gasoline, spray paint, butane), steroids, other drugs, or unknown drugs.

33 Excess Alcohol Use Within the Past Year

Check **"No"** if the patient has not used alcohol to excess within the past 12 months.

Check **"Yes"** if the patient has used alcohol to excess within the past 12 months.

Check "**U**nknown" if it is not known if the patient used alcohol to excess within the past 12 months.

This information is intended to assess the ability of the patient to adhere to antituberculosis drug therapy. Excessive use of alcohol within the past year should be sought as an indicator of recent activity (e.g., when did the patient last have a drink). Since the patient interview for excess alcohol use is often negative initially, it may be necessary to inquire of the patient at multiple visits. If, during the course of TB treatment, information is obtained concerning this variable, please update this variable.

There is no standard definition for excess alcohol use. Excess alcohol use can be assessed using different methods. Reliable indicators of excess alcohol use include participation in Alcoholics Anonymous[7] or alcohol treatment programs (e.g., outpatient, residential or inpatient, halfway house, prison or jail treatment, or other self help). There are also numerous screening instruments that can be helpful in identifying persons who may use alcohol to excess (e.g., CAGE, AUDIT, MAST). Other indicators include hospitalizations for alcohol related medical conditions [e.g., delirium tremors (DT's), pancreatitis, cirrhosis].

The National Household Survey on Drug Abuse assesses alcohol use by asking quantity and frequency of use within the past month. It does not assess if a person has or had a longer history of alcohol use. "Binge alcohol use was defined as drinking five or more drinks on the same occasion (at the same time or within a couple of hours of each other) on at least 1 day in the past 30 days. A drink was defined as a can or bottle of beer, a glass of wine or a wine cooler, a shot of liquor, or a mixed drink containing alcohol. Heavy alcohol use was defined as drinking five or more drinks on the same occasion on each of 5 or more days in the past 30 days."

[7]

34 Additional TB Risk Factors

Indicate any additional TB risk factors that the TB patient may have (*select all that apply*). Documentation of additional TB risk factors from the medical records or a reliable source (e.g., health care provider) is preferred. Undocumented (e.g. verbal reporting from the patient or non-health care provide) reporting is not acceptable. Please note that other specific TB risk factors (e.g., occupation, HIV) are collected elsewhere by the RVCT.

Check **"Contact of MDR-TB Patient",** if the TB patient for which the RVCT form is being completed is a contact of a multidrug resistant (MDR) TB patient, regardless of whether the MDR-TB case was infectious or not. Multidrug resistant TB is defined as resistance to at least isoniazid and rifampin. If this MDR-TB patient was the only known contact for the patient for whom you are completing the RVCT, check "Contact of MDR-TB patient" and do not check "Contact of infectious TB patient." The association between the TB patients may have been found through investigation (e.g., a formal contact investigation) or identified as an incidental finding. For the purpose of this question, the contact should be recent and should not have occurred more than 2 years ago. This question is being asked because clinical management of the TB patient may be affected if the TB patient is a contact of a documented MDR-TB patient. If the contact MDR patient has an RVCT number, add MDR patient RVCT number to Question 3 as "Linking State Case Number" with the reason "Epidemiologically Linked Case." ."

Check **"Contact of Infectious TB Patient"**, if the TB patient for whom the RVCT form is being completed is a contact of an infectious TB patient. If this infectious TB patient is known to have had multidrug resistant TB, and the TB patient for whom the RVCT form is being completed was not a contact of any other infectious TB patient, check only "Contact of MDR-TB patient" and do not check "Contact of infectious TB patient." Multidrug resistant (MDR) TB is defined as a resistance to at least isoniazid and rifampin. The association between the TB patients may have been found through investigation (e.g., a formal contact investigation) or identified as an incidental finding. For the purpose of this question, the contact should be recent and should not have occurred more than 2 years ago. This question is being asked because clinical management of the TB patient may be affected if the TB patient is a contact of a documented MDR-TB patient. If the contact MDR patient has an RVCT number, add MDR patient RVCT number to Question 3 as "Linking State Case Number" with the reason "Epidemiologically linked case."

Check **"Missed Contact",** if after having been diagnosed with TB disease, the TB patient for whom the RVCT form is being completed was found to have been a contact of a known TB patient. For the purpose of this question, the contact should be recent and should not have occurred more than 2 years ago. DO NOT include TB patients identified as having TB disease during a contact investigation or as a result of a contact investigation in this choice, because these patients are not "missed contacts" since they were identified during a contact investigation, despite having TB disease. This "risk factor" is trying to capture those TB patients that could be identified as a preventable case of TB.

Check **"Incomplete LTBI Treatment",** if patient was previously identified as having latent TB infection (LTBI) and was not treated completely for LTBI. This "risk factor" is trying to capture those TB patients that could be identified as a preventable case of TB.

Check **"Tumor necrosis factor-alpha (TNF-α) antagonist therapy"**, if the TB patient had recently or has been receiving tumor necrosis factor-alpha (TNF-α) antagonist therapy at the time of TB diagnosis. The Food and Drug Administration (FDA) has approved TNF-α antaqgonist therapy for treatment of rheumatoid arthritis and other selected autoimmune diseases. The FDA has also recently determined that TB disease is a potential adverse reaction from treatment with TNF-α antagonists. The three currently FDA approved TNF-α antagonists are infliximab (Remicade®), etanercept (Enbrel®), and adalimumab (Humira®).

