

Oct 04, 2024

Sinai SCENT TMC - Bronchoscopy Lung Collection

DOI

dx.doi.org/10.17504/protocols.io.bp2l628yrgqe/v1

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DOI: **dx.doi.org/10.17504/protocols.io.bp2l628yrgqe/v1**

Protocol Citation: Monica Kraft, Santos Bermejo 2024. Sinai SCENT TMC - Bronchoscopy Lung Collection. **protocols.io**
<https://dx.doi.org/10.17504/protocols.io.bp2l628yrgqe/v1>

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Protocol status: Working

We use this protocol and it's working

Created: June 24, 2024

Last Modified: October 04, 2024

Protocol Integer ID: 102324

Abstract

Cellular senescence is a stress-response, as well as a critical component of cell fate during development, repair, resilience, and normal aging. Deepening and broadening our investigations into cellular senescence in normal conditions will advance our knowledge of healthy aging as well as age-related disabilities, thereby leading to integrated and inclusive approaches to Gero-Protection and Gero-Therapeutics.

Goal and Objective

- 1 This project aims to collect, handle, store, and allocate normal healthy lung tissues and biofluids for constructing cellular senescence maps according to the standards established by the Steering Committee of the SenNet consortium. It seeks to identify senescent cell differences across the body, human health states, and lifespans. The NIH Cellular Senescence Network (SenNet) Program was established to comprehensively identify and characterize the differences in senescent cells across the body, across various states of human health, and across the lifespan. The Senescent Cell Evaluations in Normal Tissues (SCENT) Tissue Mapping Center (TMC) builds on the strengths at our institutions as well as external established research collaborations. As a centralized TMC for the SenNet consortium (Duke University – ISMMS), this study will provide a diverse, heterogeneous cohort of respiratory track tissues samples from healthy individuals. To achieve this, a diverse, high-quality biorepository will be established through airway and blood sample collection from healthy adults. The goal is to provide detailed characterizations of cellular senescence in the lung and lung airway, and associated biofluids contributing significantly to advancing knowledge in human cellular senescence.

Study procedures

- 2 **Study Population/Setting**
The study population will comprise healthy adult individuals from the Icahn School of Medicine and Mount Sinai Hospital, including Mount Sinai Hospital or ISMMS employees, students, volunteers, outpatients, and any other members of the community. All research activities will take place at the Icahn School of Medicine at Mount Sinai in the Annenberg building, 18th floor, room 96 (Dr. Patty J. Lee Lab) at 1468 Madison Ave, New York, NY 10029, and at the Bronchoscopy Suite, also located in the 7th floor of the Annenberg building.
- 3 **Recruitment Goal**
Our goal is to enroll 40 healthy participants over the duration of this study. Our recruitment goal is highly feasible. We expect there will be large pool of eligible candidates since this project is targeting healthy adult individuals from the New York community.

Eligibility Criteria

- 4 **Inclusion Criteria**
 - Healthy adult participants, ≥ 18 years old (Note: for this study “Healthy” is defined as participants who have no history of lung disease, allergies, and active respiratory infection symptoms)
 - No significant active medical conditions as determined by the investigator
 - Willing and able to provide informed consent and adhere to visit/protocol requirements.

- FEV1/FVC ratio > 0.70 and both FEV1 and FVC at least 80% of the predicted value (from spirometry)
- Normal Chest X-ray
- Normal CBC with differential, CMP, and INR (PT/PTT)

5 **Exclusion Criteria**

- History of asthma, chronic bronchitis, COPD, tuberculosis, hemoptysis, or recurrent pneumonia)
- History of respiratory/lung disease (e.g., COPD, asthma, emphysema, chronic bronchitis, tuberculosis, cystic fibrosis, lung cancer, recurrent pneumonia or other chronic lung disease)
- Active respiratory symptoms/infection within last 4 weeks
- Active smoking within the past year of conventional tobacco, inhaling of marijuana (smoking marijuana leaves or inhaling THC via e-cigarette) or other drugs. Vaping of e-cigarettes or vape pods >1 time per month in the past 6 months. Any form of tobacco qualifies, such as: 1 cigarette, 1 hookah or shisha sessions, 1 cigar, 1 pipe, etc. Any electronic (e)-device included: e-cigarette, mod, vape pen, JUUL, e-cigar, ehookah, e-pipe, vape pods, etc.
- Pregnancy or planned pregnancy in the next 2 months (i.e., during the duration of study procedures)
- Any prescription medication that while taking may be harmful to the participant, or detrimental to the research. All prescription medications will be reviewed by MPI to determine eligibility.
- Antibiotic administration or exacerbation/respiratory infection within the prior 30 days
- Underlying illnesses that may result in altered lung function (e.g., rheumatoid arthritis)
- Students or employees who are under direct supervision of any study member (to prevent undue influence or coercion)
- Allergies to medications used (or potentially used) in the study, including albuterol, acetaminophen, lidocaine, fentanyl, atropine, and midazolam.
- Any use of tricyclic antidepressants, beta-adrenergic blockers, aspirin, or other medications known to interfere with the treatment of anaphylaxis.
- Other medical or psychological conditions which, in the opinion of the investigator, might create undue risk to the participant or interfere with the participant's ability to comply with the protocol requirements.
- Nursing mothers
- Investigational medications within the last 30 days
- Poorly controlled concomitant conditions such as but not limited to obstructive sleep apnea, gastroesophageal reflux disease, chronic sinusitis/rhinitis, hypertension, diabetes where additional therapy/evaluation is required. The significance will be determined by the investigator
- Unwilling or unable to complete visit 1 procedures.
- Unwilling or unable to schedule or complete visit 2