PROTOCOL =STEPIPF
STUDYBOOK=DATA_FORMS
FORM=SCREENING

NODATA<XYES>

STEP-IPF IPFnet

Screening/History

Autoenroll SUBJNO = CTSITEPROC.RANDO_ENROLL.STUDYNO with '-' between 2nd and 3rd char and between 5th and 6th where KIT_NUMBER='3'

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) INVSITE

Subject Initials: ___ ___ ___ INITIALS

Note: INITIALS is not populated in RANDO_ENROLL. Set to enter on first page, and then populate through all pages/panels. Not verified.

Informed Consent

1 Date informed consent signed: ___/___/___ (day/month/year) CONSNTDT

2 Did subject grant permission to have his/her biological samples stored in the biospecimen repository? ..... BLDSAMPL<XYESNO> ICONSENT (TYPE 1)

☐0 No ☐1 Yes →

If Yes: Date research sample consent signed: ___/___/___ (day/month/year) BLDSAMDT

If Yes: Answer all questions below *(If not included in Consent, mark NA)*:

i Blood and biologic specimens for future use by the approved investigators in studies of pulmonary fibrosis? ..... ☐0 No ☐1 Yes ☐96 NA SPEC2I<IPFYNA>

ii Blood and biologic specimens to be used for other approved research? ..... ☐0 No ☐1 Yes ☐96 NA SPEC2II<IPFYNA>

See Next Page

Demographics

1 Date of birth: ___/___/___ (day/month/year) DOBDT DEMOG (TYPE 1)

2 Sex: ☐1 Male ☐2 Female SEX<XGENDR>

3 Ethnicity *(check only one)*: ☐1 Hispanic or Latino ☐2 Not Hispanic or Latino ETHNIC<XETHN>

4 Race *(check all that apply)*:

☐ American Indian or Alaska Native AMERIND<XYES>
☐ Asian ASIAN<XYES>
☐ Black or African American BLACK<XYES>
☐ Native Hawaiian or other Pacific Islander NATHWN<XYES>
☐ White WHITE<XYES>
☐ Other *(specify)*: _____ OTHRACE<XYES> RACESP<V:50>

Childbearing Potential (Complete for female subjects only)

Female of childbearing potential? CHILDPOT (TYPE 1)

☐0 No → If No: Provide reason *(check only one)*: ☐1 Hysterectomy ☐ Post-menopausal *(natural [12 consecutive months])* ☐2 Tubal ligation ☐98 Other *(specify)*: _____ NOCBPOT<IPFNCH> NOCBSP<V:50>

☐1 Yes CBPOT<XYESNO>

Smoking History

1 Does the subject have any history of smoking? ☐0 No → If No: Skip to next section. ☐1 Yes → If Yes: Answer questions below. SMOKING<XYESNO> SMKHIST (TYPE1)

2 Is the subject: *(check one)* ☐1 Past smoker → Date subject last smoked: ___/___/___ (month/year) PASTCURR<IPFSMK> SMOKEM<ZMONTH> SMOKEY<I:4>

☐2 Current smoker

3 How many total years has the subject smoked? ___ years SMKYEARS<F:9:3>

4 On average during that time, how many packs *(or equivalents)* per day of cigarettes did the subject smoke?

___ . ___ ___ packs per day SMOKPK<F:9.3>

Site Personnel's Initials: ___ ___ ___

Note on CRF page 1:

Version 2 of the CRF changes the response set for Informed Consent, question 2. The original response set must be maintained. Screen should allow both sets of responses:

For CRF version 2.0 16NOV2007:
(Question 2 i, ii as on annotation page 1)

For CRF version 1.0 24JUL2007
(Question 2 a,b,c,d,e as below)

a. Blood and biologic specimens for future use in pulmonary fibrosis studies SPEC2A<IPFYNA>

b. Blood and biologic specimens to be examined for inherited IPF factors SPEC2B<IPFYNA>

c. Blood and biologic specimens for use in developing improved IPF treatments SPEC2C<IPFYNA>

d. Blood and biologic specimens for use in research about other health problems SPEC2D<IPFYNA>

e. Permission to use these biologic samples in research, even after subject's death SPEC2E<IPFYNA>

STEP-IPF IPFnet

NODATA<XYES>

Screening/History

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Disease History

DISHIST (TYPE 1)

IPFCT<XYESNO>

1 Did subject have a CT consistent with diagnosis of IPF prior to consent?
- ☐ 0 No
- ☐ 1 Yes → If Yes: Date *(If multiple, provide earliest)*: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) DCTDT

2 Did subject have a surgical lung biopsy consistent with diagnosis of IPF prior to consent?
- ☐ 0 No IPFBIOP<XYESNO>
- ☐ 1 Yes → If Yes: Date *(If multiple, provide earliest)*: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) DBIOPDT

Screening Spirometry

SPIROMET (TYPE 4)

Date of assessment: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SPIRDT

Pre bronchodilator:

1 FEV_1: Actual: ___ . ___ ___ liters FEV1 <F:9:3>

2 FEV_6: Actual: ___ . ___ ___ liters FEV6 <F:9:3>

3 FVC: Actual: ___ . ___ ___ liters FVC <F:9:3>

Post bronchodilator:

4 FEV_1: Actual: ___ . ___ ___ liters PSTFEV1 <F:9:3>

5 FEV_6: Actual: ___ . ___ ___ liters PSTFEV6 <F:9:3>

6 FVC: Actual: ___ . ___ ___ liters PSTFVC<F:9:3>

Screening Echo

ECHO (TYPE 1)

1 Date of assessment: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ECHODT

2 Ejection fraction: ___ ___ ___ % EF<F9:3>

3 Right ventricular systolic pressure: ___ ___ . ___ mm Hg RVSP<F9:3>

4 Right ventricular enlargement? ☐ 0 No ☐ 1 Yes ☐ 96 NA RVENLRG<IPFYNA>

5 Right atrial enlargement? ☐ 0 No ☐ 1 Yes ☐ 96 NA RAENLRGL<IPFYNA>

Lung Volume

LGVOLUME (TYPE 1)

Date of assessment: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) LUNGVLDT

1 Total lung capacity *(TLC)*: ___ . ___ ___ liters TLC<F:9:3>

2 Functional residual capacity *(FRC)*: ___ . ___ ___ liters FRC<F:9:3>

3 Slow vital capacity *(SVC)*: ___ . ___ ___ liters SVC<F:9:3>

STEP-IPF IPFnet

NODATA<XYES>

Screening/History

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Screening 6-Minute Walk Test (6MWT)

Date of assessment: ___ ___ / ___ ___ ___ / ___ ___ (day / month / year) WALKDT WALKTM (See page 10) WALK (TYPE 4)

1 Pre-walk modified Borg Dyspnea Scale rating: PREBORG<IPFBRG><V:3>

0 0 0.5 0.5 1 1 2 2 3 3 4 4 5 5 6 6 7 7 8 8 9 9 10 10 97 97 Not done

2 Resting room air SpO_2: ___ ___ ___ % RESTSPO2<F:9:3>

3 Was supplemental O_2 used during walk? $_0$ No $_1$ Yes → If Yes: Specify: ___ liters/min SUPPLOXY<XYESNO> SUPO2<F9:3> SUPSPO2<F9:3>

SpO_2 on Supplemental O_2 : ___ ___ ___ %

4 Was walk performed? $_0$ No → Provide reason: ___ WLKND<XYESNO> WLKNDSP<V:100>

$_1$ Yes

5 Was a walking aid necessary to perform the 6MWT?

$_0$ No WALKAID<XYESNO>

$_1$ Yes → If Yes: Specify (check only one): $_1$ Cane $_2$ Walker $_{98}$ Other (specify): ___ TYPEAID<IPFAID><I:3> AIDSP<V:100>

WALKTIME (TYPE 4)PS

6 Minutes	Heart Rate	SpO_2
Pre-walk	___ ___ ___ bpm	
1 minute	___ ___ ___ bpm	___ ___ ___ %
2 minutes	___ ___ ___ bpm	___ ___ ___ %
3 minutes	___ ___ ___ bpm	___ ___ ___ %
4 minutes	___ ___ ___ bpm	___ ___ ___ %
5 minutes	___ ___ ___ bpm	___ ___ ___ %
6 minutes	___ ___ ___ bpm	___ ___ ___ %
Three minutes of recovery after completion or stop of 6-Minute Walk Test		
1 minute 1 Minute Post	___ ___ ___ bpm	___ ___ ___ %
2 minutes 2 Minutes Post	___ ___ ___ bpm	___ ___ ___ %
3 minutes 3Minutes Post	___ ___ ___ bpm	___ ___ ___ %

WALKTMTP<IPFTMT><I:3>

0= 1= 2= 3= 4= 5= 6= 7= 8= 9=

WLKHR<I:3>

WLKSPO2<F:9:3>

6 Did subject desaturate ($SpO_2 \leq 88\%$)? $_0$ No DESATURA<XYESNO>

$_1$ Yes → If Yes: Walk duration at desaturation: ___ min / ___ sec DESATMIN<I:3> DESATSEC<I:3>

Walk distance at desaturation: ___ ___ ___ meters DESATDIS<F:9:3>

Lowest SpO_2	Distance Walked	Did Subject Complete 6-Minute Walk?	If Stopped Early: Specify Reason (Check only one)
LOWSPO2<F:9:3> ___ ___ ___ . ___ %	DISTANCE<F:9:3> ___ ___ ___ meters	$_0$ No → If No: WLKMIN<I:3> WLKSEC<I:3> Duration: ___ / ___ (min / sec) $_1$ Yes COMPLWLK<XYESNO>	$_1$ SpO_2 < 80% $_2$ Developed signs and symptoms requiring termination of test $_{98}$ Other (specify): ___ STOPREA<IPFREA><I:3> STPOTHSP<V:100>

7 Post-walk modified Borg Dyspnea Scale rating: POSTBORG<IPFBRG><V:3>

0 0 0.5 0.5 1 1 2 2 3 3 4 4 5 5 6 6 7 7 8 8 9 9 10 10 97 97 Not done

Site Personnel's Initials: ___ ___ ___

WHITE and YELLOW—Duke Clinical Research Institute • PINK—retain at site

STEP_IPF VERSION 7.0 _17SEP2009

NODATA<XYES>

STEP-IPF IPFnet

Screening/History

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

High-Resolution Computed Tomography (HRCT)/Diagnosis of IPF

HRCTDT <DATE>

HRCT (TYPE 1)

Date of HRCT: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

	Clinical Center HRCTINT <IPFHRC><I:3>
1 Interpretation of HRCT *(check only one)*: 3. Inconsistent with IPF (Previous choice) 4. Suggests alternative diagnosis (addition to the code list)	☐ 1 Definite IPF ☐ 2 Consistent with IPF ☐ 4 Suggests alternative diagnosis PULATDIA <F:9:3>
2 Pulmonary artery diameter:	___ . ___ ___ cm AORTADIA <F:9:3>
3 Aorta diameter:	___ . ___ ___ cm LUNGDIST <IPFLNG><I:3>
4 Predominant craniocaudal distribution of abnormality *(check only one)*:	☐ 1 Lower lung ☐ 2 Mid-lung ☐ 3 Upper lung ☐ 4 Diffuse AXDIST <IPFAXL><I:3>
5 Predominant axial distribution *(check only one)*:	☐ 1 Peripheral ☐ 2 Central/peribronchovascular ☐ 3 Diffuse RETICULR <IPFABP>
6 Reticular abnormality:	☐ 0 Absent ☐ 1 Present HONECOMB<IPFABP>
7 Honeycombing:	☐ 0 Absent ☐ 1 Present GRDGLASS <IPFABP>
8 Extensive ground glass abnormality *(extent > reticular abnormality)*:	☐ 0 Absent ☐ 1 Present MICRONDL <IPFABP>
9 Profuse micronodules *(present in upper, mid, and lower lung zones)*:	☐ 0 Absent ☐ 1 Present CYSTS <IPFABP>
10 Discrete cysts *(not in areas of honeycombing)*:	☐ 0 Absent ☐ 1 Present MOSAIC<IPFABP>
11 Mosaic attenuation:	☐ 0 Absent ☐ 1 Present AIRTRAP<IPFABP>
12 Air trapping:	☐ 0 Absent ☐ 1 Present CONSOLID <IPFABP>
13 Consolidation:	☐ 0 Absent ☐ 1 Present

NODATA<XYES>

STEP-IPF IPFnet

Screening/History

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site #, subject #)   Subject Initials: ___ ___ ___

Surgical Lung Biopsy/Diagnosis of IPF

SLBIOP (TYPE 1)

Date of biopsy: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SLBDT <DATE>   ☐97 Not done SLBNODN <XYES>

	Clinical Center	Central	Tie-breaker TBNOTDN <XYES> ☐97 Not done	Adjudication ADJNOTDN <XYES> ☐97 Not done
	CCSCARR <XYES>	CESCARR <XYES>	TBSCARR<XYES>	ADJSCARR <XYES>
1 Criteria for diagnosis of UIP (*check those present*): CCPRES <IPFQUA><I:3>	☐ Clear evidence of scarring, architectural distortion, ± honeycombing CCFIBRO <XYES> ☐ Presence of fibroblast foci → If Present: Check quantity: 1 1 + 2 2 + 3 3 + ☐ Presence of patchy involvement of lung parenchyma CCPAREN <XYES> ☐ Absence of features against a diagnosis of UIP CCUIPDX <XYES>	☐ Clear evidence of scarring, architectural distortion, ± honeycombing CEFIBRO <XYES> ☐ Presence of fibroblast foci → If Present: Check quantity: 1 1 + 2 2 + 3 3 + CEPRES <IPFQUA><I:3> ☐ Presence of patchy involvement of lung parenchyma CEPAREN <XYES> ☐ Absence of features against a diagnosis of UIP CEUIPDX <XYES>	☐ Clear evidence of scarring, architectural distortion, ± honeycombing TBFIBRO <XYES> ☐ Presence of fibroblast foci → If Present: Check quantity: 1 1 + 2 2 + 3 3 + TBPRES <IPFQUA><I:3> ☐ Presence of patchy involvement of lung parenchyma TBPAREN <XYES> ☐ Absence of features against a diagnosis of UIP TBUIPDX <XYES>	☐ Clear evidence of scarring, architectural distortion, ± honeycombing ADJFIBRO <XYES> ☐ Presence of fibroblast foci → If Present: Check quantity: 1 1 + 2 2 + 3 3 + ADJPRES <IPFQUA><I:3> ☐ Presence of patchy involvement of lung parenchyma ADJPAREN <XYES> ☐ Absence of features against a diagnosis of UIP ADJUIPDX <XYES>
2 First choice diagnosis (*check only one*):	☐1 UIP CCCHOIC <IPFIST><I:3> ☐2 NSIP ☐3 Chronic HP CCCHSP <V:50> ☐4 Other (*specify*): ________	☐1 UIP CECHOIC <IPFIST><I:3> ☐2 NSIP ☐3 Chronic HP CECHSP <V:50> ☐4 Other (*specify*): ________	☐1 UIP TBCHOIC <IPFIST> ☐2 NSIP ☐3 Chronic HP TBCHSP <V:50> ☐4 Other (*specify*): ________	☐1 UIP ADJCHOIC <IPFIST><I:3> ☐2 NSIP ☐3 Chronic HP ADJCHSP <V:50> ☐4 Other (*specify*): ________
3 Confidence of diagnosis of UIP (*check only one*):	☐1 Definite ☐2 Probable ☐3 Possible ☐4 Not UIP CCDIAG <IPFDIA><I:3>	☐1 Definite ☐2 Probable ☐3 Possible ☐4 Not UIP CEDIAG <IPFDIA><I:3>	☐1 Definite ☐2 Probable ☐3 Possible ☐4 Not UIP TBDIAG <IPFDIA><I:3>	☐1 Definite ☐2 Probable ☐3 Possible ☐4 Not UIP ADJDIAG <IPFDIA><I:3>

