**ANCILLARY STUDY**



**PROPOSAL AND TRACKING FORM**

FORM CODE: **AST**

VERSION: **1.0 01/16/2024**

0a) Tracking #: **AS**    / **SA**

*Note: Please leave item 0a blank. It will be entered by the GIC staff upon submission review.*

***Instructions:*** *This form is used to facilitate the review and tracking process for ancillary studies and is available on the study website here:* [*Link*](https://www5.cscc.unc.edu/spiromics/ancillary-studies)*. The user guide can be accessed by clicking the link in the top right corner of the screen. If you run into any issues while completing the form and/or have questions, please reach out to Genomics and Informatics Center at UNC Chapel Hill (GIC) staff directly.*

*Note:*

* *Investigators who are not affiliated with SPIROMICS or SOURCE are invited to propose ancillary studies. However, please note that unaffiliated investigators are required to collaborate with a SPIROMICS or SOURCE investigator (aka sponsor). A list of affiliated investigators can be found on the study website as well as the* [*Ancillary Studies Policies and Procedures*](https://www5.cscc.unc.edu/spiromics/sites/default/files/documents/SPIROMICS_SOURCE_Ancillary_Studies_Policies_and_Procedures.pdf) *(of which should be reviewed prior to submission).*
* *Investigators are encouraged to contact the GIC to discuss the proposal before submitting if it involves existing biospecimen use. If blood, DNA, RNA, urine, sputum, or other biospecimens are required, please refer to and review the review criteria section of the* [*Ancillary Studies Policies and Procedures*](https://www5.cscc.unc.edu/spiromics/sites/default/files/documents/SPIROMICS_SOURCE_Ancillary_Studies_Policies_and_Procedures.pdf) *available on the study website (prior to submission).*
* *The Ancillary Studies Committee will request review at relevant committees and working groups before considering approval. Investigators should work with the GIC to schedule discussions with these committees and working groups once the ancillary study is submitted for consideration. This process can take time therefore investigators wishing to obtain approval of an ancillary study should begin the process well in advance of any pending deadlines.*

**Administrative Information**

1) Date of submission:   /   /

2) Associated study (please select all that apply):

2a)  SPIROMICS

2b)  SOURCE

2c)  Other

2c1) If Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3) Research scope (please select one):

COPD research1

Non-COPD research2

Other3

3a) If Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4) Full title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4a) Brief overview of the ancillary study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Note: Please restrict your response in item 4a to 400 characters or less.*

4b) May the proposer last name, ancillary study title, and a brief overview be shared via the cohort’s publicly accessible website?

No0

Yes1

*Note: The proposer last name, ancillary study title, and brief overview will only be posted to the website if approved by the cohort Ancillary Studies and Steering Committees. The details of the proposal will not be shared publicly but only with the cohort committee members for required reviews.*

5) Proposer/Lead investigator name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If not listed in item 5:

5a) First name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5b) Last name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5c) Title (select all that apply):

5c1)  MD

5c2)  DO

5c3)  PhD

5c4)  MPH

5c5)  MS

5c6)  Other

5c6a) If Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5d) Institution or corporation affiliation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5e) Address:

5e1) Address line 1: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5e2) Address line 2: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5e3) City: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5e4) State: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5e5) Zip code:

5f) Phone number: (  )    -

5g) Email address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5h) Sponsoring investigator name (if applicable):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5i) Any collaborating investigator(s)?

No0**→ Go to 6**

Yes1

5i1) Collaborating investigator name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5i2) Collaborating investigator name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5i3) Collaborating investigator name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5i4) Collaborating investigator name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5i5) Collaborating investigator name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5j) Any other collaborating investigator(s) not listed in 5h or 5i1-5i5?

No0**→ Go to 6**

Yes1

5j1) Other collaborating investigator name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5j2) Other collaborating investigator name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5j3) Other collaborating investigator name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5j4) Other collaborating investigator name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5j5) Other collaborating investigator name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

6) Is this ancillary study proposal associated with a grant submission?

No0**→ Go to 7**

Yes1

If Yes:

6a) Grant title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

6b) Grant due date:   /   /

6c) Study start date:   /   /

6d) Study end date:   /   /

7) Are you requesting a Letter of Support to accompany your grant submission?

No0

Yes1

8) Is the NIH the primary funding source?

No0**→ Go to 9**

Yes1

8a) If Yes, what is the grant program and funding mechanism?

K081

K232

KL23

R014

U015

U246

Other7

8a1) If Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Note: If the funding mechanism for your ancillary study is not in the above list, a complete list of grant programs and funding codes can be found here:* [*Link*](https://grants.nih.gov/grants/funding/funding_program.htm)

8b) What is the targeted study section?

