Ancillary Studies Policies and Procedures

Ancillary Studies are managed by the COPDGene® Ancillary Studies and Publications Committee.

COPDGene® Ancillary Studies and Publications Committee

James Crapo, MD, Co-Chair
John Hokanson, PhD, Co-Chair
Jeffrey Curtis, MD
Dawn DeMeo, MD
Mark Dransfield, MD
Doug Everett, PhD
Marilyn Foreman, MD
MeiLan Han, MD, MS
Craig Hersh, MD
Victor Kim, MD
David Lynch, MD
Barry Make, MD
Elizabeth Regan, MD, PhD
Edwin Silverman, MD, PhD
Matt Strand, PhD
Executive Secretary: Sara Penchev
Staff: Carla Wilson

Mission:

The mission of the COPDGene Ancillary Studies and Publications Committee is to facilitate research using the COPDGene cohort and to facilitate the rapid publication and presentation of the highest quality research from the COPDGene investigator teams.

This Policies and procedures document will include the following appendices:

- Appendix A – COPDGene Ancillary Study Proposal Requirements
- Appendix B – Data Sharing and Access Policy, Data Request Form, and Data Access Investigator Certification Form
- Appendix C – Biospecimen Request Form & Biospecimen Request Investigator Certification
- Appendix D – Ancillary Studies Investigator Annual Progress Report

Definition of an Ancillary Study:

A COPDGene ancillary study is one that extends research questions or resources beyond that in the original program. Several types of ancillary studies will be included:

1. Analytical Ancillary Studies: Additional analyses of the main study data, which are not included in the main analyses of the study;
2. Supplemental Ancillary Studies: Use of COPDGene study data from one or more clinical centers in concert with additional data collection at those clinical centers on their study participants

3. Related Ancillary Studies: Ongoing studies that include COPDGene study participants at Clinical Centers that may overlap with main study goals (e.g., candidate gene studies, radiology studies).

All three of these types of ancillary studies will require review and approval by the Ancillary Studies and Publications Committee. It may be done as a component of the primary COPDGene funding or may derive funding from other than COPDGene funds.

Examples include studies funded by investigator-initiated NIH research awards (R01s), grants from academic institutions, private sources (e.g., drug companies), or those performed at no cost (generally because of the special interest of a researcher). Ancillary studies involve the collection of new data, either directly from participants or from previously collected samples, images, or other sources (e.g., medical records).

Philosophy:

Investigators individually and collaboratively are encouraged to propose and conduct ancillary studies. Such studies enhance the value of COPDGene and ensure the continued interest of the diverse group of investigators who are critical to the successes of the study as a whole. They provide an exceptional opportunity for investigators, both within and outside of COPDGene, to conduct additional projects at minimal cost.

At each level of review, highest priority will be given to studies that:

1. Do not interfere with the main COPDGene objectives
2. Have the highest scientific merit
3. Produce the smallest burden on COPDGene participants and the least demand on COPDGene resources, such as blood samples
4. Demonstrate willingness to follow the COPDGene guideline for data sharing
5. Have the potential to develop new sources of funding to exploit the opportunities created by the COPDGene core program
6. Require the unique characteristics of the COPDGene cohort
7. Demonstrate a feasible plan for funding additional costs of the study.

Necessary Approvals:

The COPDGene Ancillary Studies and Publications Committee and Executive Committee must approve ancillary study proposals prior to implementation. The COPDGene Ancillary Studies and Publications Committee provides initial review and makes recommendations to the Executive Committee. Once an ancillary study is approved, the investigator will receive an approval letter from the Executive Secretary of the Ancillary Studies and Publications Committee. All approved COPDGene Ancillary Studies are tracked and a list is available on the COPDGene website: https://dccweb.njhealth.org/sec/COPDGene/rptAncillaryStudies.cfm.

Responsibilities of Ancillary Study Investigators:

1. Costs: The investigator applying for an ancillary study may be required to provide the additional funds required to conduct the study. The Executive Committee will determine

whether or not proposed ancillary studies can be supported in whole or in part by the COPDGene primary study resources. The Ancillary Studies and Publications Committee and the Executive Committee will be concerned with both the obvious and the hidden costs to COPDGene entailed by an ancillary study (such as costs to the Data Coordinating Center for coordinating the additional data collection, costs to Clinical Centers, and costs to our Biological Repository for retrieving samples, etc). The costs associated with the transfer of data and/or Biospecimens are the responsibility of the requestor. Cost estimates can be provided prior to submission of the proposal.