Site Personnel's Initials: ___ ___ ___

STEP-IPF IPFnet

NODATA<XYES>

Screening/History

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Past Medical History/Physical Findings

Does the subject have a known current or past history of: MEDHIST1 (TYPE 1)

1	Coronary artery disease CADHIST<XYESNO>	☐0 No	☐1 Yes	
2	Acute MI ACUTEMI<XYESNO>	☐0 No	☐1 Yes	
3	Valvular heart disease VALVULAR<XYESNO>	☐0 No	☐1 Yes →	If Yes: Specify: VALVUSP<V:100>
4	Heart failure *(congestive heart failure or congestive heart disease)* HFAILURE<XYESNO>	☐0 No	☐1 Yes	
5	Atrial fibrillation ATRIALFB<XYESNO>	☐0 No	☐1 Yes	
6	Intermittent claudication CLAUDICA<XYESNO>	☐0 No	☐1 Yes	
7	Cirrhosis or other serious, chronic liver disease LIVERDIS<XYESNO>	☐0 No	☐1 Yes	
8	Diabetes DIABETES<XYESNO>	☐0 No	☐1 Yes	
9	Lung cancer LGCANCER<XYESNO>	☐0 No	☐1 Yes	
10	Other cancer *(excluding basal cell carcinoma)* OTHCAN<XYESNO>	☐0 No	☐1 Yes →	If Yes: Specify: OTHCANSP<V:100>
11	Gastroesophageal reflux disorders *(GERD)* GERD<XYESNO>	☐0 No	☐1 Yes →	If Yes: Check all that apply: ☐ Barrett's esophagus BARRETS<XYES> ☐ Hiatal hernia HIATALHN<XYES> ☐ Gastroesophageal reflux → REFLUX<XYES> **How diagnosed** *(check all that apply)*: ☐ 24 hr pH monitoring PHMONITR<XYES> ☐ Endoscopy ENDOSCOP<XYES> ☐ Upper GI/barium swallow test UPBARIUM<XYES> ☐ Symptoms of heartburn HTBURN<XYES> OR ☐ Unknown GDIAUNK<XYES> **Non-pharmaceutical interventions** *(check all that apply)*: ☐ Sleeping with the head end of the bed elevated with 6" to 8" blocks on the floor ELEV<XYES> ☐ Sleeping in a recliner RECLIN<XYES> ☐ Limiting foods and beverages that cause symptoms FOOD<XYES> ☐ Avoiding lying down flat for 3 hours after a meal NOFLAT<XYES> ☐ Avoiding bedtime snacks BEDSNK<XYES> ☐ Eating small meals SMLMEAL<XYES> ☐ Fundoplication surgery FUNDSURG<XYES>
12	Sleep apnea *(central or obstructive)* SLPAPNEA<XYESNO>	☐0 No	☐1 Yes →	If Yes: CPAP treatment *(check only one)*: ☐0 None ☐1 Daily CPAP<IPFCPA> ☐2 Intermittent

Site Personnel's Initials: ___ ___ ___

Past Medical History/Physical Findings (continued)

MEDHIST2 (TYPE 1)

Does the subject have a known current or past history of:		
13 Asthma	☐0 No ☐1 Yes	ASTHMA<XYESNO>
14 Evidence of pulmonary hypertension HYPERTEN<XYESNO>	☐0 No ☐1 Yes →	If Yes: Source (check all that apply): HYPRECHO<XYES> ☐ Echo ☐ Cath HYPRCATH<XYES>
15 Emphysema or chronic bronchitis	☐0 No ☐1 Yes	EMPHYSEM<XYESNO>
16 Connective tissue features (thought clinically insignificant) CNTISSUE<XYESNO>	☐0 No ☐1 Yes →	If Yes: Check all that apply: RAYNAUDS<XYES> ☐ Raynaud's POSANA<XYES> ☐ Positive ANA → Titer: 1: ___ ___ ___ ANATITER <I:3> POSRF<XYES> ☐ Positive RF → Level: _____ IU/mL RFLEVEL<I:3> MYALGIA<XYES> ☐ Significant arthralgia/myalgia SICCA<XYES> ☐ Sicca symptoms DYSPHAGA<XYES> ☐ Dysphagia OTHTIS<XYES> ☐ Other (specify): _____ OTHTISSP V:100>
17 Exposure to organic or inorganic antigens known to cause interstitial lung disease (thought clinically insignificant)	☐0 No ☐1 Yes	ANTIGENS<XYESNO>
18 Clubbing	☐0 No ☐1 Yes	CLUBBING<XYESNO>
19 Bibasilar, inspiratory crackles	☐0 No ☐1 Yes	CRACKLES<XYESNO>
20 Jugular venous distension	☐0 No ☐1 Yes	JVD<XYESNO>
21 Increased P_2	☐0 No ☐1 Yes	INCSEPPT<XYESNO>
22 Peripheral edema	☐0 No ☐1 Yes	PEREDEMA<XYESNO>
23 Other significant condition/finding OTHC1<XYES>	☐1 Yes →	If Yes: Specify: _____ OTHC1SP <V:100> _____
24 Other significant condition/finding OTHC2<XYES>	☐1 Yes →	If Yes: Specify: _____ OTH2CSP <V:100> _____

Prior Medications

Record any non-study medications taken within 30 days of randomization, including over-the-counter and prescription drugs, and herbal remedies, with the exception of medications taken to treat gastroesophageal disorders, including GERD and Barrett's esophagus *(record on GERD Prior Medication page)*.

MEDLOG(TYPE 4)R

	Medication Name	Start Date	Stop Date OR ☑ if Continuing	Indication
1	MEDROWNO<I:3> MEDICATN<V:100>	MEDSTRDT ___/___/___ (day/month/year)	MEDSTPDT ___/___/___ OR ☐ Continuing MEDCONTU<XYES>	THERAPY<V:100>
2	WHODRUG_B2 WHONAME<V:80> WHOCODE<V:32> CODETM<DATETIME> CODER<V:20> WORKFLOW<V:5> CONFLVL<V:2> MATCHES<V:4> WHODRUG_ATC_B2 ATC_TERM<V:110> ATC_CODE<V:40> CODETIM2<DATETIME> CODER2<V:20> WORKFLO2<V:5> CONFLVL2<V:2> MATCHES2<V:4> THERAP2<V:100>	___/___/___	___/___/___ OR ☐ Continuing	
3		___/___/___	___/___/___ OR ☐ Continuing	
4		___/___/___	___/___/___ OR ☐ Continuing	
5		___/___/___	___/___/___ OR ☐ Continuing	
6		___/___/___	___/___/___ OR ☐ Continuing	
7		___/___/___	___/___/___ OR ☐ Continuing	
8		___/___/___	___/___/___ OR ☐ Continuing	
9		___/___/___	___/___/___ OR ☐ Continuing	
10		___/___/___	___/___/___ OR ☐ Continuing	

GERD Prior Medications

Record any medications taken to treat gastroesophageal disorders, including GERD and Barrett's esophagus (e.g., proton pump inhibitors, antacids, H_2 receptor antagonists, metoclopramide), taken within 30 days of randomization, including over-the-counter and prescription drugs and herbal remedies. GERDLOG (TYPE 4)R

Medication Name	Dose	Frequency (Check only one)	Start Date	Stop Date OR Check if Continuing	Indication (Check all that apply)
1 GERDRWNO<I:3> MEDICATN<V:100> ☐ Check if self-prescribed	___ ___ ___ ☐ mg ☐ tab ☐ tsp ☐ Other GERDOSE<I:3> GDOSEUNT<IPFGDO><I:3>	☐ QD ☐ BID ☐ TID ☐ QID ☐ PRN (≥ 1/wk) ☐ PRN (< 1/wk) GERDFREQ<IPFREQ>	___/___/___ day/month/year MEDSTRDT	___/___/___ day/month/year OR ☐ Continuing MEDSTPDT MEDCONTU<XYES>	☐ IPF ☐ Heartburn symptoms ☐ Cough ☐ Hiatal hernia ☐ Barrett's esophagus ☐ Other (specify): GRDIPF<XYES> GRDHTBRN<XYES> GRDCOF<XYES> GRDHH<XYES> GRDBARET<XYES> GRDOTH<XYES> GRDOSP<V:100>
2 SELFMEDS<XYES> WHODRUG_B2 WHONAME<V:80> WHOCODE<V:32> CODETM<DATETIME> CODER<V:20> WORKFLOW<V:5> CONFLVL<V:2> MATCHES<V:4> ☐ Check if self-prescribed	___ ___ ___ ☐ mg ☐ tab ☐ tsp ☐ Other	☐ QD ☐ BID ☐ TID ☐ QID ☐ PRN (≥ 1/wk) ☐ PRN (< 1/wk)	___/___/___ day/month/year	___/___/___ day/month/year OR ☐ Continuing	☐ IPF ☐ Heartburn symptoms ☐ Cough ☐ Hiatal hernia ☐ Barrett's esophagus ☐ Other (specify):
3 ☐ Check if self-prescribed	___ ___ ___ ☐ mg ☐ tab ☐ tsp ☐ Other	☐ QD ☐ BID ☐ TID ☐ QID ☐ PRN (≥ 1/wk) ☐ PRN (< 1/wk)	___/___/___ day/month/year	___/___/___ day/month/year OR ☐ Continuing	☐ IPF ☐ Heartburn symptoms ☐ Cough ☐ Hiatal hernia ☐ Barrett's esophagus ☐ Other (specify):
4 WHODRUG_ATC_B2 ATC_TERM<V:110> ATC_CODE<V:40> CODETIM2<DATETIME> CODER2<V:20> WORKFLO2<V:5> CONFLVL2<V:2> MATCHES2<V:4> GERDIPF<V:100> HARD CODE AS 'GERD' ☐ Check if self-prescribed	___ ___ ___ ☐ mg ☐ tab ☐ tsp ☐ Other	☐ QD ☐ BID ☐ TID ☐ QID ☐ PRN (≥ 1/wk) ☐ PRN (< 1/wk)	___/___/___ day/month/year	___/___/___ day/month/year OR ☐ Continuing	☐ IPF ☐ Heartburn symptoms ☐ Cough ☐ Hiatal hernia ☐ Barrett's esophagus ☐ Other (specify):
5 ☐ Check if self-prescribed	___ ___ ___ ☐ mg ☐ tab ☐ tsp ☐ Other	☐ QD ☐ BID ☐ TID ☐ QID ☐ PRN (≥ 1/wk) ☐ PRN (< 1/wk)	___/___/___ day/month/year	___/___/___ day/month/year OR ☐ Continuing	☐ IPF ☐ Heartburn symptoms ☐ Cough ☐ Hiatal hernia ☐ Barrett's esophagus ☐ Other (specify):

NODATA<XYES>

STEP-IPF IPFnet

FORM=PRERAND

SEE ANNOTATION PAGE 3

Pre-Randomization Walk 1

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

6-Minute Walk Test (6MWT)

Date and time of assessment: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) WALKTM WALK (TYPE4)

1 Pre-walk modified Borg Dyspnea Scale rating:
☐ 0 ☐ 0.5 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 97 Not done

2 Resting room air SpO_2: ___ ___ ___ %

3 Was supplemental O_2 used during walk? ☐ 0 No ☐ 1 Yes → If Yes: Specify: _____ liters/min
SpO_2 on Supplemental O_2 : ___ ___ ___ %

4 Was walk performed? ☐ 0 No → Provide reason: _____
☐ 1 Yes

5 Was a walking aid necessary to perform the 6MWT?
☐ 0 No
☐ 1 Yes → If Yes: Specify *(check only one)*: ☐ 1 Cane ☐ 2 Walker ☐ 98 Other *(specify)*: _____

6 Minutes	Heart Rate	SpO_2 WALKTIME(TYPE4)PS
Pre-walk	___ ___ ___ bpm	
1 minute	___ ___ ___ bpm	___ ___ ___ %
2 minutes	___ ___ ___ bpm	___ ___ ___ %
3 minutes	___ ___ ___ bpm	___ ___ ___ %
4 minutes	___ ___ ___ bpm	___ ___ ___ %
5 minutes	___ ___ ___ bpm	___ ___ ___ %
6 minutes	___ ___ ___ bpm	___ ___ ___ %
Three minutes of recovery after completion or stop of 6-Minute Walk Test		
1 minute	___ ___ ___ bpm	___ ___ ___ %
2 minutes	___ ___ ___ bpm	___ ___ ___ %
3 minutes	___ ___ ___ bpm	___ ___ ___ %

6 Did subject desaturate ($SpO_2 \leq 88\%$)? ☐ 0 No
☐ 1 Yes → If Yes: Walk duration at desaturation: _____ min / _____ sec
Walk distance at desaturation: ___ ___ ___ meters

Lowest SpO_2	Distance Walked	Did Subject Complete 6-Minute Walk?	If Stopped Early: Specify Reason (Check only one)
___ ___ ___ . ___ %	___ ___ ___ meters	☐ 0 No → If No: Duration: ___/___ (min / sec) ☐ 1 Yes	☐ 1 SpO_2 < 80% ☐ 2 Developed signs and symptoms requiring termination of test ☐ 98 Other *(specify)*: _____

7 Post-walk modified Borg Dyspnea Scale rating:
☐ 0 ☐ 0.5 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 97 Not done

Site Personnel's Initials: ___ ___ ___

WHITE and YELLOW—Duke Clinical Research Institute • PINK—retain at site PAGEREP = 1