Clinical Integrative Cardiovascular and Hematological Sciences (CCHS)1

Cardiovascular Differentiation and Development Study Section (CDD)2

Respiratory Sciences Small Business Activities SEP (RCCS 11)3

Lung Cellular, Molecular, And Immunobiology Study Section (LCMI)4

Lung Injury, Repair, and Remodeling Study Section (LIRR)5

Respiratory Integrative Biology and Translational Research Study Section (RIBT)6

Integrative Myocardial Physiology/Pathophysiology A (MPPA)7

Integrative Myocardial Physiology/Pathophysiology B (MPPB)8

Therapeutic Development and Preclinical Studies (TDPS)9

Other10

8b1) If Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Note: If the targeted study section for your ancillary study is not in the above list, a complete list of study sections can be found here:* [*Link*](https://public.csr.nih.gov/StudySections)

9) Is there another funding source (instead of or in addition to the NIH)?

No0**→ Go to 10**

Yes1

9a) If Yes, please list: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

10) Is this ancillary study currently approved or under review by an Institutional Review Board (IRB) or

equivalent process?

No0**→ Go to 11**

Yes1

10a) If Yes, is the research deemed "Exempt" (defined as research that places subjects at no more than

minimal risk, i.e., the risk one experiences in daily living)?

No0

Yes1

11) Does this ancillary study involve the support or collaboration of a for-profit corporation?

No0**→ Go to 12**

Yes1

11a) If Yes, please describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

12) Estimated direct costs per year (please provide an estimate if final figures are not available):

12a) Year 1: $    ,    ,

12b) Year 2: $    ,    ,

12c) Year 3: $    ,    ,

12d) Year 4: $    ,    ,

12e) Year 5: $    ,    ,

12f) Year 6: $    ,    ,

12g) Year 7: $    ,    ,

12h) Total: $    ,    ,

13) When do you expect to start this ancillary study?

Immediately after ancillary committee approval1

Within 6-12 months after ancillary committee approval2

Only after the proposed study is approved and funded3

Other4

13a) If Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

14) Was this ancillary study presented to a committee(s) and/or working group(s)?

No0 **→ Go to 15**

Yes1

If Yes, please select all committees and/or working groups that the proposal was presented to:

14a)  Bronchoscopy

14b)  Data Quality

14c)  Exacerbation

14d)  Genetics, Genomics, and Biomarkers

14e)  Imaging

14f)  Physiology

14g)  Social and Environmental Exposures

14h)  Other

14h1) If Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Data & Analysis Information**

15) Where will the data analysis be performed for this ancillary study? (please select one)

Data Coordinating Center at UNC Chapel Hill1

Other data coordinating center2

Study site3

Other4

15a) If Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

16) Does the ancillary study only require use of existing data, and therefore no additional participant contact/

data collection will be required?

No0**→ Go to 17**

Yes1

If Yes, please select all existing data required for this ancillary study:

16a)  SPIROMICS Baseline / Visit 1

16b)  SPIROMICS Visit 2

16c)  SPIROMICS Visit 3

16d)  SPIROMICS Visit 4

16e)  SPIROMICS Visit 5

16f)  SPIROMICS I Exacerbation Substudy

16g)  SPIROMICS II Visit 5 Exacerbation Substudy

16h)  SPIROMICS I Bronchoscopy Substudy

16i)  SPIROMICS II Visit 5 Bronchoscopy Substudy

16j)  SPIROMICS I Repeatability Substudy

16k)  SPIROMICS I Endpoints Substudy

16l)  SPIROMICS II Visit 5 Heart Failure Ancillary Study

16m)  SPIROMICS II Visit 5 C4R Ancillary Study

16n)  SPIROMICS GWAS

16o)  SPIROMICS TOPMed sequencing

16p)  SPIROMICS Metabolomics

16q)  SOURCE Baseline / Visit 1

16r)  SOURCE 18 Month / Visit 2

16s)  SOURCE 3 Year / Visit 3

16t)  SOURCE Bronchoscopy Substudy

16u)  SPIROMICS Ancillary Study

16u1) If SPIROMICS Ancillary Study data, please specify:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

16v)  SOURCE Ancillary Study

16v1) If SOURCE Ancillary Study data, please specify:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

16w)  Other

16w1) If Other, please specify:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

17) Will existing biospecimens be requested as part of this ancillary study?

No0**→ Go to 18**

Yes1

If Yes, please select all that apply:

17a)  Sputum

17b)  DNA

17c)  RNA

17d)  Whole Blood

17e)  Plasma

17f)  Serum

17g)  Urine

17h)  Hair

17i)  Nasal

17j)  Buccal

17k)  Exhaled breath condensate

17l)  Stool

17m)  Other

17m1) If Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

18) Will existing scans, tapes, digital images, tracings, etc. from the Imaging, Echo, or MRI Reading Centers

be requested and analyzed as part of this ancillary study?

No0**→ Go to 19**

Yes1

If Yes, please select all that apply:

18a)  CT

18b)  Echo

18c)  MRI

19) Will the analysis of previously collected data/biospecimens/images result in new data?

No0

Yes1

20) Could the analysis be done on data/biospecimens/images from an alternate time point?

No0

Yes1

**Genetic Information (defined as any data from a participant’s DNA or RNA):**

21) Will existing genetic and genomic data be used in this ancillary study?

No0 **→ Go to 22**

Yes1

21a) Will this ancillary study use existing DNA or RNA samples to produce new sequence data?

