



*SUBPOPULATIONS AND INTERMEDIATE  
OUTCOME MEASURES IN COPD STUDY*

## **Data Access Policy**

## SPIROMICS Overview and Design

### Study Objectives:

The Subpopulations and Intermediate Outcome Measures in COPD Study (SPIROMICS) supports the prospective collection and analysis of phenotypic, biomarker, genetic, genomic, and clinical data from participants with and without chronic obstructive pulmonary disease (COPD) for the purpose of identifying patient subpopulations and surrogate markers for use in future clinical trials. Secondary aims are to clarify the natural history of COPD, to develop bioinformatics resources that will enable the utilization and sharing of data in studies of COPD and related diseases, and to create a collection of clinical, biomarker, radiographic, and genetic data that can be used by external investigators for other studies of COPD.

### Study Design:

SPIROMICS is a cohort study that will enroll approximately 3,200 participants at six clinical centers over three years. Participants will be distributed across four enrollment strata (i.e., Non-smokers, Smokers without COPD, Mild/Moderate COPD, and Severe COPD) as shown in Table 1. All participants will have three study-related visits (Baseline, Follow-up at 1 Year, and Follow-up at 3 Years). During the study visits, clinic staff conduct physical examinations and tests, collect biological specimens (e.g., blood, urine, and sputum), and administer a series of questionnaires to study participants. Participants also receive quarterly follow-up calls to assess health status and determine if an exacerbation has occurred.

**Table 1. SPIROMICS Enrollment Strata**

	<b>Non-Smokers (Stratum 1)</b>	<b>Smokers (Stratum 2)</b>	<b>Mild/Moderate COPD (Stratum 3)</b>	<b>Severe COPD (Stratum 4)</b>
<b>Smoking Status</b>	< 1 pack-year	> 20 pack-years	> 20 pack-years	> 20 pack-years
<b>Bronchodilator Status for Assessing Lung Function</b>	Pre-bronchodilator	Post-bronchodilator	Post-bronchodilator	Post-bronchodilator
FEV <sub>1</sub> /FVC ratio criteria	FEV <sub>1</sub> /FVC > .7	FEV <sub>1</sub> /FVC > .7	FEV <sub>1</sub> /FVC < .7	FEV <sub>1</sub> /FVC < .7
Other Lung Function Criteria	FVC>LLN	FVC>LLN	FEV <sub>1</sub> > 50% pred.	FEV <sub>1</sub> < 50% pred.
<b>Sample Size</b>	N = 200 (6.25%)	N = 600 (18.75%)	N = 1800 (56.25%)	N = 600 (18.72%)

## Data Access Options

There are three avenues for accessing SPIROMICS data:

- 1) Proposing a paper in collaboration with a SPIROMICS investigator
- 2) Proposing an ancillary study
- 3) Requesting access to publically available data

### Proposing a paper in collaboration with a SPIROMICS investigator

To access data by proposing a paper, you must first submit a manuscript proposal form to the SPIROMICS GIC. It is the policy of the SPIROMICS Steering Committee (SC) and its Publications and Presentation Committee (PPC) that all manuscripts and presentations deriving from SPIROMICS data obtained from SPIROMICS participants, including questionnaire, imaging, biomarker, genetics, local and ancillary, be submitted to the committee for scientific review. If necessary, the PPC will also establish priorities for the Genomics and Informatics Center (GIC) to process, analyze, and/or verify data reporting.

All SPIROMICS manuscript or abstract proposals submitted for review must be championed or sponsored by a SPIROMICS Principal Investigator.

Copies of the Publications Policy and the Manuscript Proposal form are available on the study website ([www.spiromics.com](http://www.spiromics.com)) under Publications → Policies and Forms.

A list of the currently available datasets is available on the study website under Obtaining SPIROMICS Data. Requests for datasets for approved manuscripts (i.e., new datasets that are not part of the above referenced list) will be charged a base cost of \$1,000.00. Additional cost may be charged depending on the complexity of the request and the amount of data requested. For more details on dataset preparation costs, please see the SPIROMICS Dataset Reimbursement Cost memo under Obtaining SPIROMICS Data.

### Proposing an ancillary study

To access data by proposing an ancillary study, you must first submit an ancillary study proposal to the SPIROMICS GIC. The SPIROMICS Ancillary Studies Committee, Steering Committee, Monitoring Board, and NHLBI must approve ancillary study proposals prior to submission for funding to ensure that the study:

1. Does not interfere with the main SPIROMICS objectives
2. Has the highest scientific merit
3. Produces the smallest burden on SPIROMICS participants and the least demand on SPIROMICS resources, such as blood samples
4. Requires the unique characteristics of the SPIROMICS cohort
5. Is consistent with and can further the overall goals of SPIROMICS

In addition, priority for studies requesting biological samples will be highest if they:

1. Do not make use of samples from those participants with the fewest samples;
2. Use thawed samples whenever possible;
3. Assays desired can be done on more than one sample type to allow selection of the most abundant type available (e.g. serum or EDTA plasma);
4. Use the smallest sample volume or sample size possible; evidence of attempts to minimize volumes will be examined by relevant subcommittees (e.g., Sputum).
5. Can be integrated with other studies to conserve sample or limit freeze-thaw cycles.

To see a copy of the full ancillary studies policy and form, please look under Ancillary Studies → AS Policies, Forms and Guidelines on the study website ([www.spiromics.com](http://www.spiromics.com)).

#### Requesting access to one of the publically available datasets

Interested investigators may request access to publically available data, which includes summary tables and datasets. A list of the available data is posted on the study website under Obtaining SPIROMICS Data.

In order to request access to summary or individual-level datasets, investigators must first submit a Data Access Request Form outlining the intended use of the dataset. The SPIROMICS Data Sharing Committee will review the request, and, if approved the investigator will need to complete the Publications Embargo Acknowledgement Form and, for individual level datasets, a data materials and distribution agreement (DMDA). Data request forms can be found on the study website under Obtaining SPIROMICS Data.