STEP_IPF VERSION 7.0 _17SEP2009

NODATA<XYES>

STEP-IPF IPFnet

FORM=PRERAND
Page added

SEE ANNOTATION PAGE 3

Pre-Randomization Walk 2

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

6-Minute Walk Test (6MWT)

WALK (TYPE4)

Date and time of assessment: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

1 Pre-walk modified Borg Dyspnea Scale rating:
☐ 0 ☐ 0.5 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 97 Not done

2 Resting room air SpO_2: ___ ___ ___ %

3 Was supplemental O_2 used during walk? ☐ 0 No ☐ 1 Yes → If Yes: Specify: _____ liters/min
SpO_2 on Supplemental O_2 : ___ ___ ___ %

4 Was walk performed? ☐ 0 No → Provide reason: _____
☐ 1 Yes

5 Was a walking aid necessary to perform the 6MWT?
☐ 0 No
☐ 1 Yes → If Yes: Specify *(check only one)*: ☐ 1 Cane ☐ 2 Walker ☐ 98 Other *(specify)*: _____

WALKTIME(TYPE4)PS

6 Minutes	Heart Rate	SpO_2
Pre-walk	___ ___ ___ bpm	
1 minute	___ ___ ___ bpm	___ ___ ___ %
2 minutes	___ ___ ___ bpm	___ ___ ___ %
3 minutes	___ ___ ___ bpm	___ ___ ___ %
4 minutes	___ ___ ___ bpm	___ ___ ___ %
5 minutes	___ ___ ___ bpm	___ ___ ___ %
6 minutes	___ ___ ___ bpm	___ ___ ___ %
Three minutes of recovery after completion or stop of 6-Minute Walk Test		
1 minute	___ ___ ___ bpm	___ ___ ___ %
2 minutes	___ ___ ___ bpm	___ ___ ___ %
3 minutes	___ ___ ___ bpm	___ ___ ___ %

6 Did subject desaturate ($SpO_2 \leq 88\%$)? ☐ 0 No
☐ 1 Yes → If Yes: Walk duration at desaturation: _____ min / _____ sec
Walk distance at desaturation: ___ ___ ___ meters

Lowest SpO_2	Distance Walked	Did Subject Complete 6-Minute Walk?	If Stopped Early: Specify Reason (Check only one)
___ ___ ___ . ___ %	___ ___ ___ meters	☐ 0 No → If No: Duration: ___/___ (min / sec) ☐ 1 Yes	☐ 1 SpO_2 < 80% ☐ 2 Developed signs and symptoms requiring termination of test ☐ 98 Other *(specify)*: _____

7 Post-walk modified Borg Dyspnea Scale rating:
☐ 0 ☐ 0.5 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 97 Not done

Site Personnel's Initials: ___ ___ ___

STEP-IPF IPFnet

NODATA<XYES>

FORM=ENROLLMENT

Enrollment/Week 0

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Visit date: ___/___/___ VISITDT (day/month/year)

VISTDATE (TYPE 4)

**SEE ADDITIONAL ANNOTATION AT BOTTOM OF PAGE

Eligibility

Did the subject meet all eligibility criteria? INCL1<I:3> INCL2<I:3> INCL3<I:3>

☐0 No → If No: Inclusion criteria not met: #____, #____, #____

Exclusion criteria present: #EXCL1<I:3>, #EXCL2<I:3>

ELIGIBLE (TYPE 1)

☐1 Yes ELIGCRIT<XYESNO>

EXCL3<I:3>

Randomization

Date of randomization: ___/___/___ RANDT (day/month/year)

RANDOM (TYPE 1)

NYHA Functional Class

Current NYHA heart failure classification (check only one): 1= ☐ I 2= ☐ II 3= ☐ III 4= ☐ IV

NYHACLAS<XKCLAS>

NYHA (TYPE 4)

Vital Signs

1 Weight: ___ ___ ___ ☐1 lb ☐2 kg WEIGHT <F:9:3> WTUNITS<XWGTU>

VITALS (TYPE 4)

2 Height: HEIGHT <F:9:3> ☐1 in ☐2 cm HTUNITS<XHGTU> (Height only on page 11)

BPSYS<I:3> BPDIA<I:3>

3 Blood pressure: ___ ___ ___/___ ___ ___ mm Hg (systolic/diastolic)

4 Heart rate: HRATE<I:3> bpm

SPO2<F9:3> ONLY ON PAGE 112

**VISTDATE PANEL

(FOR PAGE 47 and 86 ONLY) EARLYTER <XYES>

(FOR PAGE 112 ONLY) UNSCHREA<IPFUNS> AND UNSCHSP<V:100>

STEP-IPF IPFnet

NODATA<XYES>

Enrollment/Week 0

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Spirometry*

SPIROMET(TYPE 4)

Date of assessment: ___/___/___ (day/month/year) SPIRDT

1 FEV_1: Actual: ___.___ liters FEV1 <F:9:3>

2 FEV_6: Actual: ___.___ liters FEV6 <F:9:3>

3 FVC: Actual: ___.___ liters FVC<F:9:3>

SEE ANNOTATION P.2
NOTE: DO NOT ADD QUESTIONS 4,5,6

Diffusing Capacity of the Lung for Carbon Monoxide (DLCO)*

DLCO(TYPE 4)

Date of assessment: ___/___/___ (day/month/year) DLCODT

1 DLCO: Actual: ___.___ mL/min/mm Hg → Altitude-corrected DLCO *(National Jewish only)*: ___.___ mL/min/mm Hg DLCO<F:9:3> ALTIDLCO<F:9:3>

2 VI *(inspired volume)*: ___.___ liters VI<F:9:3>

3 VA *(alveolar volume)*: ___.___ liters VA<F:9:3>

Arterial Blood Gas (ABG)*

ABG(TYPE 4)

Date of assessment: ___/___/___ (day/month/year) ABGASDT

1 Barometric pressure: ___ mm Hg BARPRESS><I:3>

2 Clinic altitude *(check only one)*: ☐1 < 4000 ft ☐2 ≥ 4000 ft ALTITUDE<IPFALT><I:3>

3 FiO_2: ___ % FIO2<I:3>

4 pH: ___.___ PH<F:9:3>

5 PaO_2: ___ mm Hg PAO2<I:3>

6 $PaCO_2$: ___ mm Hg PACO2<I:3>

7 SaO_2: ___ % SAO2<I:3>

*Screening visit may be used if within 14 days of enrollment.

STEP-IPF IPFnet

NODATA<XYES>

Enrollment/Week 0

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Self-administered Questionnaires

Date administered: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SELFQDT

SELFREPT(TYPE 4)

1	EuroQol EURORPT<IPFSEF><I:3>	☐ 1 Attached	☐ 97 Not done	
2	SF-36 SF36RPT<IPFSEF><I:3>	☐ 1 Attached	☐ 97 Not done	
3	UCSD Shortness-of-Breath UCSDRPT<IPFSEF><I:3>	☐ 1 Attached	☐ 97 Not done	
4	St. George's Respiratory STGRGRPT<IPFSEF><I:3>	☐ 1 Attached	☐ 97 Not done	
5	ICECAP ICERPT<IPFSEF><I:3>	☐ 1 Attached	☐ 97 Not done	
6	Gender Substudy Questionnaire GENDRPT<IPFSEF><I:3>	☐ 1 Attached	☐ 97 Not done	☐ 96 NA (male)

Site Personnel's Initials: ___ ___ ___

EuroQol Questionnaire EQ-5D English version for the U.S.

By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.

EUROQOL1 (TYPE 4)

1 Mobility:

EQMOB<IPFEMO><I:3>

- ☐1 I have no problems in walking about
- ☐2 I have some problems in walking about
- ☐3 I am confined to bed

2 Self-care:

EQSC<IPFESC><I:3>

- ☐1 I have no problems with self-care
- ☐2 I have some problems washing or dressing myself
- ☐3 I am unable to wash or dress myself

3 Usual activities (e.g., work, study, housework, family, or leisure activities):

EQUA<IPFEUA><I:3>

- ☐1 I have no problems with performing my usual activities
- ☐2 I have some problems with performing my usual activities
- ☐3 I am unable to perform my usual activities

4 Pain/discomfort:

EQPAIN<IPFEPN><I:3>

- ☐1 I have no pain or discomfort
- ☐2 I have moderate pain or discomfort
- ☐3 I have extreme pain or discomfort

5 Anxiety/depression:

EQANX<IPFEAN><I:3>

- ☐1 I am not anxious or depressed
- ☐2 I am moderately anxious or depressed
- ☐3 I am extremely anxious or depressed

STOP.
Please let your study coordinator know that you are ready for the EuroQol Thermometer worksheet.

EuroQol Thermometer Response (Study staff use only)

Response to the EuroQol thermometer *(0–100)*: ___ ___ ___ EURTHERM<I:3>

EuroQol Questionnaire EQ-5D (continued)

Because all replies are anonymous, it will help us to understand your answers better if we have a little background data from everyone, as covered in the following questions.

EUROQOL2 (TYPE 4)

1 Have you experienced serious illness: *in you yourself?* ☐0 No ☐1 Yes EQILLYOU<XYESNO>
in your family? ☐0 No ☐1 Yes EQILLFAM<XYESNO>
in caring for others? ☐0 No ☐1 Yes EQILLOTH<XYESNO>

2 What is your age in years? _____ EQAGE<F:9:3>

3 Are you *(please check appropriate box)*: ☐1 Male ☐2 Female EQGENDR<XGENDR>

4 Are you *(please check only one)*: ☐1 A current smoker ☐2 An ex-smoker ☐3 A never smoker EQSMK<IPFESM><I:3>

5 Do you now, or did you ever, work in health or social services?
☐0 No EQWKHL<XYESNO>
☐1 Yes → If Yes: In what capacity? _____ EQWKHLSP <V:100>

6 Which of the following best describes your main activity *(please check only one)*?
☐1 Employed (including self employment)
☐2 Retired
☐3 Keeping house
☐4 Student
☐5 Seeking work
☐98 Other (please specify): _____ EQACTSP<V:100>

EQACT<IPFEAC><I:3>

7 What is the highest level of education you have completed *(please check only one)*?
☐1 Some high school or less
☐2 High school graduate or GED
☐3 Vocational college or some college
☐4 College degree
☐5 Professional or graduate degree

EQEDU<IPFEDU><I:3>

8 If you know your zip code, please write it here: ___ ___ ___ ___ ___ EQZIP<I:5>

SF-36 Assessment

SF36_1(TYPE 4)

1 In general, would you say your health is: SF1<XCOND><I:3>

☐1 Excellent ☐2 Very good ☐3 Good ☐4 Fair ☐5 Poor

2 Compared to one year ago, how would you rate your health in general now? SF2<IPFHLT><I:3>

☐1 Much better than one year ago ☐3 About the same as one year ago ☐5 Much worse now than one year ago

☐2 Somewhat better than one year ago ☐4 Somewhat worse than one year ago

3 The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. **Vigorous activities,** such as running, lifting heavy objects, participating in strenuous sports SF3A<IPFACT><I:3>	☐1	☐2	☐3
b. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf SF3B<IPFACT><I:3>	☐1	☐2	☐3
c. Lifting or carrying groceries SF3C<IPFACT><I:3>	☐1	☐2	☐3
d. Climbing **several** flights of stairs SF3D<IPFACT><I:3>	☐1	☐2	☐3
e. Climbing **one** flight of stairs SF3E<IPFACT><I:3>	☐1	☐2	☐3
f. Bending, kneeling or stooping SF3F<IPFACT><I:3>	☐1	☐2	☐3
g. Walking **more than a mile** SF3G<IPFACT><I:3>	☐1	☐2	☐3
h. Walking **several blocks** SF3H<IPFACT><I:3>	☐1	☐2	☐3
i. Walking **one block** SF3I<IPFACT><I:3>	☐1	☐2	☐3
j. Bathing or dressing yourself SF3J<IPFACT><I:3>	☐1	☐2	☐3

4 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
a. Cut down on the **amount of time** you spend on work or other activities SF4A<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5
b. **Accomplished less** than you would like SF4B<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5
c. Were limited in the **kind** of work or other activities SF4C<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5
d. Had **difficulty** performing the work or other activities *(for example, it took extra effort)* SF4D<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5

5 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
a. Cut down on the **amount of time** you spend on work or other activities SF5A<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5
b. **Accomplished less** than you would like SF5B<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5
c. Did work or other activities **less carefully than usual** SF5C<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5

SF-36 Assessment (continued)

6 During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

☐1 Not at all ☐2 Slightly ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

SF6<IPFXTN><I:3>

SF36_2(TYPE 4)

7 How much bodily pain have you had during the past 4 weeks?

☐1 None ☐2 Very mild ☐3 Mild ☐4 Moderate ☐5 Severe ☐6 Very severe

SF7<IPFBPN><I:3>

8 During the past 4 weeks, how much did pain interfere with your normal work *(including both work outside the home and housework)*?

SF8<IPFXTN<I:3>>

☐1 Not at all ☐2 Slightly ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

9 These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of life? SF9A<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5
b. Have you been very nervous? SF9B<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5
c. Have you felt so down in the dumps that nothing could cheer you up? SF9C<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5
d. Have you felt calm and peaceful? SF9D<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5
e. Did you have a lot of energy? SF9E<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5
f. Have you felt downhearted and depressed? SF9F<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5
g. Did you feel worn out? SF9G<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5
h. Have you been happy? SF9H<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5
i. Did you feel tired? SF9I<IPFTIM><I:3>	☐1	☐2	☐3	☐4	☐5

10 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities *(like visiting friends, relatives, etc.)*?