Check **"Post-organ transplantation"** if the TB patient has a history of solid organ transplantation (e.g., renal, cardiac).

Check **"Diabetes Mellitus",** if the TB patient has diabetes mellitus (Type I or Type II) at the time of TB diagnosis. Diabetes may be controlled by medication or diet.

Check **"End-Stage Renal Disease"** (i.e., ESRD), if the TB patient has end-stage renal disease or chronic renal failure at the time of TB diagnosis.

Check **"Immunosuppression",** if the TB patient has immunosuppression due to either a medical condition or medication, such as hematological or reticuloendothelial malignancies [e.g., leukemia, Hodgkin's lymphoma, carcinoma of the head or neck], or immunosuppressive therapy, such as prolonged use of high dose adrenocorticosteriods (e.g., prednisone).

- If the TB patient has diabetes mellitus or end-stage renal disease, check either "diabetes mellitus" and/or "end-stage renal disease" for this question, and <u>do not check</u> "immunosuppression" unless the patient has another immunosuppressive condition.
- If the patient is infected with HIV, complete "HIV Status at Time of Diagnosis" – Question 26, and <u>do not check</u> "immunosuppression" for this question, unless the patient has another immunosuppressive condition.

Check **"Other",** if the TB patient has a TB risk factor <u>not</u> included in the above choices [e.g., undernutrition (e.g., intestinal bypass surgery for obesity, gastrectomy, jejunoileal bypass, chronic malabsorption syndromes), silicosis, travel to a TB endemic country]. Do not include under "Other" risk factors identified in Questions 27-33 (i.e., risk due to being homeless within past year – Question 27, residence status at diagnosis [correctional facility – Question 28, long-term care facility – Question 29], , primary occupation within the past year – Question 30, or drug or alcohol use within the past year – Questions 31 - 33). Additional space ("***Specify*** _____ ") is provided to write comments regarding "Other" reasons.

Check **"None",** if no TB risk factors could be identified.

35 Immigration Status at First Entry to the U.S.

If a TB patient was born in one of the 50 United States, born abroad of a U.S. citizen parent (e.g., born on a military installation), or born in one of the U.S. Territories, U.S. Island Areas, or U.S. Outlying Areas (e.g., American Samoa, Federated States of Micronesia, Guam, Republic of the Marshall Islands, Commonwealth of the Northern Mariana Islands, Republic of Palau, Puerto Rico, U.S. Virgin Islands) then a visa would not be issued and **"Not Applicable/U.S.-born"** should be checked. Of note, people born in Puerto Rico, U.S. Virgin Islands, and Guam are U.S. citizens.

For persons not under the option of "**Not Applicable/US-born,**" *select one* of the following choices:

NOTE: If the patient had a visa at first entry to the U.S., specify the type of visa. A reliable verbal source is acceptable. There are 2 main types of legal immigration status: permanent residents and non-immigrants (visa issued for specific purpose and time period). Permanent residents (e.g., immigrants) are issued an alien resident card (i.e., green card) and should carry this card with them. Non-immigrants with visas (e.g., student, tourist, employment, "V" visa, "K" visa) should be aware of their visa type which is stated in their passport (e.g., I-94 arrival document stapled in passport). Refugees are separate from the two main categories above; they should have an arrival document (I-94 card) showing their status as a refuges and they should carry this card with them.

- Check **"Immigrant Visa"** for foreign-born TB patients who first entered the U.S. with permanent resident status (e.g., immigrants).
- Check **"Student Visa"** for foreign-born TB patients who first entered the U.S on a student visa. This is a non-immigrant visa and is obtained by an alien coming temporarily to the U.S. to pursue a full course of study in an approved institution.
- Check **"Employment Visa"** for foreign-born patients who first entered the U.S with a non-immigrant employment visa (an alien coming to the U.S. to work for a temporary period of time). There are many different non-immigrant employment visas depending upon type of work. (Note: Some persons entering the U.S. for work are immigrants; they should be checked as "immigrants").
- Check **"Tourist Visa"** for foreign-born TB patients who first entered the U.S temporarily for business or pleasure. This is a non-immigrant visa.
- Check "**Family/Fiancé Visa**" for foreign-born TB patients who first entered the U.S with a "V" visa or "K" visa. A "V" visa is a non-immigrant category that allows a spouse or child of a U.S. lawful permanent resident to live and work in the U.S. A "K" visa is a non-immigrant category that allows a fiancé of a U.S. citizen to temporarily enter the U.S. for a specific purpose (i.e., marriage).
- Check **"Refugee"** for foreign-born patients who first entered the U.S as refugees. A refugee is a person who is outside his or her country of nationality who is unable or unwilling to return to that country because of persecution or a well-founded fear of persecution.
- Check **"Asylee or Parolee"** for foreign-born patients who first entered the U.S seeking asylum or who are parolees. An asylee is an alien in the U.S. 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 must meet the same criteria as a refugee; the only difference is the location of the person upon application – the potential asylee is in the U.S. or applying for admission at a port of entry, and the potential refugee is outside the U.S. A parolee is an alien, appearing to be inadmissible to the inspecting officer, allowed to enter the U.S. under urgent humanitarian reasons or when that alien's entry is determined to be for significant public benefit.
- Check **"Other Immigration Status"** for foreign-born TB patients who first entered the U.S with other immigration status, which is <u>not</u> Immigrant, Refugee, Asylee, Parolee, Student, Tourist, Employment, "V" visa, or "K" visa status, and is not "Unknown." This includes foreign-born persons who were not required to obtain a visa (e.g., foreign-born visitors from specific countries such as Canada that are part of the U.S. visa waiver program and are not required to

obtain visas if visiting the U.S. for short periods of time (e.g., ≤90 days)), or those who entered the U.S. with no official immigration status at entry (e.g., "undocumented" status).

