BASIC PROTOCOL FOR INVESTIGATOR-INITIATIED RESEARCH

# NOTE: This page contains instructions on the use of this template and should not be included as part of the protocol.

1. This template can be used for most study designs. It contains the essential elements that the Medical Research & Ethics Committee (MREC) looks for when reviewing a protocol.
2. Users must read the <hints/instructions> carefully and insert relevant information only.
3. Where possible, examples of the information required are shown as

<Example: These are suggested information that can be used>

1. If a section is not relevant, do not delete the section. Instead type **NOT APPLICABLE**.

# Study Protocol

**Prevalence and Factors Associated with Tuberculosis (TB) Treatment Compliance in Petaling District, Malaysia: A Cross Sectional Study**

**Protocol number, version number and date: - Name and Institution of Principal investigator:**

Dr. Lee Soo Cheng, Pejabat Kesihatan Daerah Petaling

# Name and Institution of Co-Investigators:

Dr. Zaharah Binti Zainuddin, Pejabat Kesihatan Daerah Petaling

Dr Sudeash Rajakrishnan, Pejabat Kesihatan Daerah Petaling

# Name and address of Sponsor:

# -

# Study site/s:

Pejabat Kesihatan Daerah Petaling

**List of Abbreviations**

<List commonly used abbreviations/acronyms>

|  |  |
| --- | --- |
| TB | Tuberculosis |

# Research Synopsis

|  |  |
| --- | --- |
| Study title | **Prevalence and Factors Associated with Tuberculosis (TB) Treatment Compliance in Petaling District, Malaysia: A Cross Sectional Study** |
| Study Population | The study population is all registered TB patients in the Malaysian National MyTB database in district of Petaling from 2017 to 2022. |
| Study Design | The study is divided into two sections. In section1, a cross-sectional study will be carried out to determine the prevalence and factors associated with treatment default among all TB patients in Petaling district. In section 2, a cross-sectional study will be carried out to determine the prevalence and factors associated with re-treatment case among all TB defaults in Petaling district. |
| General Objective | The aim of this study is to determine the prevalence and factors associated with TB treatment compliance in Petaling District. |
| Specific Objectives | 1. To determine the prevalence of treatment default among TB patients in Petaling District. 2. To determine the factors (sociodemographic, occupational profile, diagnosis profile, health facilities) associated with treatment default among TB patients in Petaling District. 3. To determine the prevalence of re-treatment cases among TB defaults in Petaling District. 4. To determine the factors (sociodemographic, occupational profile, diagnosis profile, health facilities, social issues, intervention) associated with re-treatment case among TB defaults in Petaling District. |

|  |  |
| --- | --- |
|  |  |
| Study endpoints/outcomes | 1. Identification of non-modifiable and modifiable risk factors can facilitate early targeted intervention. 2. Evaluate current intervention carried out for treatment defaulters. |
| Sample Size | Section 1: 9078 registered TB patients  Section 2: 1272 registered TB defaulters |
| Study Duration | 21st September 2023 - 21st September 2024 |