☐1 All of the time ☐2 Most of the time ☐3 Some of the time ☐4 A little of the time ☐5 None of the time

SF10<IPFTIM><I:3>

11 How **True** or **False** is each of the following statements for you? SF11A<IPFTRU><I:3>	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people	☐1	☐2	☐3	☐4	☐5
b. I am as healthy as anybody I know SF11B<IPFTRU><I:3>	☐1	☐2	☐3	☐4	☐5
c. I expect my health to get worse SF11C<IPFTRU><I:3>	☐1	☐2	☐3	☐4	☐5
d. My health is excellent SF11D<IPFTRU><I:3>	☐1	☐2	☐3	☐4	☐5

NODATA<XYES>

Enrollment/Week 0

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ Subject Initials: ___ ___ ___
site # subject #

UCSDSOB1(TYPE 4)

UCSD Shortness-of-Breath Questionnaire UCSD SOBQ

When I do, or if I were to do, the following tasks, I would rate my breathlessness as: All <I:1> <IPFUCS>	None At All				Severe	Maximal/ Unable To Do Because of Breathlessness
	0=	1=	2=	3=	4=	5=
1 At rest UCSD1	0	1	2	3	4	5
2 Walking on a level at your own pace UCSD2	0	1	2	3	4	5
3 Walking on a level with others your age UCSD3	0	1	2	3	4	5
4 Walking up a hill UCSD4	0	1	2	3	4	5
5 Walking up stairs UCSD5	0	1	2	3	4	5
6 While eating UCSD6	0	1	2	3	4	5
7 Standing up from a chair UCSD7	0	1	2	3	4	5
8 Brushing teeth UCSD8	0	1	2	3	4	5
9 Shaving and/or brushing hair UCSD9	0	1	2	3	4	5
10 Showering/bathing UCSD10	0	1	2	3	4	5
11 Dressing UCSD11	0	1	2	3	4	5
12 Picking up and straightening UCSD12	0	1	2	3	4	5

UCSD Shortness-of-Breath Questionnaire UCSD SOBQ (continued)

All <I:1> <IPFUCS>

When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All				Severe	Maximal/ Unable To Do Because of Breathlessness
	0=	1=	2=	3=	4=	5=
13 Doing dishes UCSD13	0	1	2	3	4	5
14 Sweeping/vacuuming UCSD14	0	1	2	3	4	5
15 Making bed UCSD15	0	1	2	3	4	5
16 Shopping UCSD16	0	1	2	3	4	5
17 Doing laundry UCSD17	0	1	2	3	4	5
18 Washing car UCSD18	0	1	2	3	4	5
19 Mowing lawn UCSD19	0	1	2	3	4	5
20 Watering lawn UCSD20	0	1	2	3	4	5
21 Sexual activities UCSD21	0	1	2	3	4	5
How much do these limit you in your daily life?						
22 Shortness of breath UCSD22	0	1	2	3	4	5
23 Fear of "hurting myself" UCSD23	0	1	2	3	4	5
24 Fear of shortness of breath UCSD24	0	1	2	3	4	5

St. George's Respiratory Questionnaire (SGRQ) (English for the United States)

STGRG1 (TYPE 4)

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you the most problems, rather than what the doctors and nurses think your problems are.

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

Before completing the questionnaire:
Please check one box to show how you describe your current health:

CURHLTH<IPFCHL><I:3>

1 ☐ Very good
2 ☐ Good
3 ☐ Fair
4 ☐ Poor
5 ☐ Very poor

St. George's Respiratory Questionnaire Part 1

STGRG2 (TYPE 4)

Please describe how often your respiratory problems have affected you over the past 4 weeks.

Please check ☑ one box for each question.	Almost Every Day	Several Days a Week	A Few Days a Month	Only with Respiratory Infections	Not At All
All are <XYES>					
1 Over the past 4 weeks, I have coughed:	STG1A ☐	STG1B ☐	STG1C ☐	STG1D ☐	STG1E ☐
2 Over the past 4 weeks, I have brought up phlegm (sputum):	STG2A ☐	STG2B ☐	STG2C ☐	STG2D ☐	STG2E ☐
3 Over the past 4 weeks, I have had shortness of breath:	STG3A ☐	STG3B ☐	STG3C ☐	STG3D ☐	STG3E ☐
4 Over the past 4 weeks, I have had wheezing attacks:	STG4A ☐	STG4B ☐	STG4C ☐	STG4D ☐	STG4E ☐

5 How many times during the past 4 weeks have you suffered from severe or very unpleasant respiratory attacks? Please check ☑ one:

- ☐ More than 3 times STG5A<XYES>
- ☐ 3 times STG5B<XYES>
- ☐ 2 times STG5C<XYES>
- ☐ 1 time STG5D<XYES>
- ☐ None of the time STG5E<XYES>

6 How long did the worst respiratory attack last? Please check ☑ one:
(Go to question 7 if you did not have a severe attack)

- ☐ A week or more STG6A<XYES>
- ☐ 3 or more days STG6B<XYES>
- ☐ 1 or 2 days STG6C<XYES>
- ☐ Less than a day STG6D<XYES>

7 Over the past 4 weeks, in a typical week, how many good days (with few respiratory problems) have you had? Please check ☑ one:

- ☐ No good days STG7A<XYES>
- ☐ 1 or 2 good days STG7B<XYES>
- ☐ 3 or 4 good days STG7C<XYES>
- ☐ Nearly every day was good STG7D<XYES>
- ☐ Every day was good STG7E<XYES>

8 If you wheeze, is it worse when you get up in the morning? Please check ☑ one:

- ☐ 0 No
- ☐ 1 Yes

STG8<XYESNO>

St. George's Respiratory Questionnaire Part 2

STGRG3 (TYPE 4)

Section 1

9 How would you describe your respiratory condition? Please check ☑ one:

- ☐ The most important problem I have STG9A<XYES>
- ☐ Causes me quite a lot of problems STG9B<XYES>
- ☐ Causes me a few problems STG9C<XYES>
- ☐ Causes me no problems STG9D<XYES>

10 If you have ever held a job *(please check ☑ one)*:

- ☐ My respiratory problems made me stop working altogether STG10A<XYES>
- ☐ My respiratory problems interfere with my job or made me change my job STG10B<XYES>
- ☐ My respiratory problems do not affect my job STG10C<XYES>

Section 2

These are questions about what activities usually make you feel short of breath these days.

For each statement, please check ☑ **the box** that applies to you **these days.**

11 Sitting or lying still	STG11A<IPFTOF><I:3>	☐1 True	☐0 False
Washing or dressing yourself	STG11B<IPFTOF><I:3>	☐1 True	☐0 False
Walking around the house	STG11C<IPFTOF><I:3>	☐1 True	☐0 False
Walking outside on a level ground	STG11D<IPFTOF><I:3>	☐1 True	☐0 False
Walking up a flight of stairs	STG11E<IPFTOF><I:3>	☐1 True	☐0 False
Walking up hills	STG11F<IPFTOF><I:3>	☐1 True	☐0 False
Playing sports or other physical activities	STG11G<IPFTOF><I:3>	☐1 True	☐0 False

Section 3

12 These are more questions about your cough and shortness of breath these days.

For each statement, please check ☑ **the box** that applies to you **these days.**

Coughing hurts	STG12A<IPFTOF><I:3>	☐1 True	☐0 False
Coughing makes me tired	STG12B<IPFTOF><I:3>	☐1 True	☐0 False
I am short of breath when I talk	STG12C<IPFTOF><I:3>	☐1 True	☐0 False
I am short of breath when I bend over	STG12D<IPFTOF><I:3>	☐1 True	☐0 False
My coughing or breathing disturbs my sleep	STG12E<IPFTOF><I:3>	☐1 True	☐0 False
I get exhausted easily	STG12F<IPFTOF><I:3>	☐1 True	☐0 False

St. George's Respiratory Questionnaire Part 2 (continued)

STGRG4 (TYPE 4)

Section 4

13 These are questions about other effects that your respiratory problems may have on you <u>these days</u>.

For each statement, please check ☑ ***the box*** that applies to you ***these days.***

My cough or breathing is embarrassing in public STG13A<IPFTOF><I:3>	☐1 True	☐0 False
My respiratory problems are a nuisance to my family, friends or neighbors STG13B<IPFTOF><I:3>	☐1 True	☐0 False
I get afraid or panic when I cannot catch my breath STG13C<IPFTOF><I:3>	☐1 True	☐0 False
I feel that I am not in control of my respiratory problems STG13D<IPFTOF><I:3>	☐1 True	☐0 False
I do not expect my respiratory problems to get any better STG13E<IPFTOF><I:3>	☐1 True	☐0 False
I have become frail or an invalid because of my respiratory problems STG13F<IPFTOF><I:3>	☐1 True	☐0 False
Exercise is not safe for me STG13G<IPFTOF><I:3>	☐1 True	☐0 False
Everything seems too much of an effort STG13H<IPFTOF><I:3>	☐1 True	☐0 False

Section 5

14 These are questions about your respiratory treatment. If you are not receiving treatment, +go to Section 6.

For each statement, please check ☑ ***the box*** that applies to you ***these days.***

My treatment does not help me very much STG14A<IPFTOF><I:3>	☐1 True	☐0 False
I get embarrassed using my medication in public STG14B<IPFTOF><I:3>	☐1 True	☐0 False
I have unpleasant side effects from my medication STG14C<IPFTOF><I:3>	☐1 True	☐0 False
My treatment interferes with my life a lot STG14D<IPFTOF><I:3>	☐1 True	☐0 False

St. George's Respiration Questionnaire Part 2 (continued)

Section 6

STGRG5 (TYPE 4)

15 These are questions about how your activities might be affected by your respiratory problems.

For each statement, please check ☑ **the box** that applies to you ***because of your respiratory problems.***

I take a long time to get washed or dressed ..... STG15A<IPFTOF><I:3>	☐1 True	☐0 False
I cannot take a bath or shower, or I take a long time to do it ..... STG15B<IPFTOF><I:3>	☐1 True	☐0 False
I walk slower than other people my age, or I stop to rest ..... STG15C<IPFTOF><I:3>	☐1 True	☐0 False
Jobs such as household chores take a long time, or I have to stop to rest ..... STG15D<IPFTOF><I:3>	☐1 True	☐0 False
If I walk up one flight of stairs, I have to go slowly or stop ..... STG15E<IPFTOF><I:3>	☐1 True	☐0 False
If I hurry or walk fast, I have to stop or slow down ..... STG15F<IPFTOF><I:3>	☐1 True	☐0 False
My breathing makes it difficult to do things such as walk up hills, carry ... such as weeding, dance, bowl, or play ..... STG15G<IPFTOF><I:3>	☐1 True	☐0 False
My breathing makes it difficult to do things such as carry heavy loads, dig in the garden or shovel snow, jog or walk briskly (5 miles per hour), play tennis or swim ..... STG15H<IPFTOF><I:3>	☐1 True	☐0 False
My breathing makes it difficult to do things such as very heavy manual work, ride a bike, run, swim fast, or play competitive sports ..... STG15I<IPFTOF><I:3>	☐1 True	☐0 False

Alert on screen: Following question is not on pre-version 3 CRFs

Section 7

16 We would like to know how your respiratory problems <u>usually</u> affect your daily life.

For each statement, please check ☑ **the box** that applies to you ***because of your respiratory problems.***

I cannot play sports or do other physical activities ..... STG16A<IPFTOF><I:3>	☐1 True	☐0 False
I cannot go out for entertainment or recreation ..... STG16B<IPFTOF><I:3>	☐1 True	☐0 False
I cannot go out of the house to do the shopping ..... STG16C<IPFTOF><I:3>	☐1 True	☐0 False
I cannot do household chores ..... STG16D<IPFTOF><I:3>	☐1 True	☐0 False
I cannot move far from my bed or chair ..... STG16E<IPFTOF><I:3>	☐1 True	☐0 False

St. George's Respiratory Questionnaire (continued)

STGRG6 (TYPE 4)

Here is a list of other activities that your respiratory problems may prevent you from doing. (You do not have to check these; they are just to remind you of ways your shortness of breath may affect you.)

- Going for walks or walking the dog
- Doing activities or chores at home or in the garden
- Sexual intercourse
- Going to a place of worship, or a place of entertainment
- Going out in bad weather or into smoky rooms
- Visiting family or friends or playing with children

Please write in any other important activities that your respiratory problems may stop you from doing:

STGLIST<V:200>

17 Now please check the box *(one only)* that you think best describes how your respiratory problems affect you:

- ☐ It does not stop me from doing anything I would like to do — STG17A<XYES>
- ☐ It stops me from doing one or two things I would like to do — STG17B<XYES>
- ☐ It stops me from doing most of the things I would like to do — STG17C<XYES>
- ☐ It stops me from doing everything I would like to do — STG17D<XYES>

Before you finish, would you please make sure that you have answered all the questions.

Thank you for completing this questionnaire.

ICECAP Questionnaire

By placing a check ☑ in one box in each group below, please indicate which statement best describes your quality of life at the moment.

ICECAP (TYPE 4)

Love and Friendship ICELOVE<IPFLUV><I:3>	☐1 I can have **all** of the love and friendship that I want ☐2 I can have **a lot** of the love and friendship that I want ☐3 I can have **a little** of the love and friendship that I want ☐4 I cannot have **any** of the love and friendship that I want
Thinking about the future ICEFUTR<IPFFUT><I:3>	☐1 I can think about the future **without any** concern ☐2 I can think about the future with **only a little** concern ☐3 I can only think about the future with **some** concern ☐4 I can only think about the future with **a lot** of concern
Doing things that make you feel valued ICEVALUE<IPFVAL><I:3>	☐1 I am able to do **all** of the things that make me feel valued ☐2 I am able to do **many** of the things that make me feel valued ☐3 I am able to do **a few** of the things that make me feel valued ☐4 I am unable to do **any** of the things that make me feel valued
Enjoyment and pleasure ICEENJOY<IPFJOY><I:3>	☐1 I can have **all** of the enjoyment and pleasure that I want ☐2 I can have **a lot** of of the enjoyment and pleasure that I want ☐3 I can have **a little** of the enjoyment and pleasure that I want ☐4 I cannot have **any** of the enjoyment and pleasure that I want
Independence ICEINDEP<IPFIND><I:3>	☐1 I am able to be **completely** independent ☐2 I am able to be independent **in many things** ☐3 I am able to be independent in **a few things** ☐4 I am **unable** to be at all independent

STEP-IPF IPFnet

NODATA<XYES>

Enrollment/Week 0

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Gender Substudy Questionnaire

To be completed by female participants only

GENDERSS (TYPE 1)

We want to thank you in advance for answering several additional questions. Because the cause of IPF is not well understood, we are trying to learn more about who gets the disease. We know that in general, women are less likely to develop pulmonary fibrosis. This may be related to estrogen, a hormone more common in women. Therefore we are asking that all female study participants answer several questions related to estrogen exposure which may help us better understand the disease.