- Check **"Unknown"** for jurisdictions with directives or policies forbidding asking a TB patient their immigration status; foreign-born TB patients who do not know their immigration status at first entry to the U.S; those who may have had a visa at entry to the U.S., but the type of visa is unknown; and those who refuse to respond.

36 Date Therapy Started

Enter the date (month, day, year) the patient began multidrug therapy for TB disease or suspected TB disease. This may be one of several dates:

a. Date patient first ingested medication, if documented from a medical record, such as hospital or clinic or directly observed therapy (DOT) record,

OR

b. Date medication was first dispensed to the patient, as documented by medical or pharmacy record,

OR

c. Date medication was first prescribed to the patient by health care provider, as documented by medical record or by prescription given to patient.

Date of ingestion is the preferred date for this field. If date of ingestion is not known, enter date of dispensation. If neither of those dates is known, enter date of prescription. Patient history without medical documentation is not acceptable.

If an exact date cannot be determined based on the above guidelines, a partial date may be entered in this field. The 2-digit "month" and 4-digit "year" of the date must be valid values, but "99" may be entered for the 2-digit "day" of the date if the exact day therapy was started is not known. For example, if after following the above guidelines an exact Date Therapy Started cannot be determined for a patient known to have started therapy in August of 2007, enter "08/99/2007" on the form. If the month, day, or year therapy started is not known, enter "99/99/9999" on the form.

37 Initial Drug Regimen

Indicate the drug regimen initially prescribed for treatment of TB disease and taken for at least two weeks. The two-week requirement should eliminate most of the record updates necessitated by changes in regimen when treatment is begun. If it is not feasible to determine the initial regimen of at least two weeks duration, record the initial regimen on which the patient was known to have been placed.

For each drug listed:

Check **"No",** if the drug is known not to be part of the initial regimen.
Check **"Yes",** if the drug is known to be part of the initial regimen.
Check **"Unknown",** if it is not known whether the drug is part of the initial regimen.
For combination drugs (e.g., Rifamate, Rifater) - - i.e., code "yes" for each of the individual drugs that are included as components of the combination drug. For example, for Rifamater, code "yes" for Isoniazid and "yes" for Rifampin.

NOTE: For **"Other"** drugs include only antituberculosis drugs, do not include pyridoxine (vitamin B6).

FOLLOW UP REPORT – 1 (Initial Drug Susceptibility Report)

This report should be completed for culture-positive cases only. Complete and submit this report as soon as initial drug susceptibility results are available.

Copy patient name, address, Zip Code, state reporting, year counted and case number(s) from page 1 of the RVCT form. These data are retained at the local level for identification purposes and are not sent to CDC.

Enter Year Counted, State Case Number, and City/County Case Number for data entry purposes.

38 Genotyping Accession Number

Check **"No",** if no isolate was submitted for genotyping. "No" does not indicate that no results were received or that "untypeable" results were reported.

Check **"Yes",** if an isolate was submitted for genotyping for this case, irrespective of genotyping results.

Enter the "**Genotyping Accession Number"** for the episode. If multiple isolates have been submitted for one patient, please consult with your laboratorian or genotyping surveillance coordinator to identify the correct genotyping accession number for current episode.

In 2004, CDC established the National Tuberculosis (TB) Genotyping Service (NTGS) to genotype one *M. tuberculosis* isolate from every culture-confirmed TB patient in the United States. Under the current design, genotyping data must be matched to surveillance data at the local level for optimal programmatic use. No mechanism systematically collects linked genotyping data at a national level. Including a genotyping variable on the RVCT will ensure a comprehensive national view of the molecular epidemiology of TB in the U.S, and may assist state and local programs to identify outbreaks of TB cases that are genotypically linked.

The genotyping accession number is the number assigned by the genotyping reference laboratory. Under the current contracts, for those states receiving service through the "California Lab," the format of the genotyping accession number is presented as YY (the two digit year) "L" and four digits (e.g., 05L1234); for those states receiving service through the "Michigan Lab" the format of the genotyping accession number is presented as YY (the two digit year), "RF," and four digits (e.g., 06RF5678). In some instances where the CDC lab may be performing the genotyping service, the format of the genotyping accession number is presented as YY (the two digit year), "-"(dash), and six digits (e.g., 06-012345). When entering the genotyping accession number, begin at the first box and continue to fill to the right (i.e., left justified). Include all dashes or letters. Do not include additional zeros in the remaining boxes beyond the number provided by the reference lab.

39 Initial Drug Susceptibility Testing

If drug susceptibility testing was performed on multiple initial specimens, select the specimen associated with the primary or major site of disease, the initial specimen from the major site of disease that yields the best or most information concerning drug susceptibility results, or the initial culture-positive isolate.

Was initial drug susceptibility testing done?

Check **"Yes"** if the patient has an isolate collected prior to or within 14 days of initiation of therapy upon which drug susceptibility testing was performed and enter the type of specimen on which drug susceptibility testing was performed. If it was a sputum specimen, check **"Sputum."** If it was not a sputum specimen, select the appropriate anatomic code from the Anatomic Code list (see Appendix V), and enter the code in the boxes provided. If the specimen type was unknown, leave the boxes blank.