2. Additional Funding: PIs who plan to propose an ancillary study with the intention of seeking grant funding should consult with the COPDGene Administrative Core to determine what level of involvement will be required of the COPDGene Program and the associated costs. In general, this will result in a subcontract proposal to be included in the PI's grant application. COPDGene will provide a letter of support when requested, for investigators applying for funding.
3. Confidentiality and Identification of COPDGene Participants: Confidentiality of individually identifiable data about COPDGene participants must be assured. As a general rule, no personal identification of participants will be provided to ancillary studies staff. There are no assurances that participants will be able to be identified and contacted in the future for the purposes of an ancillary study.
4. Clinical Implications of Findings: The proposing investigator must clearly delineate any findings of clinical significance that may result from the study, including genetic findings, and propose how these will be handled, including reporting to participants and their physicians and providing recommendations for follow up. This includes incidental findings, such as pathology identified from an imaging study that is not the focus of the study.
5. Genetic Studies: Ancillary studies should complement and not overlap with the primary research goals of the COPDGene study.
6. Inclusion of COPDGene Investigator(s): A COPDGene investigator must be included as a co-investigator on an ancillary study. This individual is responsible for presenting the study to the Ancillary Studies and Publications Committee, monitoring the study to assure continuing compatibility with COPDGene and serving as a liaison to the COPDGene Ancillary Studies and Publications Committee. In addition, each manuscript and abstract is expected to include a COPDGene investigator.
7. IRB Approval: The appropriate institution review boards must approve all ancillary studies before they are performed. IRB approval is not required to submit a proposal for an ancillary study to COPDGene.
8. Final Application or Proposal: For ancillary studies involving a new grant application, a copy of the final proposal as submitted for funding should be sent to the COPDGene Administrative Core.
9. Industry Participation: Proposals for industry sponsorship or collaboration are encouraged. It will be the responsibility of the PI of the ancillary study to obtain agreement through an appropriate contractual mechanism that all data relevant to the COPDGene ancillary study will follow the open access and data sharing policies of COPDGene.

10. Status Reports: The ancillary study PI is responsible to keep the COPDGene Administrative Core apprised of major developments in the life of the application or proposal, including success of funding, start date, changes in protocol, completion and any resulting publications or presentations. Please see Appendix D- Ancillary Studies Investigator Annual Progress Report.
11. Review of Publications and Presentations: Manuscript proposals based on approved ancillary studies should be submitted to and approved by the COPDGene Ancillary Studies and Publications Committee. All publications, presentations and abstracts from an approved ancillary study should be reviewed and approved by the COPDGene Ancillary Studies and Publications Committee prior to submission or presentation, in accordance with the COPDGene general rules for publications and presentations and the COPDGene Publications Policies and Procedures document.
12. Termination of Ancillary Study: The Executive Committee by majority vote may terminate an ancillary study if it judges that the study has become too burdensome, its scientific value has diminished, or it has failed to make substantial progress toward completion of its goals.

COPDGene Ancillary Study Review Procedures

1. Principal Investigator should submit the ancillary study proposal to the COPDGene Administrative Core Executive Secretary (c/o Sara Penchev, PenchevS@NJHealth.org). The Ancillary Studies Policies and Procedures will be posted on the open access portion of our study web site:

   https://dccweb.njhealth.org/sec/COPDGene/Ancillary.cfm

   Questions should be directed to the COPDGene Administrative Core (c/o Sara Penchev).

   Ancillary Study meetings will be scheduled the first and third Thursday of every month. Complete proposal forms (including Data and Biospecimens requests) should be sent to the Executive Secretary no later than the Monday before each meeting.

   COPDGene website access will be needed to access the policies and access form. If one does not have website access, the COPDGene sponsor of the proposal may submit the form on the requester's behalf.

   Prior to submitting a proposal, investigators should access the below website to search title key words to identify potential for overlap:

   https://dccweb.njhealth.org/sec/COPDGene/ListAncillaryStudies.cfm

   To search the list, select Control+F on your keyboard and search key words individually.
2. The COPDGene Administrative Core will conduct an initial review of proposals for administrative compliance and to determine involvement of other COPDGene Centers. If the proposal is not complete, it will be returned by e-mail to the investigator for revision and resubmission.
3. The COPDGene Administrative Core will forward the proposal by e-mail to the COPDGene Ancillary Studies and Publications Committee and to relevant COPDGene

centers and/or committees with the meeting agenda on the Monday prior to the meeting. The chairs of the Ancillary Studies and Publications Committee will review the proposals on a conference call or will handle the review by e-mail.