1 At what age did you begin monthly menstruation *(monthly period)*?	PERIOD<I:3> _____ years old
2 Have you reached menopause?	☐0 No → If No, skip to question 4 ☐1 Yes MENOPAUS<XYESNO>
3 If you have reached menopause, at what age did that occur?	_____ years old MENOAGE<F:9:3>
4 Did you ever use oral contraceptive medications?	☐0 No → If No, skip to question 6 ☐1 Yes NOPREG<XYESNO>
5 If you did use oral contraceptives, for how many years?	_____ years NOPREGYS<F:9:3>
6 Did you ever use hormone replacement therapy?	☐0 No → If No, skip to question 8 ☐1 Yes HRT<XYESNO>
7 If you did use hormone replacement therapy, for how many years?	_____ years HRTYRS<F:9:3>
8 Have you ever been pregnant *(include miscarriages, abortions)*?	☐0 No → If No, skip to question 14 ☐1 Yes PREGNANT<XYESNO>
9 If you have been pregnant, how old were you at the time of your first pregnancy?	_____ years old PREGNAGE<F:9:3>
10 How many times have you been pregnant?	_____ PREGNUMB<I:3>
11 What were the sex of your children, born and unborn? *(Check only one)* BABYGEND<IPFBAB><I:3>	☐1 All male 99 = UNKNOWN ☐2 All female ☐3 Male and female
12 Did you ever breastfeed?	☐0 No → If No, skip to question 14 ☐1 Yes BRESFEED<XYESNO>
13 If you did breastfeed, for approximately how many total months did you breastfeed *(total for all pregnancies)*?	_____ months BRFEEDNO<F:9:3>
14 Have you ever had an ovary removed?	☐0 No → If No, end of questions ☐1 Yes OVREM<XYESNO>
15 If you had an ovary removed, was one removed or both?	☐1 One ☐2 Both OVNUM<IPFOVR><1:3>
16 At what age was your ovary or ovaries removed?	_____ years old OVAGE<F:9:3>

STEP-IPF IPFnet

FORM=WEEK1

NODATA<XYES>

Week 1

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Visit date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SEE ANNOTATION P.11 VISTDATE (TYPE 4)

Vital Signs

1 Weight: ___ ___ ___ ☐1 lb ☐2 kg

3 Heart rate: ___ ___ ___ bpm

VITALS (TYPE 4)

2 Blood pressure: ___ ___ ___ / ___ ___ ___ mm Hg (systolic / diastolic)

SEE ANNOTATION P.11

NOTE: EXCEPT NO HEIGHT or SPO2

GERD Substudy Review

Record all GERD related medications in the GERD Concomitant Medications log

1 Have there been any changes in the subject's GERD status since last visit?

GERDSUB(TYPE 4)

☐0 No → Skip to question 3 GERDCHGS<XYESNO>

☐1 Yes → If Yes: Check only one:

1 ☐1 Newly diagnosed → Record on Adverse Event Log GERDSTAT<IPFGST><I:3>

How diagnosed (check all that apply): GUPGI<XYES> GENDO<XYES>

☐ 24 hr pH monitoring ☐ Endoscopy ☐ Upper GI/barium swallow test GPHMON<XYES>

☐ Symptoms of heartburn OR ☐ Unknown GUNK<XYES> GHBSYM<XYES>

2 ☐2 Changes in non-pharmaceutical interventions

98 ☐98 Other (including medications only) → Skip to question 3

2 If newly diagnosed GERD or changes in non-pharmaceutical interventions, answer all questions below:

Sleeping with the head end of the bed elevated with 6" to 8" blocks on the floor	☐0 No	☐1 Yes	GELEV<XYESNO>
Sleeping in a recliner	☐0 No	☐1 Yes	GRECLIN<XYESNO>
Limiting foods and beverages that cause symptoms	☐0 No	☐1 Yes	GFOOD<XYESNO>
Avoiding lying down flat for 3 hours after a meal	☐0 No	☐1 Yes	GNOFLAT<XYESNO>
Avoiding bedtime snacks	☐0 No	☐1 Yes	GBEDSNK<XYESNO>
Eating small meals	☐0 No	☐1 Yes	GSMLMEAL<XYESNO>

3 Have there been any changes in the subject's obstructive sleep apnea status since last visit?

☐0 No → Skip to Safety Review APNEACHG<XYESNO>

☐1 Yes → If Yes: Check only one:

☐1 Newly diagnosed → Record on Adverse Event Log NEWAPNEA<IPFACH><I:3>

☐2 Changes in CPAP treatment

☐98 Other (including medications only) → Skip to Safety Review

4 If newly diagnosed sleep apnea or changes in CPAP treatment, specify current CPAP treatment:

☐0 None ☐1 Daily ☐2 Intermittent NEWCPAP<IPFCPA><I:3>

Safety Review

Has the subject experienced unexplained worsened dyspnea or cough since last visit, triggering unscheduled medical care *(e.g., clinic, study visit, hospitalization)*?

☐0 No ☐1 Yes → If Yes: Please send support materials for acute exacerbation review. SAFETY (TYPE 4)

WORSDYSP<XYESNO>

Record any new Adverse Events on the Adverse Event Log page.

Record any new or changed medications on the Concomitant Medications Log page.

STEP-IPF IPFnet

FORM=WEEK6

NODATA<XYES>

Week 6

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Visit date: ___/___/___ (day / month / year)

VISTDATE (TYPE 4)

SEE ANNOTATION P.11

Vital Signs

VITALS (TYPE 4)

1 Weight: ___ ___ ___ ☐1 lb ☐2 kg

2 Blood pressure: ___ ___ ___/___ ___ ___ mmHg (systolic / diastolic)

3 Heart rate: ___ ___ ___ bpm

SEE ANNOTATION P.11
NOTE: EXCEPT NO HEIGHT or SPO2

NYHA Functional Class

NYHA (TYPE 4)

Current NYHA heart failure classification *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

SEE ANNOTATION P.11

Spirometry

SPIROMET(TYPE 4)

Date of assessment: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

1 FEV_1: Actual: ___ . ___ ___ liters

2 FEV_6: Actual: ___ . ___ ___ liters

3 FVC: Actual: ___ . ___ ___ liters

SEE ANNOTATION P.2
NOTE: DO NOT ADD QUESTIONS 4,5,6

Diffusing Capacity of the Lung for Carbon Monoxide (DLCO)

DLCO (TYPE 4)

Date of assessment: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

1 DLCO: Actual: ___ ___ . ___ ___ mL/min/mm Hg → Altitude-corrected DLCO *(National Jewish only)*: ___ ___ . ___ ___ mL/min/mm Hg

2 VI *(inspired volume)*: ___ . ___ ___ liters

3 VA *(alveolar volume)*: ___ . ___ ___ liters

SEE ANNOTATION P.12

6-Minute Walk Test (6MWT)

Date of assessment: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

WALK (TYPE 4)

1 Pre-walk modified Borg Dyspnea Scale rating:
☐ 0 ☐ 0.5 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 97 Not done

2 Resting room air SpO_2: ___ ___ ___ %

3 Was supplemental O_2 used during walk? ☐ 0 No ☐ 1 Yes → If Yes: Specify: _____ liters/min
SpO_2 on Supplemental O_2 : ___ ___ ___ %

4 Was walk performed? ☐ 0 No → Provide reason: _____
☐ 1 Yes

5 Was a walking aid necessary to perform the 6MWT?
☐ 0 No
☐ 1 Yes → If Yes: Specify *(check only one)*: ☐ 1 Cane
☐ 2 Walker
☐ 98 Other *(specify)*: _____

WALKTIME (TYPE 4)

6 Minutes	Heart Rate	SpO_2
Pre-walk	___ ___ ___ bpm	
1 minute	___ ___ ___ bpm	___ ___ ___ %
2 minutes	___ ___ ___ bpm	___ ___ ___ %
3 minutes	___ ___ ___ bpm	___ ___ ___ %
4 minutes	___ ___ ___ bpm	___ ___ ___ %
5 minutes	___ ___ ___ bpm	___ ___ ___ %
6 minutes	___ ___ ___ bpm	___ ___ ___ %
Three minutes of recovery after completion or stop of 6-Minute Walk Test		
1 minute	___ ___ ___ bpm	___ ___ ___ %
2 minutes	___ ___ ___ bpm	___ ___ ___ %
3 minutes	___ ___ ___ bpm	___ ___ ___ %

6 Did subject desaturate ($SpO_2 \leq 88\%$)? ☐ 0 No
☐ 1 Yes → If Yes: Walk duration at desaturation: _____ min / _____ sec
Walk distance at desaturation: ___ ___ ___ meters

Lowest SpO_2	Distance Walked	Did Subject Complete 6-Minute Walk?	If Stopped Early: Specify Reason (Check only one)
___ ___ ___ . ___ %	___ ___ ___ meters	☐ 0 No → If No: Duration: ___ / ___ (min / sec) ☐ 1 Yes	☐ 1 SpO_2 < 80% ☐ 2 Developed signs and symptoms requiring termination of test ☐ 98 Other *(specify)*: _____

7 Post-walk modified Borg Dyspnea Scale rating:
☐ 0 ☐ 0.5 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 97 Not done

Site Personnel's Initials: ___ ___ ___

NODATA<XYES>

STEP-IPF IPFnet

THIS IS A REPEATING PAGE

Week 6

Subject ID: 02 - ___ ___ ___ (site #) - ___ ___ ___ (subject #) Subject Initials: ___ ___ ___

Urgent or Inpatient Admissions

Has the subject been admitted to the hospital, emergency room/urgent care, assisted living/nursing facility, or rehabilitation center since the last study visit *(do not include protocol-specific study visits)*? ☐0 No ☐1 Yes → If Yes: Provide details below.

INPATNT (TYPE 4)R

UIANUMB<I:3> URGENT<XYESNO>	Reason for Admission	Major Procedures Performed	Discharge Destination *(check only one)*
1 **Admission date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ADMITDT **Discharge date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) DISCHDT **Admission type** *(check only one)*: ADMITYPE<IPFHSP><I:3> ☐1 Hospital ☐2 ER/urgent care ☐3 Assisted living/nursing facility ☐4 Rehabilitation center	HOSPREAS<V:100> RESPREL<XYES> ☐1 Check if respiratory-related.	MAJPROC<V:100>	DISCHDES<IPFDCH><I:3> ☐1 Home ☐2 Assisted living/nursing facility ☐3 Rehab center ☐4 Transfer to other hospital ☐5 Subject died ☐98 Other *(specify)*: DISCGSP<V:100>
2 **Admission date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Discharge date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Admission type** *(check only one)*: ☐1 Hospital ☐2 ER/urgent care ☐3 Assisted living/nursing facility ☐4 Rehabilitation center	☐1 Check if respiratory-related.		☐1 Home ☐2 Assisted living/nursing facility ☐3 Rehab center ☐4 Transfer to other hospital ☐5 Subject died ☐98 Other *(specify)*:
3 **Admission date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Discharge date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Admission type** *(check only one)*: ☐1 Hospital ☐2 ER/urgent care ☐3 Assisted living/nursing facility ☐4 Rehabilitation center	☐1 Check if respiratory-related.		☐1 Home ☐2 Assisted living/nursing facility ☐3 Rehab center ☐4 Transfer to other hospital ☐5 Subject died ☐98 Other *(specify)*:

Outpatient Visits

Has the subject required any non-urgent outpatient visits since the last study visit *(do not include protocol-specific study visits)*?

☐0 No ☐1 Yes → If Yes: Provide details below.

OUTPATNT (TYPE 4)PS

NONURGNT<XYESNO>

	Provider Type (PROVTYPE<IPFPRO><I:3>) (OUTPTSP<V:100>)	No. of Respiratory-related Visits	No. of Non-respiratory-related Visits
1=	1 Pulmonologist	RESVITNO<I:3>	NONRESNO<I:3>
2=	2 Cardiologist		
3=	3 Other specialist: _____		
4=	4 Primary care physician *(or NP or PA)*		
5=	5 OT or PT		
6=	6 Mental health provider		
7=	7 Other *(specify)*: _____		

Self-administered Questionnaires

Date administered: ___/___/___ (day/month/year) SEE ANNOTATION P. 13 No GENDRPT SELFREPT (TYPE 4)

1	EuroQol	☐1 Attached	☐97 Not done
2	SF-36	☐1 Attached	☐97 Not done
3	UCSD Shortness-of-Breath	☐1 Attached	☐97 Not done
4	St. George's Respiratory	☐1 Attached	☐97 Not done
5	ICECAP	☐1 Attached	☐97 Not done

GERD Substudy Review

Record all GERD related medications in the GERD Concomitant Medications log

SEE ANNOTATION P. 28 GERDSUB (TYPE 4)

1 Have there been any changes in the subject's GERD status since last visit?

☐0 No → Skip to question 3

☐1 Yes → If Yes: Check only one:

☐1 Newly diagnosed → Record on Adverse Event Log

How diagnosed *(check all that apply)*:

☐ 24 hr pH monitoring ☐ Endoscopy ☐ Upper GI/barium swallow test

☐ Symptoms of heartburn OR ☐ Unknown

☐2 Changes in non-pharmaceutical interventions

☐98 Other (including medications only) → Skip to question 3

2 If newly diagnosed GERD or changes in non-pharmaceutical interventions, answer all questions below:

Sleeping with the head end of the bed elevated with 6" to 8" blocks on the floor	☐0 No	☐1 Yes
Sleeping in a recliner	☐0 No	☐1 Yes
Limiting foods and beverages that cause symptoms	☐0 No	☐1 Yes
Avoiding lying down flat for 3 hours after a meal	☐0 No	☐1 Yes
Avoiding bedtime snacks	☐0 No	☐1 Yes
Eating small meals	☐0 No	☐1 Yes

3 Have there been any changes in the subject's obstructive sleep apnea status since last visit?

☐0 No → Skip to Safety Review

☐1 Yes → If Yes: Check only one:

☐1 Newly diagnosed → Record on Adverse Event Log

☐2 Changes in CPAP treatment

☐98 Other (including medications only) → Skip to Safety Review

4 If newly diagnosed sleep apnea or changes in CPAP treatment, specify current CPAP treatment:

☐0 None ☐1 Daily ☐2 Intermittent

Safety Review

Has the subject experienced unexplained worsened dyspnea or cough since last visit, triggering unscheduled medical care *(e.g., clinic, study visit, hospitalization)*?

SEE ANNOTATION P. 28 SAFETY (TYPE 4)

☐0 No ☐1 Yes → If Yes: Please send support materials for acute exacerbation review.

Record any new Adverse Events on the Adverse Event Log page.

Record any new or changed medications on the Concomitant Medications Log page.

EuroQol Questionnaire EQ-5D English version for the U.S.

By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.

EUROQOL1(TYPE 4)

1 Mobility:
- ☐1 I have no problems in walking about
- ☐2 I have some problems in walking about
- ☐3 I am confined to bed

2 Self-care:
- ☐1 I have no problems with self-care
- ☐2 I have some problems washing or dressing myself
- ☐3 I am unable to wash or dress myself

3 Usual activities (e.g., work, study, housework, family, or leisure activities):
- ☐1 I have no problems with performing my usual activities
- ☐2 I have some problems with performing my usual activities
- ☐3 I am unable to perform my usual activities

4 Pain/discomfort:
- ☐1 I have no pain or discomfort
- ☐2 I have moderate pain or discomfort
- ☐3 I have extreme pain or discomfort

5 Anxiety/depression:
- ☐1 I am not anxious or depressed
- ☐2 I am moderately anxious or depressed
- ☐3 I am extremely anxious or depressed

STOP.
Please let your study coordinator know that you are ready for the EuroQol Thermometer worksheet.