Check **"No"** if no initial drug susceptibility testing was performed, or if drug susceptibility isolate was collected > 14 days after initiation of therapy.

Check **"Unknown"** if it is not known whether initial drug susceptibility testing was performed.

NOTE: If the answer is **"No"** or **"Unknown"**, *do not* complete the remainder of this form (Follow Up Report – 1: Initial Drug Susceptibility Report).

40 Initial Drug Susceptibility Results

Record the results of initial drug susceptibility testing on the first isolate for which drug susceptibility testing was performed. Drug susceptibility testing procedures should comply with approved and accepted guidelines. If drug susceptibility testing was performed on multiple initial specimens, select the specimen associated with the primary or major site of disease, the initial specimen from the major site of disease that yields the best or most information concerning drug susceptibility results, or the initial culture-positive isolate. It is strongly recommended that the same specimen should be used to record drug susceptibility testing for first and second-line antituberculosis drugs. For example, if drug susceptibility testing was done on first-line antituberculosis drugs on a specific specimen, and resistance to one or more drug was noted, thus prompting drug susceptibility testing to be done for second-line antituberculosis drugs – this testing should be done on the same specimen. These results should be used to complete this variable, even if the results are received at different times. If drug susceptibility testing for second-line antituberculosis drugs is done after testing for first-line antituberculosis drugs on the same specimen, update this variable when results become available. If however, a second specimen is needed to record drug susceptibility testing for second-line antituberculosis drugs, this specimen should be collected as close as possible in time to when the first specimen was collected to record drug susceptibility testing for first-line antituberculosis drugs (e.g., interval between specimen collections <4 weeks).

NOTE: 1) **"Other Quinolones"** *excludes* Ciprofloxacin, Gatifloxacin, Levofloxacin, Moxifloxacin, and Ofloxacin since they are already choices on the list.

For each drug listed:

Check **"Resistant"** if there was any degree of resistance, even partial resistance or resistance at a low concentration of the drug or other than completely susceptible result.
Check **"Susceptible"** only if completely susceptible.
Check **"Not done"** if susceptibility testing was not done for this drug.
Check **"Unknown"** if it is not known whether the test was performed or the results were unavailable.

NOTE: Additional space is provided at the bottom of the form to write comments regarding the case of tuberculosis reported on the Initial Drug Susceptibility Report (e.g., name of the laboratory that performed drug susceptibility testing).

NOTE: If radiometric and conventional results on the same specimen differ (e.g., one is positive and the other is negative), discuss the results with your laboratory, clinician or TB expert, or contact the Surveillance Chief, Surveillance Section, Division of TB Elimination, CDC to determine how to best code this variable.

FOLLOW UP REPORT – 2 (Case Completion Report)

This form should be completed for all patients who were alive at the time TB was diagnosed. Enter data into this report as soon as information becomes available during patient follow up. This report should be completed when the case is closed to supervision.

Copy patient name, address, Zip Code, state reporting, year counted and case number(s) from page 1 of the RVCT form. These data are retained at the local level for identification purposes and are not sent to CDC.

Enter Year Counted, State Case Number, and City/County Case Number for data entry purposes.

41 Sputum Culture Conversion Documented

Provide information on sputum culture conversion only for patients with initially positive sputum cultures. Sources for documentation of sputum culture conversion include medical records and laboratory reports.

NOTE:	Do not complete this question if the patient was not sputum culture positive, as indicated on Question 18. Do not complete this question for patients without initially positive sputum cultures who have positive cultures from other pulmonary specimens (e.g., bronchoscopy fluid) – Question 20.

Check **"No"** if a patient with an initially positive sputum culture had no subsequent negative sputum cultures (e.g., all follow-up cultures were positive, patient could not produce sputum after therapy started, or no follow-up sputum cultures obtained).

Check **"Yes"** if a patient had an initially positive sputum culture followed by one or more consistently negative sputum cultures. There should be no positive cultures after the one or more consistently negative sputum cultures.

Check **"Unknown"** if the results of all follow-up cultures are unknown, or if it is not known if follow-up cultures were obtained.

If "Yes":

Enter the date (month, day, year) **when the first consistently negative sputum culture was collected**. This should be done *only* for patients who had one or more positive sputum cultures and who subsequently had at least one documented negative culture. This date should be at least one week after the last positive culture was obtained. There should be no positive cultures after this date. This information may be available from medical records or laboratory reports. A complete date is required. Partial dates are not acceptable. If the month, day, and year the first consistently negative sputum culture was obtained are not all known, enter "99/99/9999" on the form.

If "No", enter reason for not documenting sputum culture conversion *(select one)*:

- Check **"Clinically improved: No follow-up sputum despite induction"** if repeat sputum collection was attempted, including induced sputum collection, but patient was not able to produce sputum due to clinical improvement.
- Check **"No follow-up sputum collection"** if induction was not attempted (e.g., if the health care provider did not order a repeat specimen, or if there were no facilities or equipment for induction).
- Check **"Died"** if the patient died before having an opportunity to submit sputum to document whether the sputum culture had converted.
- Check **"Patient lost"** if the patient was lost to follow-up before having an opportunity to submit a sputum to document whether the sputum culture had converted.
- Check **"Patient refused"** if the patient refused to provide a sputum specimen for a repeat culture.
- Check **"Other"** if there was another reason not included in the above choices, such as treatment failure or the patient moved outside the U.S.
- Check **"Unknown"** if the reason for not obtaining a repeat sputum culture to document sputum culture conversion is unknown.