4. Ancillary Study proposals approved by a majority vote of the Ancillary Studies and Publications Committee will be discussed by the Executive Committee during its regular weekly conference calls. The Ancillary Studies and Publications Committee and/or the Executive Committee may also invite the PI (and/or the PI's COPDGene sponsor) to present the proposal and answer questions and then absent him/herself during the subsequent discussion and voting. Once the Ancillary Study is approved, the Administrative Core Executive Secretary will send an approval letter to the requester.
5. If the proposal requires revisions, the comments of the Ancillary Studies and Publications Committee (and Executive Committee, if applicable) will be sent to the PI. The PI must address these comments in a separate letter that accompanies the revised proposal and send these to the COPDGene Administrative Core Executive Secretary. Revised proposals will be reviewed by the Ancillary Studies and Publications Committee at the next meeting. If approved by the Ancillary Studies and Publications Committee, the revised proposal will go to the Executive Committee where a majority vote will be the basis for a final decision. A proposed ancillary study which is returned for revision will be considered to be withdrawn if a revised proposal is not received within 12 months.
6. Submission and receipt date of all Ancillary Study Proposals will be tracked by the COPDGene Administrative Core. The Administrative Core will also maintain the submission proposal form, approval letter, protocol, and other supporting documents as applicable in a restricted access file depot. A list of all ancillary studies approved by the COPDGene Ancillary Studies and Publications Committee will be maintained on the COPDGene website.
7. **Approval of an Ancillary Study does not automatically include approval of resulting publications. Manuscript proposals for results arising from this ancillary study should be submitted to the COPDGene Ancillary Studies and Publications Committee in accordance with the COPDGene Publications Policies and Procedures.**

APPENDIX A

COPDGene Ancillary Study Proposal Requirements

Submit proposal to the COPDGene Administrative Core (c/o Sara Penchev, PenchevS@NJHealth.org). For scientific and technical questions regarding this application, contact Dr. John Hokanson (john.hokanson@ucdenver.edu).

PART I: Basic Information and Checklist of Key Components

1. Date of Submission:
2. Proposed Title:
3. Proposing Investigator's Name and Contact Information (include email):
4. COPDGene Sponsor (if different from above):
5. Co-author Names and Email Addresses (Note: All proposals will be made available to COPDGene investigators to allow for additional interested co-authors):

6. Have all co-authors reviewed and approved this document? (required):

   ☐ Yes ☐ No

PART II: Description (Please limit this section to 2 pages if possible.)

1. Research Question with Hypothesis and Specific Aims:
2. Research Design – Primary Methods and Procedures to be Employed:
3. Brief Analysis Plan and Methods:
4. Impact on the Main Study. For example:
   a. Burden on study participants
   b. Impact on DCC
   c. Impact on Core resources

5. Number and Name of Clinical Sites to be Involved and Number of Subjects Needed:
6. Projected Costs:
   a. Data Coordinating Center
   b. Imaging Core
   c. Genetics Core
   d. Biorepository
   e. Other
7. Are any Biological Specimens requested? If so, the separate COPDGene Biospecimen Request Form must be completed and also indicate when in the protocol this will be done. Appendix C of this document.

8. Is genetic, imaging or phenotypic data requested? If so, the separate COPDGene Data Request Form must be completed. Appendix B of this document.
9. How will the Ancillary Study be funded?
10. Will data from this study be made publicly available?
11. Will the study use the main COPDGene consent, an amended COPDGene consent, or a separate consent? Attach copy of proposed consent.
12. List and explain all additional data to be collected.

APPENDIX B

Data Sharing and Access Policy

Genetic, Imaging and Phenotype Data on the COPDGene Cohort

Access to and use of the COPDGene data requires protection of the confidentiality of the subjects and assurance of scientific integrity with regard to the use of the data. COPDGene data can be accessed through dbGaP and also can be directly accessed through collaboration with COPDGene investigators. An institution, company or investigator who seeks access to the COPDGene data directly from the COPDGene Investigators will be required to agree to the following:

1. All data (genetic, imaging and phenotype) obtained from COPDGene will be used in a manner that protects the privacy and confidentiality of the participant subjects. No attempt will be made to identify subjects or link data to personal information that is readily identifiable or to contact COPDGene subjects in relationship to genetic, imaging or phenotype data.
2. Analysis of the COPDGene data will be limited to conformance with the consent groups for genetic studies. Some COPDGene subjects have agreed to allow use of their genetic information into any disease, while others limited their sample use to smoking-related disorders.
3. The data will not be distributed to other individuals without approval from COPDGene.
4. The data will be treated confidentially, physically secured, and will not be directly accessible from the internet. Authorized users will adhere to information technology practices in all aspects of data management to assure that only authorized individuals can gain access to the COPDGene data sets.
5. The data must be destroyed if requested by the COPDGene Executive Committee. It is understood that this applies to the original COPDGene data; it does not apply to new, appropriately de-identified data that may be generated.
6. The COPDGene Executive Committee will be notified within twenty-four (24) hours of the user becoming aware that there has been any unauthorized data sharing, breaches of data security, or inadvertent data releases that may compromise data confidentiality.
7. Manuscripts resulting from COPDGene data must be submitted for approval by the COPDGene Executive Committee prior to publication or presentation at public meetings.
8. The COPDGene data, in whole or in part, may not be sold to any individual at any point in time for any purpose.
9. An investigator may not move the COPDGene data from one institution or company to another, in whole or in part, without the written approval of the COPDGene Executive Committee.
10. Use of COPDGene data on portable media, such as a CD, flash drive, or laptop, is discouraged. A limited data set (containing subject identifiers) must be encrypted when stored on a portable device.

Data Request Form

Send Data Request Form to: Elizabeth Regan, MD, PhD, Associate Director of COPDGene: ReganE@NJHealth.org

* The costs associated with the transfer of data are the responsibility of the requestor. Cost estimates can be provided prior to submission of the proposal.

Investigator: _____
Date: _____
Title of Ancillary Study: _____
Ancillary Study Number: _____

☐ Smoking-related disease study ☐ Other Disease(s) not related to smoking

Subject Selection (check one or more)

☐ Phase 1 Final Analysis Primary 10,300

☐ Exclusionary Disease: ILD & Bronchiectasis (n=64)

Or Specific GOLD classification

- ☐ GOLD 0 – Smoker Controls (n=4388)
- ☐ GOLD 1 (n=794)
- ☐ GOLD 2 (n=1922)
- ☐ GOLD 3 (n=1162)
- ☐ GOLD 4 (n=606)
- ☐ GOLD Unclassified (n=1257)
- ☐ Nonsmoker Normals (n=108)

☐ Match predefined subject list (attach .csv, .xls, etc.)

☐ Custom criteria (ex. "if percent Emphysema > 40%") Specify in Additional Comments.

☐ Phase 2 First 2000, P1-P2

Output File Format

☐ SAS ☐ JMP ☐ Tab-delimited TXT

Phenotypic Data

☐ Visit 1 Phenotype data

☐ Longitudinal Periodic Phone/Web Surveys, collapsed to subject-level, n-8690+

Genetic Data

☐ COPDGene GWAS, PLINK format (9970 subjects, file size= 1.5GB)

☐ GWAS with Imputed Data, PLINK format (10146 subjects, file size=138.5 GB)

☐ Exome Chip (2313 subjects, file size=145 MB)

☐ Exome Sequencing

To reduce file size on GWAS or Imputed data, you can request specific SNPs and/or chromosomes:
Specific Chromosome _____
Specific SNPs and/or region _____

Imaging Data

☐ CT Scans (file size approx.. 0.3 GB per subject/series/reconstruction)

- ☐ Inspiratory
- ☐ Expiratory
- ☐ Standard Reconstruction
- ☐ Sharp Reconstruction

☐ Quantitative Data

- ☐ Lung volume, Percent below thresholds, Mean attenuation (Histo)
- ☐ Lobar data, as above
- ☐ Airway measurements- Inspiratory only, unless Expiratory is specified (limited)(
- ☐ LAC

Additional Requests/Comments:

All data to be sent will be de-identified unless a limited dataset request has been approved and data use agreements are signed.

Request for a Limited Data Set (containing subject identifiers/dates)		
	IRB Approved Protocol	**Data Use Agreement**
Genetic Data		
Imaging Data		
Phenotypic Data		

Method of data transfer: Total size of files will impact possible methods. Total size < 8 GB can be transferred via secure SFTP. *CT scans will require the requestor to supply a portable hard drive.*

Name and Email Address for Data Recipients:

Data Access
Investigator Certification Form
Required prior to transfer of data.