EuroQol Thermometer Response (Study staff use only)

Response to the EuroQol thermometer *(0–100)*: ___ ___ ___

EuroQol Questionnaire EQ-5D (continued)

Because all replies are anonymous, it will help us to understand your answers better if we have a little background data from everyone, as covered in the following questions.

EUROQOL2 (TYPE 4)

1 Have you experienced serious illness: *in you yourself?* ☐0 No ☐1 Yes
in your family? ☐0 No ☐1 Yes
in caring for others? ☐0 No ☐1 Yes

2 What is your age in years? _____

3 Are you *(please check appropriate box)*: ☐1 Male
☐2 Female

4 Are you *(please check only one)*: ☐1 A current smoker
☐2 An ex-smoker
☐3 A never smoker

5 Do you now, or did you ever, work in health or social services?
☐0 No
☐1 Yes → If Yes: In what capacity? _____

6 Which of the following best describes your main activity *(please check only one)*?
☐1 Employed (including self employment)
☐2 Retired
☐3 Keeping house
☐4 Student
☐5 Seeking work
☐98 Other (please specify): _____

7 What is the highest level of education you have completed *(please check only one)*?
☐1 Some high school or less
☐2 High school graduate or GED
☐3 Vocational college or some college
☐4 College degree
☐5 Professional or graduate degree

8 If you know your zip code, please write it here: ___ ___ ___ ___ ___

SF-36 Assessment

SF36_1 (TYPE 4)

1 In general, would you say your health is:

☐1 Excellent ☐2 Very good ☐3 Good ☐4 Fair ☐5 Poor

2 Compared to one year ago, how would you rate your health in general now?

☐1 Much better than one year ago ☐3 About the same as one year ago ☐5 Much worse now than one year ago

☐2 Somewhat better than one year ago ☐4 Somewhat worse than one year ago

3 The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. **Vigorous activities,** such as running, lifting heavy objects, participating in strenuous sports	☐1	☐2	☐3
b. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐1	☐2	☐3
c. Lifting or carrying groceries	☐1	☐2	☐3
d. Climbing **several** flights of stairs	☐1	☐2	☐3
e. Climbing **one** flight of stairs	☐1	☐2	☐3
f. Bending, kneeling or stooping	☐1	☐2	☐3
g. Walking **more than a mile**	☐1	☐2	☐3
h. Walking **several blocks**	☐1	☐2	☐3
i. Walking **one block**	☐1	☐2	☐3
j. Bathing or dressing yourself	☐1	☐2	☐3

4 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
a. Cut down on the **amount of time** you spend on work or other activities	☐1	☐2	☐3	☐4	☐5
b. **Accomplished less** than you would like	☐1	☐2	☐3	☐4	☐5
c. Were limited in the **kind** of work or other activities	☐1	☐2	☐3	☐4	☐5
d. Had **difficulty** performing the work or other activities *(for example, it took extra effort)*	☐1	☐2	☐3	☐4	☐5

5 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
a. Cut down on the **amount of time** you spend on work or other activities	☐1	☐2	☐3	☐4	☐5
b. **Accomplished less** than you would like	☐1	☐2	☐3	☐4	☐5
c. Did work or other activities **less carefully than usual**	☐1	☐2	☐3	☐4	☐5

SF-36 Assessment (continued)

SF36_2 (TYPE 4)

6 During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

☐1 Not at all ☐2 Slightly ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

7 How much bodily pain have you had during the past 4 weeks?

☐1 None ☐2 Very mild ☐3 Mild ☐4 Moderate ☐5 Severe ☐6 Very severe

8 During the past 4 weeks, how much did pain interfere with your normal work *(including both work outside the home and housework)*?

☐1 Not at all ☐2 Slightly ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

9 These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of life?	☐1	☐2	☐3	☐4	☐5
b. Have you been very nervous?	☐1	☐2	☐3	☐4	☐5
c. Have you felt so down in the dumps that nothing could cheer you up?	☐1	☐2	☐3	☐4	☐5
d. Have you felt calm and peaceful?	☐1	☐2	☐3	☐4	☐5
e. Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5
f. Have you felt downhearted and depressed?	☐1	☐2	☐3	☐4	☐5
g. Did you feel worn out?	☐1	☐2	☐3	☐4	☐5
h. Have you been happy?	☐1	☐2	☐3	☐4	☐5
i. Did you feel tired?	☐1	☐2	☐3	☐4	☐5

10 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities *(like visiting friends, relatives, etc.)*?

☐1 All of the time ☐2 Most of the time ☐3 Some of the time ☐4 A little of the time ☐5 None of the time

11 How **True** or **False** is each of the following statements for you?

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people	☐1	☐2	☐3	☐4	☐5
b. I am as healthy as anybody I know	☐1	☐2	☐3	☐4	☐5
c. I expect my health to get worse	☐1	☐2	☐3	☐4	☐5
d. My health is excellent	☐1	☐2	☐3	☐4	☐5

SEE ANNOTATION P. 18

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ Subject Initials: ___ ___ ___
site # subject #

UCSDSOB1 (TYPE 4)

UCSD Shortness-of-Breath Questionnaire UCSD SOBQ

When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All				Severe	Maximal/ Unable To Do Because of Breathlessness
1 At rest	0	1	2	3	4	5
2 Walking on a level at your own pace	0	1	2	3	4	5
3 Walking on a level with others your age	0	1	2	3	4	5
4 Walking up a hill	0	1	2	3	4	5
5 Walking up stairs	0	1	2	3	4	5
6 While eating	0	1	2	3	4	5
7 Standing up from a chair	0	1	2	3	4	5
8 Brushing teeth	0	1	2	3	4	5
9 Shaving and/or brushing hair	0	1	2	3	4	5
10 Showering/bathing	0	1	2	3	4	5
11 Dressing	0	1	2	3	4	5
12 Picking up and straightening	0	1	2	3	4	5

UCSD Shortness-of-Breath Questionnaire UCSD SOBQ (continued)

When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All				Severe	Maximal/ Unable To Do Because of Breathlessness
13 Doing dishes	0	1	2	3	4	5
14 sweeping/vacuuming	0	1	2	3	4	5
15 Making bed	0	1	2	3	4	5
16 Shopping	0	1	2	3	4	5
17 Doing laundry	0	1	2	3	4	5
18 Washing car	0	1	2	3	4	5
19 Mowing lawn	0	1	2	3	4	5
20 Watering lawn	0	1	2	3	4	5
21 Sexual activities	0	1	2	3	4	5
How much do these limit you in your daily life?						
22 Shortness of breath	0	1	2	3	4	5
23 Fear of "hurting myself"	0	1	2	3	4	5
24 Fear of shortness of breath	0	1	2	3	4	5

SEE ANNOTATION P. 20

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

St. George's Respiratory Questionnaire (SGRQ) (English for the United States)

STGRG1 (TYPE 4)

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you the most problems, rather than what the doctors and nurses think your problems are.

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

Before completing the questionnaire:
Please check one box to show how you describe your current health:

- ☐ Very good
- ☐ Good
- ☐ Fair
- ☐ Poor
- ☐ Very poor

St. George's Respiratory Questionnaire Part 1

Please describe how often your respiratory problems have affected you over the past 4 weeks.

STGSG2(TYPE 4)

Please check ☑ one box for each question.	Almost Every Day	Several Days a Week	A Few Days a Month	Only with Respiratory Infections	Not At All
1 Over the past 4 weeks, I have coughed:	☐	☐	☐	☐	☐
2 Over the past 4 weeks, I have brought up phlegm (sputum):	☐	☐	☐	☐	☐
3 Over the past 4 weeks, I have had shortness of breath:	☐	☐	☐	☐	☐
4 Over the past 4 weeks, I have had wheezing attacks:	☐	☐	☐	☐	☐

5 How many times during the past 4 weeks have you suffered from severe or very unpleasant respiratory attacks? Please check ☑ one:

- ☐ More than 3 times
- ☐ 3 times
- ☐ 2 times
- ☐ 1 time
- ☐ None of the time

6 How long did the worst respiratory attack last? Please check ☑ one:

(Go to question 7 if you did not have a severe attack)

- ☐ A week or more
- ☐ 3 or more days
- ☐ 1 or 2 days
- ☐ Less than a day

7 Over the past 4 weeks, in a typical week, how many good days (with few respiratory problems) have you had? Please check ☑ one:

- ☐ No good days
- ☐ 1 or 2 good days
- ☐ 3 or 4 good days
- ☐ Nearly every day was good
- ☐ Every day was good

8 If you wheeze, is it worse when you get up in the morning? Please check ☑ one:

- ☐$_0$ No
- ☐$_1$ Yes

SEE ANNOTATION P. 22

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

St. George's Respiratory Questionnaire Part 2

Section 1

STGRG3 (TYPE 4)

9 How would you describe your respiratory condition? Please check ☑ one:

- ☐ The most important problem I have
- ☐ Causes me quite a lot of problems
- ☐ Causes me a few problems
- ☐ Causes me no problems

10 If you have ever held a job *(please check ☑ one)*:

- ☐ My respiratory problems made me stop working altogether
- ☐ My respiratory problems interfere with my job or made me change my job
- ☐ My respiratory problems do not affect my job

Section 2

These are questions about what activities usually make you feel short of breath these days.

For each statement, please check ☑ **the box** that applies to you **these days.**

11 Sitting or lying still	☐1 True	☐0 False
Washing or dressing yourself	☐1 True	☐0 False
Walking around the house	☐1 True	☐0 False
Walking outside on a level ground	☐1 True	☐0 False
Walking up a flight of stairs	☐1 True	☐0 False
Walking up hills	☐1 True	☐0 False
Playing sports or other physical activities	☐1 True	☐0 False

Section 3

12 These are more questions about your cough and shortness of breath these days.

For each statement, please check ☑ **the box** that applies to you **these days.**

Coughing hurts	☐1 True	☐0 False
Coughing makes me tired	☐1 True	☐0 False
I am short of breath when I talk	☐1 True	☐0 False
I am short of breath when I bend over	☐1 True	☐0 False
My coughing or breathing disturbs my sleep	☐1 True	☐0 False
I get exhausted easily	☐1 True	☐0 False

St. George's Respiratory Questionnaire Part 2 (continued)

Section 4

STGRG4 (TYPE 4)

13 These are questions about other effects that your respiratory problems may have on you <u>these days</u>.

For each statement, please check ☑ ***the box*** that applies to you ***these days.***

My cough or breathing is embarrassing in public	☐1 True	☐0 False
My respiratory problems are a nuisance to my family, friends or neighbors	☐1 True	☐0 False
I get afraid or panic when I cannot catch my breath	☐1 True	☐0 False
I feel that I am not in control of my respiratory problems	☐1 True	☐0 False
I do not expect my respiratory problems to get any better	☐1 True	☐0 False
I have become frail or an invalid because of my respiratory problems	☐1 True	☐0 False
Exercise is not safe for me	☐1 True	☐0 False
Everything seems too much of an effort	☐1 True	☐0 False

Section 5

14 These are questions about your respiratory treatment. If you are not receiving treatment, +go to Section 6.

For each statement, please check ☑ ***the box*** that applies to you ***these days.***

My treatment does not help me very much	☐1 True	☐0 False
I get embarrassed using my medication in public	☐1 True	☐0 False
I have unpleasant side effects from my medication	☐1 True	☐0 False
My treatment interferes with my life a lot	☐1 True	☐0 False

St. George's Respiration Questionnaire Part 2 (continued)

STGRG5 (TYPE 4)

Section 6

15 These are questions about how your activities might be affected by your respiratory problems.

For each statement, please check ☑ **the box** that applies to you ***because of your respiratory problems.***

I take a long time to get washed or dressed	☐1 True	☐0 False
I cannot take a bath or shower, or I take a long time to do it	☐1 True	☐0 False
I walk slower than other people my age, or I stop to rest	☐1 True	☐0 False
Jobs such as household chores take a long time, or I have to stop to rest	☐1 True	☐0 False
If I walk up one flight of stairs, I have to go slowly or stop	☐1 True	☐0 False
If I hurry or walk fast, I have to stop or slow down	☐1 True	☐0 False
My breathing makes it difficult to do things such as walk up hills, carry things up stairs, light gardening such as weeding, dance, bowl, or play	☐1 True	☐0 False
My breathing makes it difficult to do things such as carry heavy loads, dig in the garden or shovel snow, jog or walk briskly (5 miles per hour), play tennis or swim	☐1 True	☐0 False
My breathing makes it difficult to do things such as very heavy manual work, ride a bike, run, swim fast, or play competitive sports	☐1 True	☐0 False

SEE PAGE 24

SEE PAGE 24

SEE PAGE 24

Section 7

16 We would like to know how your respiratory problems usually affect your daily life.

For each statement, please check ☑ **the box** that applies to you ***because of your respiratory problems.***

I cannot play sports or do other physical activities	☐1 True	☐0 False
I cannot go out for entertainment or recreation	☐1 True	☐0 False
I cannot go out of the house to do the shopping	☐1 True	☐0 False
I cannot do household chores	☐1 True	☐0 False
I cannot move far from my bed or chair	☐1 True	☐0 False

St. George's Respiratory Questionnaire (continued)

STGRG6 (TYPE 4)

Here is a list of other activities that your respiratory problems may prevent you from doing. (You do not have to check these; they are just to remind you of ways your shortness of breath may affect you.)

- Going for walks or walking the dog
- Doing activities or chores at home or in the garden
- Sexual intercourse
- Going to a place of worship, or a place of entertainment
- Going out in bad weather or into smoky rooms
- Visiting family or friends or playing with children

Please write in any other important activities that your respiratory problems may stop you from doing:

_____

_____

_____

_____

_____

_____

_____

17 Now please check the box *(one only)* that you think best describes how your respiratory problems affect you:

- ☐ It does not stop me from doing anything I would like to do
- ☐ It stops me from doing one or two things I would like to do
- ☐ It stops me from doing most of the things I would like to do
- ☐ It stops me from doing everything I would like to do

Before you finish, would you please make sure that you have answered all the questions.

Thank you for completing this questionnaire.

ICECAP Questionnaire

By placing a check ☑ in one box in each group below, please indicate which statement best describes your quality of life at the moment.

