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INDIAN COUNCIL OF
MEDICAL RESEARCH

NIIH
NATIONAL INSTITUTE OF
IMMUNOHAEMATOLOGY

Annexure 11 (AX 11/SOP 5C/V1)

Format for Informed Consent Document Genetic Studies Institutional Ethics Committee for Research on Human Subjects ICMR - National Institute of Immunohaematology

Project Ref. No.:

- 1. Project Title and Purpose of the Study:** Telomere dysfunction in Interstitial Lung Disease (ILD) and its usefulness in precision medicine
Purpose : This study focuses on understanding how genetic factors, specifically telomere dysfunction (shortening and mutations), impact disease progression, survival, and severity in patients with Interstitial Lung Disease (ILD).

- 2. Study Procedures to be followed:**

This will be a prospective observational study for 36 months. Clinically diagnosed ILD patients will be recruited from the department of Pulmonary Medicine King Edward Memorial Hospital Parel Mumbai over a period of 3 years. A healthy control group will also be included. Assessment of autoantibodies will be done. This study will measure telomere length from DNA via quantitative PCR and identify gene variants through whole-exome sequencing (WES) and genotyping of common polymorphisms, ELISA will assess surfactant protein levels, while autoantibody tests (ANA, Anti-dsDNA, ANCA) will screen for autoimmune markers. Telomerase activity (TRAP assay) and senescence staining will be performed on cell lines to evaluate telomerase function and cellular senescence due to telomere dysfunction

- 3. Risks and Discomforts:**

The study involves collection of 15ml of peripheral blood. During the blood collection, you might feel some pain from the arm site from where the blood sample is collected. The risk of infection is minimized by the use of disposable unused syringes and needles. However, you will receive prompt treatments for these side effects

- 4. Possible benefits of the study:**

By participating in this research study, you may better understand your disease progression by monitoring telomere length associated with interstitial lung disease (ILD). This could help predict how quickly the disease may progress with short telomere length and guide potential treatment options. Genetic mutation analysis, particularly in familial ILD cases, can identify at-risk asymptomatic family members with associated gene mutation enabling early disease monitoring and preventive care. Additionally, tracking changes in telomere length and forced vital capacity (FVC) over one year could help reveal how telomere shortening relates to lung function decline, aiding in early intervention and personalized care strategies for fibrotic ILD.

- 5. What happens when the research trial stops?**

Not applicable as no drug trial is done.

- 6. Compensation for participation and Treatment and Compensation for study related injury:**

Not Applicable

7. Right to withdraw from the study:

Your participation in the study is voluntary. You will have the right to withdraw from the study at any time without giving reasons for your withdrawal and without losing the benefits of any future medical care even if you do not participate in the study.

8. Confidentiality:

All study records will be kept confidential at all times. Your identity will not be revealed except as required by law. The results of the project may be published for scientific reasons. Your identity will not be revealed in these publications.

9. Whom do you call if you have questions or problems?

a. Regarding the research study:

If you have any questions regarding this research study, you may contact
Dr. Vandana D. Pradhan

Scientist D, Department of Clinical & Experimental Immunology

ICMR-National Institute of Immunohaematology,

13th floor, New Multistoried Building, K.E.M Hospital Campus, Parel,

Mumbai-400012.

Tel. no. 022-24138518/19 (office hours 9:00am-01:00pm & 02:00pm-05:00pm)

b. Regarding rights as a Participant

If you have questions or concerns about your rights as a research participant or a concern about the study, Please feel free to address the Ethics Committee through the Ethics Office and identify yourself not by your name but by your identity number.

NIIH Ethics Committee for Human Subjects

National Institute of Immunohaematology (ICMR)

13th floor, K.E.M Hospital campus,

Parel, Mumbai 400 012,

Tel. No.: 022-24138518/19,

Email : niihethics@gmail.com

I have read or have had read to me the information given in the Informed Consent Document for this study entitled "Exploring genetic susceptibility, telomere dysfunction in relation to survival and disease progression in Interstitial Lung Disease (ILD) patients

I have received an explanation of the nature, purpose, duration, and foreseeable effects and risks of this study and what I will be expected to do. My questions have been answered satisfactorily

Institutional review board authorities may wish to examine my medical records to verify the information collected. By signing this document, I give permission for this review of my records

I understand that my identity will not be revealed in any report or publication

I give my informed and voluntary consent to take part in this research study.

Name of the Study Participant

Signature/ thumb impression of the
Study Participant

Date

Name of the Impartial Witness

Signature of the Impartial Witness

Date

Name of the Person Conducting Consent

Signature of the Person Conducting
Consent

Date