INSTRUCTIONS: BASIC Tier Data Collection Log

DEMOGRAPHICS:

A unique patient ID number will be generated by your state specific database. Use an identifier of your choice on the paper form. For your own use, you may elect to record the patient name and county of residence at the very top of the page (no patient names can be entered in the database).

For completion of the basic tier form, please complete the demographics data fields at the top of the page and indicate the reason for implementation of treatment. INH dose range is 100 – 900mg. RPT dose range is 75 – 900mg.

See key below for appropriate race categories:

Abbreviations for race:

A = Asian
AI = American Indian or Alaskan Native
B = Black/African-American or Black
PI = Native Hawaiian or Pacific Islander
W = White

DOSING & SYMPTOM REVIEW:

Each column, except for the first one, coincides with one of the 12 doses. The first entry is intended to serve as a baseline review of symptoms and is labeled Dose 0 / Baseline.

For each time that a dose is provided, please record the date pertaining to that dose and indicate whether therapy was directly observed or not.

For example:

- Week 1 - before the medications are given, there is a symptom review, and the results go under dose "0". The nurse would give the patient the first dose, and put that date at the top of the next column, labeled dose 1.
- Week 2 – the patient returns, and the nurse asks if there were any symptoms. Those results are recorded under dose "1". If ok to proceed, the patient would get the second dose, and that date would be entered at the top of the next blank column, labeled dose 2.
  - If the patient called in the next day and reported a side effect. This would be entered in the column under dose "2" with whatever associated action taken.
- Week 3 – the patient would come in, and the nurse would ask if there were any additional symptoms, which would be recorded still under dose "2". If ok to proceed, the patient would get the third dose and that date would be entered at the top of the next blank column, labeled dose 3.

Review all symptoms listed with the patient/contact and record any listed or 'other' symptoms.

If the patient/contact did not experience any symptoms, check **No** adverse reaction.

If Rx (therapy) was stopped or held, check the bottom box in the symptom review indicating Treatment was stopped or held, and complete the adverse event report on page 2.

FINAL DISPOSITION:
Indicate whether treatment was completed or stopped.

If treatment was stopped, record the date the treatment was stopped and indicate the reason for stopping: Patient Lost to follow-up, Moved, Other (please write-in reason), or Adverse Event.

If treatment is stopped due to an adverse event, complete the adverse event report on page 2.

If treatment was switched to another regimen (e.g. INH for 6 or 9 months, Rifampin for 4 months, etc.), indicate the final disposition is 'pending completion of alternate regimen' to close out that "case".

ADVERSE EVENT:
Indicate the Dose #, record whether Rx was stopped or held, complete the date the symptom began, indicate when the symptom occurred in relation to the last INH-RPT dose (symptom onset), the duration the symptom(s) lasted, and whether the patient was hospitalized.

Indicate if medication re-challenge was carried out, if yes, check whether re-challenged was with INH or RPT, or select both drugs if patient was re-challenged with both. Record the outcome. Rather than leaving all fields blank for any question, please check Unknown, if a question cannot be answered.

COMMENTS:
Briefly describe the adverse event, including symptoms, time of onset in relation to last INH-RPT dose, duration and resolution of the event, results of the rechallenge, and/or any other factors (other medical conditions, medications) that may be relevant.

LABORATORY VALUES:
Provide any laboratory test results done during the course of INH-RPT treatment.