ICECAP (TYPE 4)

Love and Friendship	☐1 I can have **all** of the love and friendship that I want ☐2 I can have **a lot** of the love and friendship that I want ☐3 I can have **a little** of the love and friendship that I want ☐4 I cannot have **any** of the love and friendship that I want
Thinking about the future	☐1 I can think about the future **without any** concern ☐2 I can think about the future with **only a little** concern ☐3 I can only think about the future with **some** concern ☐4 I can only think about the future with **a lot** of concern
Doing things that make you feel valued	☐1 I am able to do **all** of the things that make me feel valued ☐2 I am able to do **many** of the things that make me feel valued ☐3 I am able to do **a few** of the things that make me feel valued ☐4 I am unable to do **any** of the things that make me feel valued
Enjoyment and pleasure	☐1 I can have **all** of the enjoyment and pleasure that I want ☐2 I can have **a lot** of of the enjoyment and pleasure that I want ☐3 I can have **a little** of the enjoyment and pleasure that I want ☐4 I cannot have **any** of the enjoyment and pleasure that I want
Independence	☐1 I am able to be **completely** independent ☐2 I am able to be independent **in many things** ☐3 I am able to be independent in **a few things** ☐4 I am **unable** to be at all independent

STEP-IPF IPFnet

FORM=WEEK12

NODATA<XYES>

Week 12

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Visit date: ___/___/___ (day/month/year) Check if Early Termination visit for double-blind phase: ☐

EARLYTER <XYES>

SEE ANNOTATION P.11

VISTDATE (TYPE 4)

Vital Signs

1 Weight: ___ ___ ___ ☐1 lb ☐2 kg

2 Blood pressure: ___ ___ ___/___ ___ ___ mm Hg (systolic/diastolic)

3 Heart rate: ___ ___ ___ bpm

VITALS (TYPE 4)

SEE ANNOTATION P.11

NOTE: EXCEPT NO HEIGHT or SPO2

NYHA Functional Class

Current NYHA heart failure classification *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

NYHA (TYPE 4)

SEE ANNOTATION P.11

Spirometry

Date of assessment: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year)

SEE ANNOTATION P.2

NOTE: DO NOT ADD QUESTIONS 4,5,6

1 FEV_1: Actual: ___ . ___ ___ liters

2 FEV_6: Actual: ___ . ___ ___ liters

3 FVC: Actual: ___ . ___ ___ liters

SPIROMET (TYPE 4)

Diffusing Capacity of the Lung for Carbon Monoxide (DLCO)

Date of assessment: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year)

SEE ANNOTATION P.12

DLCO (TYPE 4)

1 DLCO: Actual: ___ ___ . ___ ___ mL/min/mm Hg → Altitude-corrected DLCO *(National Jewish only)*: ___ ___ . ___ ___ mL/min/mm Hg

2 VI *(inspired volume)*: ___ . ___ ___ liters

3 VA *(alveolar volume)*: ___ . ___ ___ liters

Arterial Blood Gas (ABG)

Date of assessment: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year)

ABG (TYPE 4)

1 Barometric pressure: ___ ___ ___ mm Hg

SEE ANNOTATION P.12

2 Clinic altitude *(check only one)*: ☐1 < 4000 ft ☐2 ≥ 4000 ft

3 FiO_2: ___ ___ ___ %

4 pH: ___ . ___ ___

5 PaO_2: ___ ___ ___ mm Hg

6 $PaCO_2$: ___ ___ ___ mm Hg

7 SaO_2: ___ ___ ___ %

Site Personnel's Initials: ___ ___ ___

6-Minute Walk Test (6MWT)

Date of assessment: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

WALK (TYPE4)

1 Pre-walk modified Borg Dyspnea Scale rating:
☐ 0 ☐ 0.5 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 97 Not done

2 Resting room air SpO_2: ___ ___ ___ %

3 Was supplemental O_2 used during walk? ☐ 0 No ☐ 1 Yes → If Yes: Specify: _____ liters/min
SpO_2 on Supplemental O_2 : ___ ___ ___ %

4 Was walk performed? ☐ 0 No → Provide reason: _____
☐ 1 Yes

5 Was a walking aid necessary to perform the 6MWT?
☐ 0 No
☐ 1 Yes → If Yes: Specify *(check only one)*: ☐ 1 Cane ☐ 2 Walker ☐ 98 Other *(specify)*: _____

WALKTIME(TYPE4)PS

6 Minutes	Heart Rate	SpO_2
Pre-walk	___ ___ ___ bpm	
1 minute	___ ___ ___ bpm	___ ___ ___ %
2 minutes	___ ___ ___ bpm	___ ___ ___ %
3 minutes	___ ___ ___ bpm	___ ___ ___ %
4 minutes	___ ___ ___ bpm	___ ___ ___ %
5 minutes	___ ___ ___ bpm	___ ___ ___ %
6 minutes	___ ___ ___ bpm	___ ___ ___ %
Three minutes of recovery after completion or stop of 6-Minute Walk Test		
1 minute	___ ___ ___ bpm	___ ___ ___ %
2 minutes	___ ___ ___ bpm	___ ___ ___ %
3 minutes	___ ___ ___ bpm	___ ___ ___ %

6 Did subject desaturate ($SpO_2 \leq 88\%$)? ☐ 0 No
☐ 1 Yes → If Yes: Walk duration at desaturation: _____ min / _____ sec
Walk distance at desaturation: ___ ___ ___ meters

Lowest SpO_2	Distance Walked	Did Subject Complete 6-Minute Walk?	If Stopped Early: Specify Reason (Check only one)
___ ___ ___ . ___ %	___ ___ ___ meters	☐ 0 No → If No: Duration: ___ / ___ (min / sec) ☐ 1 Yes	☐ 1 SpO_2 < 80% ☐ 2 Developed signs and symptoms requiring termination of test ☐ 98 Other *(specify)*: _____

7 Post-walk modified Borg Dyspnea Scale rating:
☐ 0 ☐ 0.5 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 97 Not done

Site Personnel's Initials: ___ ___ ___

NODATA<XYES>

STEP-IPF IPFnet

SEE ANNOTATION P. 31

Week 12

Subject ID: 02 - ___ ___ ___ (site #) - ___ ___ ___ (subject #) Subject Initials: ___ ___ ___

Urgent or Inpatient Admissions

Has the subject been admitted to the hospital, emergency room,/urgent care, assisted living/nursing facility, or rehabilitation center since the last study visit *(do not include protocol-specific study visits)*? ☐0 No ☐1 Yes → **If Yes: Provide details below.**

INPATNT (TYPE 4)R

	Reason for Admission	Major Procedures Performed	Discharge Destination *(check only one)*
1 **Admission date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Discharge date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Admission type** *(check only one)*: ☐1 Hospital ☐2 ER/urgent care ☐3 Assisted living/nursing facility ☐4 Rehabilitation center	☐1 Check if respiratory-related.		☐1 Home ☐2 Assisted living/nursing facility ☐3 Rehab center ☐4 Transfer to other hospital ☐5 Subject died ☐98 Other *(specify)*: _____ _____
2 **Admission date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Discharge date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Admission type** *(check only one)*: ☐1 Hospital ☐2 ER/urgent care ☐3 Assisted living/nursing facility ☐4 Rehabilitation center	☐1 Check if respiratory-related.		☐1 Home ☐2 Assisted living/nursing facility ☐3 Rehab center ☐4 Transfer to other hospital ☐5 Subject died ☐98 Other *(specify)*: _____ _____
3 **Admission date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Discharge date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Admission type** *(check only one)*: ☐1 Hospital ☐2 ER/urgent care ☐3 Assisted living/nursing facility ☐4 Rehabilitation center	☐1 Check if respiratory-related.		☐1 Home ☐2 Assisted living/nursing facility ☐3 Rehab center ☐4 Transfer to other hospital ☐5 Subject died ☐98 Other *(specify)*: _____ _____

Outpatient Visits

Has the subject required any non-urgent outpatient visits since the last study visit *(do not include protocol-specific study visits)*?

☐0 No ☐1 Yes → If Yes: Provide details below.

OUTPATNT (TYPE 4)PS

Provider Type	No. of Respiratory-related Visits	No. of Non-respiratory-related Visits
1 Pulmonologist		
2 Cardiologist		
3 Other specialist: _____		
4 Primary care physician *(or NP or PA)*		
5 OT or PT		
6 Mental health provider		
7 Other *(specify)*: _____		

Self-administered Questionnaires

Date administered: ___/___/___ (day / month / year)

SELFREPT (TYPE 4)

SEE ANNOTATION P. 13

No GENDRPT

1	EuroQol	☐ 1 Attached	☐ 97 Not done
2	SF-36	☐ 1 Attached	☐ 97 Not done
3	UCSD Shortness-of-Breath	☐ 1 Attached	☐ 97 Not done
4	St. George's Respiratory	☐ 1 Attached	☐ 97 Not done
5	ICECAP	☐ 1 Attached	☐ 97 Not done

GERD Substudy Review

Record all GERD related medications in the GERD Concomitant Medications log

GERDSUB (TYPE 4)

1 Have there been any changes in the subject's GERD status since last visit?

☐ 0 No → Skip to question 3

☐ 1 Yes → If Yes: Check only one:

SEE ANNOTATION P. 28

- ☐ 1 Newly diagnosed → Record on Adverse Event Log
  - How diagnosed *(check all that apply)*:
    - ☐ 24 hr pH monitoring ☐ Endoscopy ☐ Upper GI/barium swallow test
    - ☐ Symptoms of heartburn OR ☐ Unknown
- ☐ 2 Changes in non-pharmaceutical interventions
- ☐ 98 Other (including medications only) → Skip to question 3

2 If newly diagnosed GERD or changes in non-pharmaceutical interventions, answer all questions below:

Sleeping with the head end of the bed elevated with 6" to 8" blocks on the floor	☐ 0 No	☐ 1 Yes
Sleeping in a recliner	☐ 0 No	☐ 1 Yes
Limiting foods and beverages that cause symptoms	☐ 0 No	☐ 1 Yes
Avoiding lying down flat for 3 hours after a meal	☐ 0 No	☐ 1 Yes
Avoiding bedtime snacks	☐ 0 No	☐ 1 Yes
Eating small meals	☐ 0 No	☐ 1 Yes

3 Have there been any changes in the subject's obstructive sleep apnea status since last visit?

☐ 0 No → Skip to Safety Review

☐ 1 Yes → If Yes: Check only one:

- ☐ 1 Newly diagnosed → Record on Adverse Event Log
- ☐ 2 Changes in CPAP treatment
- ☐ 98 Other (including medications only) → Skip to Safety Review

4 If newly diagnosed sleep apnea or changes in CPAP treatment, specify current CPAP treatment:

☐ 0 None ☐ 1 Daily ☐ 2 Intermittent

Safety Review

SEE ANNOTATION P. 28

Has the subject experienced unexplained worsened dyspnea or cough since last visit, triggering unscheduled medical care *(e.g., clinic, study visit, hospitalization)*?

SAFETY (TYPE 4)

☐ 0 No ☐ 1 Yes → If Yes: Please send support materials for acute exacerbation review.

Record any new Adverse Events on the Adverse Event Log page.

Record any new or changed medications on the Concomitant Medications Log page.

EuroQol Questionnaire EQ-5D English version for the U.S.

By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.

EUROQOL1(TYPE 4)

1 Mobility:
- ☐ 1 I have no problems in walking about
- ☐ 2 I have some problems in walking about
- ☐ 3 I am confined to bed

2 Self-care:
- ☐ 1 I have no problems with self-care
- ☐ 2 I have some problems washing or dressing myself
- ☐ 3 I am unable to wash or dress myself

3 Usual activities (e.g., work, study, housework, family, or leisure activities):
- ☐ 1 I have no problems with performing my usual activities
- ☐ 2 I have some problems with performing my usual activities
- ☐ 3 I am unable to perform my usual activities

4 Pain/discomfort:
- ☐ 1 I have no pain or discomfort
- ☐ 2 I have moderate pain or discomfort
- ☐ 3 I have extreme pain or discomfort

5 Anxiety/depression:
- ☐ 1 I am not anxious or depressed
- ☐ 2 I am moderately anxious or depressed
- ☐ 3 I am extremely anxious or depressed

STOP.
Please let your study coordinator know that you are ready for the EuroQol Thermometer worksheet.

EuroQol Thermometer Response (Study staff use only)

Response to the EuroQol thermometer *(0–100)*: ___ ___ ___

EuroQol Questionnaire EQ-5D (continued)

Because all replies are anonymous, it will help us to understand your answers better if we have a little background data from everyone, as covered in the following questions.

EUROQOL2(TYPE 4)

1 Have you experienced serious illness: *in you yourself?* ☐0 No ☐1 Yes
in your family? ☐0 No ☐1 Yes
in caring for others? ☐0 No ☐1 Yes

2 What is your age in years? _____

3 Are you *(please check appropriate box)*: ☐1 Male
☐2 Female

4 Are you *(please check only one)*: ☐1 A current smoker
☐2 An ex-smoker
☐3 A never smoker

5 Do you now, or did you ever, work in health or social services?
☐0 No
☐1 Yes → If Yes: In what capacity? _____

6 Which of the following best describes your main activity *(please check only one)*?
☐1 Employed (including self employment)
☐2 Retired
☐3 Keeping house
☐4 Student
☐5 Seeking work
☐98 Other (please specify): _____

7 What is the highest level of education you have completed *(please check only one)*?
☐1 Some high school or less
☐2 High school graduate or GED
☐3 Vocational college or some college
☐4 College degree
☐5 Professional or graduate degree

8 If you know your zip code, please write it here: ___ ___ ___ ___ ___

SF-36 Assessment

SF36_1 (TYPE 4)

1 In general, would you say your health is:

☐1 Excellent ☐2 Very good ☐3 Good ☐4 Fair ☐5 Poor

2 Compared to one year ago, how would you rate your health in general now?

☐1 Much better than one year ago ☐3 About the same as one year ago ☐5 Much worse now than one year ago

☐2 Somewhat better than one year ago ☐4 Somewhat worse than one year ago

3 The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. **Vigorous activities,** such as running, lifting heavy objects, participating in strenuous sports	☐1	☐2	☐3
b. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐1	☐2	☐3
c. Lifting or carrying groceries	☐1	☐2	☐3
d. Climbing **several** flights of stairs	☐1	☐2	☐3
e. Climbing **one** flight of stairs	☐1	☐2	☐3
f. Bending, kneeling or stooping	☐1	☐2	☐3
g. Walking **more than a mile**	☐1	☐2	☐3
h. Walking **several blocks**	☐1	☐2	☐3
i. Walking **one block**	☐1	☐2	☐3
j. Bathing or dressing yourself	☐1	☐2	☐3

4 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
a. Cut down on the **amount of time** you spend on work or other activities	☐1	☐2	☐3	☐4	☐5
b. **Accomplished less** than you would like	☐1	☐2	☐3	☐4	☐5
c. Were limited in the **kind** of work or other activities	☐1	☐2	☐3	☐4	☐5
d. Had **difficulty** performing the work or other activities *(for example, it took extra effort)*	☐1	☐2	☐3	☐4	☐5

5 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
a. Cut down on the **amount of time** you spend on work or other activities	☐1	☐2	☐3	☐4	☐5
b. **Accomplished less** than you would like	☐1	☐2	☐3	☐4	☐5
c. Did work or other activities **less carefully than usual**	☐1	☐2	☐3	☐4	☐5

SF-36 Assessment (continued)

SF36_2 (TYPE 4)

6 During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

☐1 Not at all ☐2 Slightly ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

7 How much bodily pain have you had during the past 4 weeks?

☐1 None ☐2 Very mild ☐3 Mild ☐4 Moderate ☐5 Severe ☐6 Very severe

8 During the past 4 weeks, how much did pain interfere with your normal work *(including both work outside the home and housework)*?