Title of Study: _____

Ancillary Study Number _____ (assigned by COPDGene)

Principal Investigator: _____

COPDGene and _____ (Name of Principal Investigator) hereby enter into this Distribution Agreement.

Investigator: _____, whose principal affiliation is with _____, requests access to Study Data and/or Materials.

1. Confidentiality and Privacy of Subjects

I certify that all data (genetic, imaging, phenotypic) obtained from COPDGene will be used in a manner that protects the privacy and confidentiality of the participant subjects. No attempt will be made to identify subjects, to link specimens or data to personal information that is readily identifiable, or to contact COPDGene subjects in relation to the specimens, CT images or data.

2. Restricted Use of Data

I certify that all data obtained from COPDGene will be used for research purposes only, at this institution only, and only for the analyses described in this request. Also, the data will not be allowed to come into the possession of any other persons except those engaged in research under my direct supervision who accept these restrictions.

This Agreement is not transferable. Recipient agrees that substantive changes made to the Research Project described above, and/or appointment by Recipient of another Investigator to complete the Research Project, require execution of a new Agreement in which the new Investigator and/or new Research Project are designated.

3. Publications and Acknowledgement of COPDGene Support

I agree to follow the COPDGene Publications Policies and Procedures for publications incorporating data arising from use of the COPDGene database and to acknowledge COPDGene in all publications and presentations of studies utilizing data from COPDGene.

4. Recipient's Resulting Data to be Provided to COPDGene DCC

I agree to provide newly created analytic variables derived from the COPDGene data set to the COPDGene DCC for incorporation into the general data set. Use of new Data generated solely by the Research Project from Data distributed by COPDGene will be restricted for use by the Collaborating Investigator for 12 months after the completion of the Research Project unless other arrangements are mutually agreed upon. After 12 months, the Data generated by the Research Project will be available to all COPDGene Investigators. The COPDGene Investigator(s) agree to acknowledge the contribution of the Collaborating Investigator(s) who generated the Data from the Research Project in any and all oral and written presentations,

disclosures, and publications resulting from any and all analyses of Data generated by the Research Project under this agreement. The COPDGene Investigator will acknowledge Collaborating Investigator(s) as co-authors, as appropriate, on any publication.

5. Reporting Requirements

Recipient agrees to provide an annual report to COPDGene using the Ancillary Study Investigator Annual Progress Report Form.

6. Protection of Limited Data Sets

I certify that all limited data sets obtained from COPDGene will be properly stored, encrypted and password protected at all times and deleted after the analyses described in this request have been completed.

Requesting Investigator

Signature by the Requesting Investigator is documentation of agreement with Items 1 through 6 above.	
Signature:	Date:
Printed Name:	
Title:	
Telephone:	
E-mail address:	

APPENDIX C

Biospecimen Request Form

*The costs associated with the transfer of biospecimens are the responsibility of the requestor. Cost estimates can be provided prior to submission of the proposal.

Investigator: _____

Date: _____

Title of Ancillary Study: _____

Ancillary Study Number _____ (assigned by COPDGene)

Biospecimens – Plasma/Serum							
	GOLD Stage	**Number of Patients**	**Previously thawed acceptable ?**	**Volume requested**	**Other Inclusion/ Exclusion Criteria**	**Visit 1**	**Visit 2**
☐ **Serum**	U □						
	0 □						
	1 □						
	2 □						
	3 □						
	4 □						
	Any□						
☐ **Plasma**	U □						
	0 □						
	1 □						
	2 □						
	3 □						
	4 □						
	Any□						

Biospecimens – DNA						
	GOLD Stage	**Number of Patients**	**Plates or Tubes**	**Quantity Requested (µg)**	**Concentration Requested (ng/µl)**	**Other Inclusion/ Exclusion Criteria**
☐ **DNA**	U □					
	0 □					
	1 □					
	2 □					
	3 □					
	4 □					
	Any□					

Additional Requests/Comments:

Ship to Address:

_____

_____

_____

Biospecimen Request Investigator Certification

Required prior to shipment of specimens

Title of Study: _____
Principal Investigator: _____
NIH Grant Number (if relevant): _____

COPDGene and _____ (Name of Principal Investigator) hereby enter into this Distribution Agreement.

Investigator: _____, whose principal affiliation is with _____, requests access to Study Data and/or Materials.