No0

Yes1

*Note: If Yes, please note that we do not have consent to post to an open access database such as GEO. We only have consent to post these data to a controlled access database such as dbGaP and TOPMed.*

21b) Will this ancillary study use genetic information to address a primary aim or secondary aim of SPIROMICS or SOURCE? (please select all that apply)

21b1)  Primary aim (lung disease)

21b2)  Secondary aim (other health conditions)

21c) Will this ancillary study a gene with clear clinical implications?

No0 **→ Go to 22**

Yes1

21c1) If Yes, what are the implications/treatments associated with the genetics of this gene

and the expected frequencies of the affected individuals? Please note, that our consent does not allow report of any genetic data back to the participants, but clinically actionable genetic variation should be carefully considered on a case-by-case basis, consulting local IRB guidelines: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

22) Will the ancillary study findings have clinical implications?

No0 **→ Go to 23**

Yes1

22a) If Yes, describe the plan for reporting results to participants and providing recommendations for

follow-up: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

23) Is it your intent to use the ancillary study data to patent any process, aspect, or outcome of the analysis?

No0 **→ Go to 24**

Yes1

23a) If Yes, describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**New Data Collection**

*Note: If this ancillary study poses any burden to the participants, the clinical centers, the Reading Centers, the Data Coordinating Center at UNC Chapel Hill, or the Biospecimen Repository, please provide specifics about the expected burden as requested below.*

24) Will participants be contacted, interviewed, or examined?

No0**→ Go to 25**

Yes1

24a) Explicitly state the size and any special characteristics of the desired cohort: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

24b) Will this ancillary study require informed consent from the participants?

No0**→ Go to 24c**

Yes1

24b1) If Yes, describe participant involvement and estimate the time required of each

participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

24c) Will participants be asked to complete questionnaire(s)?

No0

Yes1

25) Will participants be asked to donate biospecimen(s)?

No0**→ Go to 26**

Yes1

If Yes, select all that apply:

25a)  Sputum

25b)  DNA

25c)  RNA

25d)  Whole Blood

25e)  Plasma

25f)  Serum

25g)  Urine

25h)  Hair

25i)  Nasal

25j)  Buccal

25k)  Exhaled breath condensate

25l)  Stool

25m)  Other

25m1) If Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

26) Will participants be asked to complete imaging studies?

No0**→ Go to 27**

Yes1

If Yes, please select all that apply:

26a)  CT

26b)  Echo

26c)  MRI

26d)  Other

26d1) If Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

27) Will participants be exposed to any ionizing radiation (e.g., from a CT scan)?

No0**→ Go to 28**

Yes1

27a) If Yes, describe the dose in mAs, efforts to minimize dose, and briefly summarize the

specifics of the protocol: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

28) Will participants be asked to complete additional study procedure(s)?

No0**→ Go to 29**

Yes1

If Yes, please select all that apply:

28a)  Oscillometry

28b)  Spirometry

28c)  Other

28c1) If Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

29) Does this ancillary study meet the definition of a clinical trial – as defined by the NIH: "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."?

No0

Yes1

30) Have clinical center PIs already agreed to participate in this ancillary study?

No0**→ Go to 31**

Yes1

30a) If Yes, please provide justification if not including all active clinical centers (if applicable):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

31) Will this ancillary study require Data Coordinating Center (DCC) at UNC Chapel Hill services?

No0**→ Go to 32**

Yes1

If Yes, select all that apply for work that will be done at or through the DCC:

31a)  Biospecimen sample selection and transfer

31b)  Data set preparation

31c)  Consultation

31d)  Statistical analyses

31e)  Data collection form design

31f)  Data management system (CDART) programming (e.g., forms, reports, queries)

31g)  Data quality assurance and compliance

31h)  Receipt of reading center data for dataset creation, storage, and dissemination

31i)  Regulatory type work (e.g., IRB, protocols, consents, etc.)

31j)  Other

31j1) If Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

32) How many manuscripts do you estimate will be written from this ancillary study?

***Instructions:*** *Please attach a brief description of the proposed ancillary study using the* [*Ancillary Study Proposal Abstract Template*](https://www5.cscc.unc.edu/spiromics/ancillary-studies)*. In addition, please attach all relevant files including MS Word and/or PDF versions of the ancillary study proposal, figures, tables, slide presentation, poster, etc. for review. Information on how to attach files can be found in the user guide linked in the top right corner.*

Attached files

**END OF FORM**

*Note: Please leave items 33 and 34 blank. They will be entered by the GIC staff upon submission review.*

33) Ancillary Studies Committee decision:

Not Approved0→ **Go to 33a; then, Go to End**

Withdrawn1→ **Go to 33a; then, Go to End**

Revise & Resubmit2→ **Go to 33a; then, Go to End**

Approved3→ **Go to 33b; then, Go to 34**

33a) Date of review:   /   /

33b) Date of approval:   /   /

34) Steering Committee decision:

Not Approved0→ **Go to 34a; then, Go to End**

Withdrawn1→ **Go to 34a; then, Go to End**

Revise & Resubmit2→ **Go to 34a; then, Go to End**

Approved2→ **Go to 34b**

34a) Date of review:   /   /

34b) Date of approval:   /   /