42 Moved

This variable will help assess whether the patient moved anytime during TB therapy. Communication between TB control programs to ensure continuity of care and submission of follow-up reports regarding a patient who is moving from one area to another should be conducted in the most efficient manner possible and the responsibility for submitting follow-up reporting generally remains with the reporting area that initially reported the case to CDC and counted it. A detailed description of the responsibility for submitting follow-up reports to CDC is outlined in the instructions for the RVCT variable "Reporting Address for Case Counting" – Question 4.

NOTE: Two states in the U.S. have a separate TB reporting area within their state that report TB cases directly to CDC. These are, 1) New York State (NYS) and New York City (NYC), and 2) Maryland (MD) and Washington D.C. (DC). For the purpose of this question, if a patient moves from 1) NYS to NYC, or NYC to NYS; or 2) MD to DC, or DC to MD, this would be considered an "out of state" move, since "state" in the context of this question is equivalent to reporting area, and "Out of state" should be selected.

NOTE: If you are one of the U.S. Territories, U.S. Island Areas, and U.S. Outlying Areas (e.g., American Samoa, Federated States of Micronesia, Guam, Republic of the Marshall Islands, Commonwealth of the Northern Mariana Islands, Republic of Palau, Puerto Rico, U.S. Virgin Islands): for the purpose of this question, you should select "Out of state", if a patient moves out of your reporting area to another U.S. Territory/Island Area/Outlying Area, or to the U.S. However, if a patient moves from your country to a country other than a U.S. Territory/Island Area/Outlying Area, or the U.S., select "Out of the U.S.."

Moved is defined as relocating one's residence, where the forwarding address is known, and results in a change in local health department jurisdictions. For example, such a move could be within a county/parish, or even within a state provided that the state is the health department jurisdiction primarily responsible for the TB case management, completing the RVCT, and assuring treatment completion.

If a patient moved within the same local health department jurisdiction, for the purpose of this question, the patient did not move – check **"No."**

If the patient moves to an area where a new local health department jurisdiction must now provide and/or coordinate TB care, then for the purpose of this question, the patient moved – check **"Yes."** In addition to determining whether a patient moved or not, it is of interest as to where the TB patient moved. For those who moved any time during their TB disease episode, identify to where the TB patient moved: (select all that apply)

- Check **"In-state, out of jurisdiction",** if the patient moved within the current state, but moved out of the local heath department jurisdiction, such as a county, city, or similar (see special situations for New York State-New York City, Maryland-Washington DC, and the US Territories/Island Areas/Outlying Areas detailed above in the NOTE). Enter the FIPS code – up to five-digits are allowed for a county code, parish code, or city code, such as a metropolitan statistical areas (MSA's) for areas or cities that have their own local health jurisdiction. Up to two FIPS codes may be entered. Federal Information Processing Standards (FIPS) are standardized unique codes assigned to geographic areas. If the patient moved more than twice, enter the two first moves.
- Check **"Out of state",** if the patient moved to another state (see special situations for New York State-New York City, Maryland-Washington DC, and the US Territories/Island Areas/Outlying Areas detailed above in the NOTEs). Enter the two-letter abbreviation or FIPS code of the state to which the patient moved. Up to two state FIPS codes may be entered. Federal Information Processing Standards (FIPS) are standardized unique codes assigned to geographic areas, such as states, outlying areas of the U.S. (e.g., Guam), and counties/parishes. If the patient moved more than twice, enter the two first moves.

- Check **"Out of the U.S.",** if the patient moved outside the U.S. to another country (see special situations for New York State-New York City, Maryland-Washington DC, and the US Territories/Island Areas/Outlying Areas detailed above in the NOTEs). Enter the two-letter abbreviation of the country to which the patient moved. Up to two country codes may be entered. If the patient moved more than twice, enter the two first moves.

If the patient moved out of the U.S., check **"Yes"** or **"No"** if transnational referral was made to another TB program or physician outside the U.S. Transnational referral includes participation in programs such as TBNet or CureTB, communication with Immigrations and Customs Enforcement to ensure case management after deportation, or individual efforts by programs to complete a case management transfer and obtain information from TB programs and physicians outside the U.S. for case completion.

43 Date Therapy Stopped

Enter the date (month, day, year) that the patient stopped taking therapy for TB disease or suspected TB disease. The time period represented by the interval between "Date Therapy Started" - Question 36 and "Date Therapy Stopped" – Question 43 is meant to encompass the entire period (including interruptions in therapy) that the patient was receiving medication to treat TB disease or suspected TB disease.

The date therapy was stopped may be updated only in special instances. For example:

1. If the case is reopened (e.g., patient lost to follow up is found, restarts therapy, and then completes therapy), the "Follow Up Report – 2: Case Completion Report" form should be updated to reflect that the patient completed therapy.

If a TB patient completed therapy, but recurs with TB disease within 12 months of having completed therapy, resulting in the further anti-TB therapy:

a. Do not update any variables on the pre-recurrence RVCT form. To capture recurrence information, without altering pre-recurrence information, a new RVCT should be completed, where:
    i. Enter the pre-recurrence RVCT "State Case Number" (e.g., RVCT number), under "Linking State Case Number" with reason "Recurrence" in Question 3, so the two forms can be linked,
    ii. Check "Verified Case: Recurrent TB within 12 months" for the variable "Count Status" – Question 5.
    iii. Complete the remainder of the RVCT form as you would normally do. This RVCT form will not be counted in the reporting area morbidity count, but rather it will provide valuable information on TB cases that recur within 12 months by allowing electronic linkage with the pre-recurrence RVCT form, and collecting data associated with the recurrence. It will also help measure program burden.