1. Confidentiality and Privacy of Tissue Donor Subjects

I certify that all specimens, images and data obtained from COPDGene will be used in a manner that protects the privacy and confidentiality of the participant subjects. No attempt will be made to identify subjects, to link specimens or data to personal information that is readily identifiable, or to contact COPDGene subjects in relation to the specimens, CT images or data.

2. Restricted Use of Biological Specimens and Data

I certify that all specimens, images and data obtained from COPDGene, and any materials derived from said specimens, will be used for research purposes only, in my laboratory only, at this institution only, and only for the experiments described in this request (see Appendix II). Also, the specimens or material derived from them and the individual-level data will not be allowed to come into the possession of any other persons except those engaged in research under my direct supervision who accept these restrictions. Recipient agrees that Biological Materials, their progeny, or unmodified or modified derivatives thereof will not be used in human experimentation of any kind.

This Distribution Agreement is not transferable. Recipient agrees that substantive changes made to the Research Project described above, and/or appointment by Recipient of another Investigator to complete the Research Project, require execution of a new Distribution Agreement in which the new Investigator and/or new Research Project are designated.

3. Publications and Acknowledgement of COPDGene Support

I agree to follow the COPDGene Publications Policies and Procedures for publications incorporating data arising from use of the COPDGene biological specimens requested and to acknowledge COPDGene in all publications and presentations utilizing specimens or data from COPDGene.

4. Annual Report

I agree to provide an Annual Progress Report regarding my use of the COPDGene biological specimens.

5. Biosafety

I am aware that all specimens distributed by the Biorepository may be infectious and potentially biohazardous. I understand that the requested specimens may pose health risks to persons handling or in the vicinity of the specimens, the environment, and the community. I certify that I

am cognizant of and will employ the appropriate biosafety standards including special practices, equipment, and facilities and will comply with all applicable institution policies and state and federal government health and safety regulations. I will also directly supervise all users of the specimens and will assure that those users are cognizant of and comply with safety standards and good laboratory practices.

6. Recipient's Resulting Data to be Provided to COPDGene DCC

Recipient agrees to provide the DCC or designee copies of all Data, including Genetic Analysis Data, which are developed based on the biologic specimens distributed by COPDGene, within 12 months of its collection unless other arrangements are mutually agreed upon.

Use of Data or Materials generated solely by the Research Project from biologic specimens distributed by COPDGene will be restricted for use by the Collaborating Investigator for 12 months after the completion of the Research Project unless other arrangements are mutually agreed upon. After 12 months, the Data and Materials generated by the Research Project will be available to all COPDGene Investigators. The COPDGene Investigator(s) agrees to acknowledge the contribution of the Collaborating Investigator(s) who generated the Data and Materials from the Research Project in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data or Materials generated by the Research Project under this agreement. The COPDGene Investigator will acknowledge Collaborating Investigator(s) or designee as co-authors, as appropriate, on any publication.

7. Costs

Cost for distribution of Biological and other Materials, including DNA, will be determined by the appropriate COPDGene laboratory and should be covered by the investigator.

8. Return or Destruction of Specimens

I certify that all specimens obtained from COPDGene, and any materials derived from said specimens, will be returned to the COPDGene Biorepository or, if approved by the COPDGene Executive Committee, destroyed after the experiments described in this request have been completed and no additional studies utilizing the same tissues will be performed without review of the new study by the COPDGene Executive Committee.

Requesting Investigator

Signature by the Requesting Investigator is documentation of agreement with Items 1 through 8 above.	
Signature:	Date:
Printed Name:	
Title:	
Telephone:	
E-mail address:	

APPENDIX D

Ancillary Study Investigator Annual Progress Report

Will be incorporated into annual IRB report if biological specimens or a limited dataset are part of this ancillary study.

Investigator: _____

Title of Ancillary Study: _____

Ancillary Study Number: _____ (assigned by COPDGene)

Please send this report and direct any questions to:

Elizabeth Regan, M.D., Ph.D., Associate Director, COPDGene, at ReganE@njhealth.org

Date Specimens/Data Received: _____
Date of This Report: _____

PROGRESS ON ANALYSES

	None	In Preparation	Submitted	Accepted*
Presentations	☐	☐	☐	☐
Publications	☐	☐	☐	☐

*If accepted, please send the citation and a paper copy or reprint (pdf) to the Administrative Core.

Brief Summary of Progress:

Signature:	Date:
Printed Name:	
Title:	
Telephone	
E-mail address:	