### RESEARCH PROTOCOL

**1. Title of The Research:**

“Radiologically advanced disease among tuberculosis patients with positive sputum AFB smear in Mogadishu, Somalia”

**2. The purpose of The Research:**

The aim of this study is to examine the radiological imaging data in patients detected AFB stain examination positivity in patients who admitted to Mogadishu Somalia Turkey Recep Tayyip Erdogan Training and Research Hospital Diagnostic Microbiology Laboratory in the last four years.

**3. The Rationale of the Study::**

We aimed to investigate the incidence of advanced signs of infection radiological findings in patients with tuberculosis in the population we serve. Since chronically infected persons can lead to the spread of tuberculosis we will consider the necessity of routine ARB screening for patients with suspicious clinics in our hospital and aimed to raise awareness about other preventive measures for the spreading of tuberculosis.

**4. Researcher's Hypothesis / Research Question:**

1. The incidence of advanced disease-related radiological imaging findings in ARB-positive patients presenting to our hospital is higher / not higher than in other countries in the region.

2. The incidence of certain laboratory parameters or radiological findings varies between ARB positive and ARB negative patients, but not.

5. Materials and Method of Research:

In this study, which will examine the distribution of retrospective data obtained from the tests studied in the 4-year period between November 2015 and November 2019, the radiological findings of approximately 400 ARB positive patients in different age and gender groups were investigated. The aim of the study is to reach new and original information about the patient profile that may be specific for the country and city where the study was conducted. For comparison, the radiological findings of 200 ARB negative patients will be examined separately.

At the end of the study, basic statistical data such as frequency, mean, ± standard deviation will be obtained and comparisons will be made by using commonly used statistical calculations such as Chi-square Test and Fisher Exact Probability Test.

5.a-Design of Research:

Quantitative 🞏 Qualitative 🞏 Compound 🞏

Retrospective 🞎 Cross-sectional 🞎 Prospective 🞎

Other (Specify the type …………........................)

5.b-Design of Research:

 -The parameters to be looked at must be written individually and explicitly,

* • Routine biochemical and immunological parameters of patients with ARB + test result
* • Computed tomography, radiographic imaging results
* • Pathological reports of biopsy results, if any
* • Age, gender, requesting clinical unit, other available demographic and clinical information notes on the HIS

 -Where and by whom parameters should be looked at should be written,

* • Radiological reports will be reviewed by Dr. Mehmet TAHTABAŞI over HIS.
* • Other laboratory parameters will be examined by Dr. Muktar Abdullahi Ali and Dr. Fatih ŞAHİNER on HIS.

 -Which of the parameters to be used in the study is routine, which should be specially requested for theresearch

* No special tests are required for this study, which will be conducted on retrospective data that is routinely requested.

-The number of patients included in the survey, the number of volunteers and their quality

* There are no sub-working groups such as volunteer group in this study, which will be carried out based on the retrospective data that are routinely requested.

 -Non-participation in research and non-research criteria

* Data of patients with repeat results of the same patient that may affect the prevalence results will be examined and excluded.

 -The criteria for withdrawal of the volunteer or patient from the study and the duration of their follow-up

* n this study, which will be conducted on routine retrospective data, no patient follow-up will be performed.

 - Criteria for termination of the research

* None

 -If necessary, measures to be taken against possible risks for teams and patients participating in the investigation, insurance and other security measures

* The study does not pose a safety risk..

-Disposal rules for waste in the result of the research (experimental animal, tissue, organ, infected material, etc.) and where to dispose

* The study will be conducted on routine retrospective data.

-An example of the follow-up forms to be used in the research should be added to the protocol.

* Follow-up form will not be used in the study.

**6. Time of Research:**

It is expected to be completed within 3 months following the approval of the ethics committee.

**7. References:**

**1.**Vefik ARICA, et al. Tüberkülozun Radyolojik Manifestasyonları İçin Yeni Kavramlar. J Kartal TR 2011;22(2):102-111.

**2.** Rathman, G., et al. "Clinical and radiological presentation of 340 adults with smear-positive tuberculosis in The Gambia." The International Journal of Tuberculosis and Lung Disease 7.10 (2003): 942-947.

**3.** Menon, Balakrishnan, et al. "Evaluation of the radiological sequelae after treatment completion in new cases of pulmonary, pleural, and mediastinal tuberculosis." Lung India: Official Organ of Indian Chest Society 32.3 (2015): 241.