For patients being treated for TB disease or suspected TB disease, "Date Therapy Stopped" should be completed as outlined below:

a. Date that the patient last ingested medication,

OR

b. Date that the medication dispensed to the patient would have run out, if the patient had taken all the medication,

OR

c. Date that the medication prescribed to the patient would have run out, if the patient had taken all the medication from the date of prescription.

Date of last ingestion is the preferred date for this field. If date of ingestion is not known, enter date that medication would have run out, based on the date of dispensation. If neither of the above dates is known, enter the date that the medication would have run out based on the date of prescription. While there may be interruptions in antituberculosis drug therapy, the final date when the patient took medication for TB disease or suspected TB should be given. "Date Therapy Stopped" should be updated if a patient was lost to follow-up and then returns and completes therapy. Patient history without medical documentation is not acceptable.

If an exact date cannot be determined based on the above guidelines, a partial date may be entered. "Month" and "Year" of the date must be valid values, but "99" may be entered for "Day" of the date if the exact day therapy was stopped is not known. For example, if after following the above guidelines an exact "Date Therapy Stopped" cannot be determined, but the month and year is known for a patient known to have stopped therapy in August of 2005, enter "08/99/2005" on the form. If month, day, and year that therapy was stopped are not known enter "99/99/9999" on the form.

44 Reason Therapy Stopped or Never Started

Provide the primary reason why TB therapy was ended and not resumed, or never started. This question should be completed when the case completed therapy or is closed. The reason therapy was stopped or never started may be updated only in special instances. For example, if the case is reopened (e.g., patient lost to follow up is found, restarts therapy within 12 months of having been found, and then completes therapy, the "Follow Up Report – 2: Case Completion Report" form should be updated (e.g., to reflect that the patient completed therapy). Do not update the RVCT, other than variables on the "Follow-up Report 2: Case Completion Report." Please refer to "What's New on the RVCT – RECURRENCE" for more information. As per the CDC counting recommendations Error: Reference source not found, a person may have more than one discrete (separate and distinct) episode of TB disease. If TB disease recurs in a person within any 12-consecutive-month period, count only the initial episode as a case for that year. However, if TB disease recurs in a person, and if more than 12 months have elapsed since the person completed therapy or was lost to supervision, the TB is considered a separate TB episode and should be counted as a new case.

Check **"Completed therapy",** if the patient successfully completed the prescribed course of therapy.

Check **"Lost",** if the patient cannot be located prior to the completion of treatment (e.g., the patient moved to an unknown location or when the address forwarding address is known, but the patient is not found at that address). Patients who move outside the U.S. and are unable to be followed are coded under "Other."

Check **"Uncooperative or refused",** if the patient refused to complete therapy (e.g., stopped taking drugs). If patient restarts treatment, the "Follow Up Report – 2: Case Completion Report" form should be updated.

Check **"Adverse treatment event",** if therapy was permanently stopped due to an adverse treatment event due to antituberculosis medications (e.g., life threatening drug reaction).

Check **"Not TB",** if the completed diagnostic evaluation determined that the diagnosis of TB is not substantiated (e.g., *M. avium* is isolated from a clinical specimen). Count Status (Q. 5) will be blank.

Check **"Died",** if the patient was alive at diagnosis but died before therapy was completed, including patients classified as alive for Status at TB Diagnosis (Q. 15) if started on at least two antituberculosis drugs prior to the day of death even though the TB case was not be verified and counted until after death.

If the patient was alive at diagnosis but died before TB therapy was completed, indicate the cause of death. Information under **"If Died"** may be filled out for cases whose reason for stopping therapy was death, who stopped therapy due to adverse treatment event then died, or patients who were lost but later determined to have died from another source such as death indices. Ideally, written documentation of the cause of death (e.g., death certificate, autopsy report, medical records) is recommended; however, a reliable verbal source (e.g., a health care provider) will be accepted.

- Check **"Related to TB disease",** if the cause of death was related or due to TB disease. If TB is listed on the death certificate as either the immediate cause, an underlying cause, or other significant condition contributing to death, then check "Related to TB disease" for whether TB was a cause of death.
- Check **"Related to TB therapy",** if TB therapy (e.g., adverse treatment event) was related to the cause of death.
- Check **"Unrelated to TB disease",** if TB disease or therapy did not have anything to do with the cause of death or if TB was not listed as either the immediate cause , an underlying cause, or other significant condition contributing to death.
- Check **"Unknown",** if the cause of death is unknown.

Check **"Other",** if therapy was discontinued for another reason not included in the above choices and is not "Unknown", such as when a patient moves outside the U.S. to another country, or when a patient moves from State A to State B, and State A notifies State B, but State B never followed up on the patient.

Check **"Unknown",** if the reason that therapy stopped is not known.

45 Reason Therapy Extended >12 months

This variable will help assess the reason(s) attributed to why antituberculosis therapy extended for more than 12 months. "Date Therapy Started" – Question 36 and "Date Therapy Stopped" – Question 43 should be used to calculate the length of antituberculosis therapy and determine if it was more than 12 months. Sources for the reasons why therapy was extended include patient medical records, patient interview, and health care provider interview.

Check **"Rifampin resistance",** if the patient had drug resistant TB that would require a treatment protocol lasting more than 12 months (e.g., resistance to at least rifampin) as per recommended TB treatment guidelines.

Check **"Adverse drug reaction",** if the patient had a significant adverse drug reaction or adverse treatment event due to antituberculosis medications that prolonged therapy (e.g., life threatening reactions, reactions requiring permanent change in antituberculosis medications).

Check **"Non- adherence",** if there were barriers to adherence to antituberculosis therapy for the patient (e.g., patient did not adhere to therapy, treatment interruption) or if the patient was non-compliant resulting in extension of therapy beyond 12 months.

Check **"Failure"**, if the patient has a positive sputum culture at or beyond month 4 of treatment. All treatment failure isolates should be compared to the initial isolate using DNA fingerprinting.

Check **"Clinically indicated – other reasons",** if the patient had clinically indicated reasons other than those listed above for extending therapy more than 12 months (e.g., central nervous system (CNS) TB, including tuberculous meningitis, severe liver disease).

Check **"Other",** if the reason does not include any of the choices listed above (e.g., health care provider choice) and is not "Unknown." Additional space is provided at the bottom of the form to write comments regarding "Other" reasons.

Check **"Unknown",** if the reason is not known.

46 Type of Outpatient Health Care Provider

For the purpose of this variable, **"Type of Outpatient Health Care Provider"** is defined as the provider who has primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT). For patients that have had multiple primary providers during their TB care, select all that apply:

NOTE:	Outpatient refers to a non-hospitalized or non-acute setting such as, a clinic or medical office. Inpatient refers to a hospitalized or acute-care setting such as a hospital, and does not necessarily refer to a patient who is in a facility; in the context of this variable, it also denotes the type of services that are provided. Some institutions, such as a hospital, correctional facility, or long-term care facility, may have both outpatient and inpatient settings.

Check **"Local/State Health Department"** if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is the local or state health department (e.g., TB program, health clinic).

Check **"Private"** if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is a private provider [e.g., private physician or health care provider, private Health Maintenance Organization (HMO), or private managed care provider]. This category also includes the private provider that has the primary responsibility for clinical outpatient decision making for a TB patient, even though the TB control program or local/state health department may be periodically contacting the private provider for the purpose of completing the RVCT and to ensure proper TB case management.

Check **"IHS, Tribal Health Department or Tribal Corporation"** if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is the Indian Health Service (IHS) or an American Indian or Alaska Native Tribal Health Department or Tribal Healthcare Corporation.

Check **"Institutional/Correctional"** if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is an institution such as, a correctional facility or a long-term care facility (e.g., nursing home, assisted living facility).

Check **"Inpatient Care Only"** if the patient did not receive any outpatient TB care. Such situations could include TB diagnosed at autopsy, patients who died prior to receiving outpatient TB care, and patients that received all of their TB care as an inpatient in a hospital or similar acute care facility.

Check **"Other"** if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is a provider that is not included in any of the other categories and is not "Unknown" (e.g., State TB Chest Hospital providing outpatient care, city/county/state owned hospitals that are not part of the health department providing outpatient care, private hospital providing outpatient care,Veterans Administration, federal program, military facility, or community-based organization (CBO).

Check **"Unknown"** if the type of health care provider is unknown. If **"Unknown"** is checked, no other choice for type of health care provider should be checked.

Examples:

If a private provider was the primary outpatient caregiver and made all the clinical decisions, but the local/state health department was providing DOT, conducting the contact investigation, and was periodically contacting the private provider for information to complete the RVCT, check "Private" for this variable. If however, this same patient after a period of time (e.g., 3 months), lost their medical insurance and then switched providers and now the local/state health department had primary responsibility for the outpatient decisions, then both "Private" and "Local/State Health Department" should be checked.

47 Directly Observed Therapy

Directly observed therapy (DOT) or supervised therapy involves the direct visual observation by a health care provider (e.g., public health nurse, outreach worker, nurse, nurse's aid) or other reliable person (e.g., homeless shelter worker) of a patient's ingestion of medication. Delivering medication to a patient without visual confirmation of ingestion does not constitute DOT. Confirmation that the medication has been swallowed may sometimes be necessary. Using such techniques as having the patient swallow a glass of water or talk following ingestion, inspecting the oral cavity with the tongue raised by the patient, or using a tongue blade to inspect between the cheek and the gums are helpful in determining if the medication has been swallowed. DOT regimens may be administered daily, three times a week, twice weekly, or weekly. DOT is not limited by the location in which it is given. DOT can be administered in the health department, correctional facility, long-term care facility, in the patient's home, or in the field, as long as the person administering the DOT is qualified. Antituberculosis medication may be, 1) self-administered (e.g., patient ingests medication dose(s) without direct visual observation by a health care provider or other reliable person), or 2) given using DOT.

Check "No, Totally Self-Administered" if no doses of medication were given under direct supervision and visual observation of ingestion by a health care provider or other reliable person.

Check "Yes, Totally Directly Observed Therapy" if the following applies for TB therapy:

For patients on a once-weekly medication regimen, DOT was given for all doses while on the once-weekly regimen.
For patients on a twice-weekly medication regimen, DOT was given for all doses while on the twicee-weekly regimen.
For patients on a thrice-weekly medication regimen, DOT was given for all doses while on the thrice-weekly regimen.
For patients on a daily medication regimen, DOT was given for five or more doses each week while on the daily regime.

Check "Yes, Both Directly Observed and Self-Administered if the following applies for TB therapy:

For patients on a once-weekly medication regimen, self-administration was given for any doses while on the once-weekly regimen.
For patients on a twice-weekly medication regimen, DOT was given for any doses while on the twicee-weekly regimen.
For patients on a thrice-weekly medication regimen, DOT was given for any doses while on the thrice-weekly regimen.
For patients on a daily medication regimen, DOT was given for four or fewer doses each week while on the daily regime.

Check "Unknown" if it is not known whether any doses of medication were given under supervision.

To calculate "Number of weeks of directly observed therapy (e.g., DOT weeks), use the following guidelines:

a. Review the patient's medication records and determine the number of medication doses given using DOT during each week or 7-day period. The number of days in a "week" is still seven, but the calculation of DOT weeks or medication weeks should be independent or not restricted to calendar weeks (e.g., Sunday through Saturday). For example, a medication week can be Monday through Sunday or Wednesday through Tuesday, as long a there are 7 days in a week.
b. If a patient "misses" a DOT dose or there is a holiday during a medication week and DOT is unable to be given that week, as long as that medication dose is given at the end of therapy using DOT to make up for the missed dose(s), that dose given at the end of treatment and can be combined with the last "partial DOT week" and counted as a full "DOT week."

For patients on a once-weekly medication regimen, count a DOT week for each once-weekly dose administered under DOT.
For patients on a twice-weekly medication regimen, count a DOT week as 2 twice-weekly doses administered under DOT.
For patients on a thrice-weekly medication regimen, count a DOT week as 3 thrice-weekly doses administered under DOT.
For patients on a daily medication regimen, count a DOT week if five or more of the week's doses were administered under DOT.

c. Often, the health department or person completing the RVCT does not have direct access to the entire patient medical record or medication log because the TB patient was managed by a provider other than the health department (e.g., private health care provider). The provider (e.g., private provider) usually does not provide DOT; rather a public health care provider (e.g., public health nurse) provides DOT and maintains the medication log. The health department periodically follows-up with the provider and when therapy is completed or the case is closed, the health department will usually complete a "close out" form. In such cases, the health department should request a copy of the medication log or review the log with the person providing DOT (e.g., public health nurse) and determine the amount of medication that was given using directly observed therapy (DOT) and to determine the DOT weeks using the above guidelines.

Enter the **"Number of weeks of directly observed therapy (DOT) weeks"** based on the total number of regimen-appropriate weeks and doses of medication ingested under directly observed supervision. The total number of DOT weeks must be less than or equal to the time period between "Date Therapy Started" – Question 36 and "Date Therapy Stopped" – Question 43.

48 Final Drug Susceptibility Testing

This variable will help assess the frequency of acquired drug resistance.

Was follow-up or final drug susceptibility testing done?

Check **"No",** if no follow-up drug susceptibility testing was done.

Check **"Yes",** if drug susceptibility testing was performed on an isolate that was collected 30 days or more after the isolate for which initial drug susceptibility testing was performed.

If "Yes", enter the collection date (month, day, year) of the **"Last isolate for which drug susceptibility testing was performed."** This date should be 30 days or more after the collection date of the initial isolate for which drug susceptibility was done (Question 40). This information is usually available from medical records or laboratory reports. A complete date is required. Partial dates are not acceptable. If the month, day, and year the isolate was collected are all not known, enter "99/99/9999" on the form.

If "Yes", enter the **"Type of specimen"** that drug susceptibility testing was performed on. If it was a sputum specimen, check **"Sputum."** If it was not a sputum specimen, select the appropriate anatomic code from the Anatomic Code list (see Appendix V), and enter the code in the boxes provided. If the specimen type was unknown, leave the boxes blank.

Check **"Unknown"** if it is not known whether follow-up drug susceptibility testing was performed.

NOTE: If the answer is **"No"** or **"Unknown"**, *do not* complete the remainder of this form (Follow Up Report – 2: Case Completion Report).

49 Final Drug Susceptibility Results

Record results for the final isolate for which drug susceptibility testing was performed. Drug susceptibility testing procedures should comply with approved and accepted guidelines. If drug susceptibility testing was performed on multiple final specimens, select the specimen associated with the primary or major site of disease, the final specimen from the major site of disease that yields the best or most information concerning drug susceptibility results, or the final culture-positive isolate. Results for this variable should not be based on drug susceptibility testing from more than one specimen.

NOTE: 1) **"Other Quinolones"** *excludes* Ciprofloxacin, Gatifloxacin, Levofloxacin, Moxifloxacin, and Ofloxacin since they are already choices on the list.

For each drug listed:

Check **"Resistant",** if there was any degree of resistance, even partial resistance or resistance at a low concentration of the drug or other than completely susceptible result.
Check **"Susceptible",** only if completely susceptible.
Check **"Not done",** if susceptibility testing was not done for this drug.
Check **"Unknown",** if it is not known whether the test was performed or the results were unavailable.

NOTE: Additional space is provided at the bottom of the form to write comments regarding the case of tuberculosis reported on the "Follow Up Report – 2: Case Completion Report" (e.g., name of the laboratory that performed drug susceptibility testing).

NOTE: If radiometric and conventional results on the same specimen differ (e.g., one is positive and the other is negative), discuss the results with your laboratory, clinician or TB expert, or contact the Surveillance Chief, Surveillance Section, Division of TB Elimination, CDC to determine how to best code this variable.