☐1 Not at all ☐2 Slightly ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

9 These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of life?	☐1	☐2	☐3	☐4	☐5
b. Have you been very nervous?	☐1	☐2	☐3	☐4	☐5
c. Have you felt so down in the dumps that nothing could cheer you up?	☐1	☐2	☐3	☐4	☐5
d. Have you felt calm and peaceful?	☐1	☐2	☐3	☐4	☐5
e. Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5
f. Have you felt downhearted and depressed?	☐1	☐2	☐3	☐4	☐5
g. Did you feel worn out?	☐1	☐2	☐3	☐4	☐5
h. Have you been happy?	☐1	☐2	☐3	☐4	☐5
i. Did you feel tired?	☐1	☐2	☐3	☐4	☐5

10 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities *(like visiting friends, relatives, etc.)*?

☐1 All of the time ☐2 Most of the time ☐3 Some of the time ☐4 A little of the time ☐5 None of the time

11 How **True** or **False** is each of the following statements for you?

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people	☐1	☐2	☐3	☐4	☐5
b. I am as healthy as anybody I know	☐1	☐2	☐3	☐4	☐5
c. I expect my health to get worse	☐1	☐2	☐3	☐4	☐5
d. My health is excellent	☐1	☐2	☐3	☐4	☐5

UCSD Shortness-of-Breath Questionnaire UCSD SOBQ

When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All				Severe	Maximal/ Unable To Do Because of Breathlessness
1 At rest	0	1	2	3	4	5
2 Walking on a level at your own pace	0	1	2	3	4	5
3 Walking on a level with others your age	0	1	2	3	4	5
4 Walking up a hill	0	1	2	3	4	5
5 Walking up stairs	0	1	2	3	4	5
6 While eating	0	1	2	3	4	5
7 Standing up from a chair	0	1	2	3	4	5
8 Brushing teeth	0	1	2	3	4	5
9 Shaving and/or brushing hair	0	1	2	3	4	5
10 Showering/bathing	0	1	2	3	4	5
11 Dressing	0	1	2	3	4	5
12 Picking up and straightening	0	1	2	3	4	5

UCSD Shortness-of-Breath Questionnaire UCSD SOBQ (continued)

When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All				Severe	Maximal/ Unable To Do Because of Breathlessness
13 Doing dishes	0	1	2	3	4	5
14 sweeping/vacuuming	0	1	2	3	4	5
15 Making bed	0	1	2	3	4	5
16 Shopping	0	1	2	3	4	5
17 Doing laundry	0	1	2	3	4	5
18 Washing car	0	1	2	3	4	5
19 Mowing lawn	0	1	2	3	4	5
20 Watering lawn	0	1	2	3	4	5
21 Sexual activities	0	1	2	3	4	5
How much do these limit you in your daily life?						
22 Shortness of breath	0	1	2	3	4	5
23 Fear of "hurting myself"	0	1	2	3	4	5
24 Fear of shortness of breath	0	1	2	3	4	5

SEE ANNOTATION P. 20

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

St. George's Respiratory Questionnaire (SGRQ) (English for the United States)

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you the most problems, rather than what the doctors and nurses think your problems are.

STGRG1(TYPE 4)

Please read the instructions carefully and ask if you do not understand anything.
Do not spend too long deciding about your answers.

Before completing the questionnaire:
Please check one box to show how you describe your current health:

- ☐ Very good
- ☐ Good
- ☐ Fair
- ☐ Poor
- ☐ Very poor

SEE ANNOTATION P. 21

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

St. George's Respiratory Questionnaire Part 1

Please describe how often your respiratory problems have affected you over the past 4 weeks.

STGRG2(TYPE 4)

Please check ☑ one box for each question.	Almost Every Day	Several Days a Week	A Few Days a Month	Only with Respiratory Infections	Not At All
1 Over the past 4 weeks, I have coughed:	☐	☐	☐	☐	☐
2 Over the past 4 weeks, I have brought up phlegm (sputum):	☐	☐	☐	☐	☐
3 Over the past 4 weeks, I have had shortness of breath:	☐	☐	☐	☐	☐
4 Over the past 4 weeks, I have had wheezing attacks:	☐	☐	☐	☐	☐

5 How many times during the past 4 weeks have you suffered from severe or very unpleasant respiratory attacks? Please check ☑ one:

- ☐ More than 3 times
- ☐ 3 times
- ☐ 2 times
- ☐ 1 time
- ☐ None of the time

6 How long did the worst respiratory attack last? Please check ☑ one:

(Go to question 7 if you did not have a severe attack)

- ☐ A week or more
- ☐ 3 or more days
- ☐ 1 or 2 days
- ☐ Less than a day

7 Over the past 4 weeks, in a typical week, how many good days (with few respiratory problems) have you had? Please check ☑ one:

- ☐ No good days
- ☐ 1 or 2 good days
- ☐ 3 or 4 good days
- ☐ Nearly every day was good
- ☐ Every day was good

8 If you wheeze, is it worse when you get up in the morning? Please check ☑ one:

- ☐ 0 No
- ☐ 1 Yes

SEE ANNOTATION P. 22

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

St. George's Respiratory Questionnaire Part 2

Section 1

9 How would you describe your respiratory condition? Please check ☑ one:

- ☐ The most important problem I have
- ☐ Causes me quite a lot of problems
- ☐ Causes me a few problems
- ☐ Causes me no problems

STGRG3(TYPE 4)

10 If you have ever held a job *(please check ☑ one)*:

- ☐ My respiratory problems made me stop working altogether
- ☐ My respiratory problems interfere with my job or made me change my job
- ☐ My respiratory problems do not affect my job

Section 2

These are questions about what activities usually make you feel short of breath these days.

For each statement, please check ☑ **the box** that applies to you **these days.**

11 Sitting or lying still	☐1 True	☐0 False
Washing or dressing yourself	☐1 True	☐0 False
Walking around the house	☐1 True	☐0 False
Walking outside on a level ground	☐1 True	☐0 False
Walking up a flight of stairs	☐1 True	☐0 False
Walking up hills	☐1 True	☐0 False
Playing sports or other physical activities	☐1 True	☐0 False

Section 3

12 These are more questions about your cough and shortness of breath these days.

For each statement, please check ☑ **the box** that applies to you **these days.**

Coughing hurts	☐1 True	☐0 False
Coughing makes me tired	☐1 True	☐0 False
I am short of breath when I talk	☐1 True	☐0 False
I am short of breath when I bend over	☐1 True	☐0 False
My coughing or breathing disturbs my sleep	☐1 True	☐0 False
I get exhausted easily	☐1 True	☐0 False

St. George's Respiratory Questionnaire Part 2 (continued)

STGRG4(TYPE 4)

Section 4

13 These are questions about other effects that your respiratory problems may have on you <u>these days</u>.

For each statement, please check ☑ ***the box*** that applies to you ***these days.***

My cough or breathing is embarrassing in public	☐1 True	☐0 False
My respiratory problems are a nuisance to my family, friends or neighbors	☐1 True	☐0 False
I get afraid or panic when I cannot catch my breath	☐1 True	☐0 False
I feel that I am not in control of my respiratory problems	☐1 True	☐0 False
I do not expect my respiratory problems to get any better	☐1 True	☐0 False
I have become frail or an invalid because of my respiratory problems	☐1 True	☐0 False
Exercise is not safe for me	☐1 True	☐0 False
Everything seems too much of an effort	☐1 True	☐0 False

Section 5

14 These are questions about your respiratory treatment. If you are not receiving treatment, +go to Section 6.

For each statement, please check ☑ ***the box*** that applies to you ***these days.***

My treatment does not help me very much	☐1 True	☐0 False
I get embarrassed using my medication in public	☐1 True	☐0 False
I have unpleasant side effects from my medication	☐1 True	☐0 False
My treatment interferes with my life a lot	☐1 True	☐0 False

St. George's Respiration Questionnaire Part 2 (continued)

Section 6

STGRG5(TYPE 4)

15 These are questions about how your activities might be affected by your respiratory problems.

For each statement, please check ☑ **the box** that applies to you ***because of your respiratory problems.***

I take a long time to get washed or dressed	☐1 True	☐0 False
I cannot take a bath or shower, or I take a long time to do it	☐1 True	☐0 False
I walk slower than other people my age, or I stop to rest	☐1 True	☐0 False
Jobs such as household chores take a long time, or I have to stop to rest	☐1 True	☐0 False
If I walk up one flight of stairs, I have to go slowly or stop	☐1 True	☐0 False
If I hurry or walk fast, I have to stop or slow down	☐1 True	☐0 False
My breathing makes it difficult to do things such as walk up hills, carry things up stairs, light gardening such as weeding, dance, bowl, or play	☐1 True	☐0 False
My breathing makes it difficult to do things such as carry heavy loads, dig in the garden or shovel snow, jog or walk briskly (5 miles per hour), play tennis or swim	☐1 True	☐0 False
My breathing makes it difficult to do things such as very heavy manual work, ride a bike, run, swim fast, or play competitive sports	☐1 True	☐0 False

SEE PAGE 24

SEE PAGE 24

SEE PAGE 24

Section 7

16 We would like to know how your respiratory problems usually affect your daily life.

For each statement, please check ☑ **the box** that applies to you ***because of your respiratory problems.***

I cannot play sports or do other physical activities	☐1 True	☐0 False
I cannot go out for entertainment or recreation	☐1 True	☐0 False
I cannot go out of the house to do the shopping	☐1 True	☐0 False
I cannot do household chores	☐1 True	☐0 False
I cannot move far from my bed or chair	☐1 True	☐0 False

St. George's Respiratory Questionnaire (continued)

Here is a list of other activities that your respiratory problems may prevent you from doing. (You do not have to check these; they are just to remind you of ways your shortness of breath may affect you.)

STGRG6(TYPE 4)

- Going for walks or walking the dog
- Doing activities or chores at home or in the garden
- Sexual intercourse
- Going to a place of worship, or a place of entertainment
- Going out in bad weather or into smoky rooms
- Visiting family or friends or playing with children

Please write in any other important activities that your respiratory problems may stop you from doing:

_____

_____

_____

_____

_____

_____

_____

17 Now please check the box *(one only)* that you think best describes how your respiratory problems affect you:

- ☐ It does not stop me from doing anything I would like to do
- ☐ It stops me from doing one or two things I would like to do
- ☐ It stops me from doing most of the things I would like to do
- ☐ It stops me from doing everything I would like to do

Before you finish, would you please make sure that you have answered all the questions.

Thank you for completing this questionnaire.

ICECAP Questionnaire

By placing a check ☑ in one box in each group below, please indicate which statement best describes your quality of life at the moment.

ICECAP(TYPE 4)

Love and Friendship	☐1 I can have **all** of the love and friendship that I want ☐2 I can have **a lot** of the love and friendship that I want ☐3 I can have **a little** of the love and friendship that I want ☐4 I cannot have **any** of the love and friendship that I want
Thinking about the future	☐1 I can think about the future **without any** concern ☐2 I can think about the future with **only a little** concern ☐3 I can only think about the future with **some** concern ☐4 I can only think about the future with **a lot** of concern
Doing things that make you feel valued	☐1 I am able to do **all** of the things that make me feel valued ☐2 I am able to do **many** of the things that make me feel valued ☐3 I am able to do **a few** of the things that make me feel valued ☐4 I am unable to do **any** of the things that make me feel valued
Enjoyment and pleasure	☐1 I can have **all** of the enjoyment and pleasure that I want ☐2 I can have **a lot** of of the enjoyment and pleasure that I want ☐3 I can have **a little** of the enjoyment and pleasure that I want ☐4 I cannot have **any** of the enjoyment and pleasure that I want
Independence	☐1 I am able to be **completely** independent ☐2 I am able to be independent **in many things** ☐3 I am able to be independent in **a few things** ☐4 I am **unable** to be at all independent

NODATA<XYES>

STEP-IPF IPFnet

THIS IS A REPEATING PAGE

FORM=DB TERM

Study Drug Log
Double-Blind Phase

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ Subject Initials: ___ ___ ___
site # subject #

STYDRUG(TYPE 4)R

Record of Study Drug Enrollment to Week 12

	Kit Number	Bottle Number (check only one)	Dispensed Date	Number of Pills Dispensed	Stop Date	Number of Pills Returned	Number of Pills Lost*
	KITROWNO<I:3>	BOTTLENO<IPFBOT><I:3>	PILSTADT		PILSTPDT	RETURNED<I:6>	
1	AKITNO<V:6> ___ ___ ___ ___ ___	☐ 1 #1 ☐ 2 #2	___ ___ / ___ ___ ___ / ___ ___ ___ ___ day month year	PILCOUNT<I:3>	___ ___ / ___ ___ ___ / ___ ___ ___ ___ day month year		LOSTPILL<I:6>
2	___ ___ ___ ___ ___	☐ #1 ☐ #2	___ ___ / ___ ___ ___ / ___ ___ ___ ___ day month year	150	___ ___ / ___ ___ ___ / ___ ___ ___ ___ day month year		
3	___ ___ ___ ___ ___	☐ #1 ☐ #2	___ ___ / ___ ___ ___ / ___ ___ ___ ___ day month year	150	___ ___ / ___ ___ ___ / ___ ___ ___ ___ day month year		
4	___ ___ ___ ___ ___	☐ #1 ☐ #2	___ ___ / ___ ___ ___ / ___ ___ ___ ___ day month year	150	___ ___ / ___ ___ ___ / ___ ___ ___ ___ day month year		

* Best estimate of number of pills not taken but not returned for any reason.

NODATA<XYES>

STEP-IPF IPFnet

Study Completion/Termination Double-Blind Phase (Weeks 0–12)

FORM=DB TERM

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Study Completion/Termination—Double-Blind Phase

TERM (TYPE 4)

1 Did the subject terminate early from this phase? TERMINAT<XYESNO>

☐ 0 No → If No: Is subject participating in the open-label phase? ☐ 0 No → If No: Reason: NOCONTIN<V:100>

☐ 1 Yes OPENLABL<XYESNO>

☐ 1 Yes → If Yes: Date of study termination: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) TERMDT

TERMREA<IPFTER><I:3>

Reason *(check primary reason)*:

- ☐ 1 Death → Complete Death Form and Expedited Event Form.
- ☐ 2 Lung transplant
- ☐ 3 Adverse event *(specify)*: _____ TERMSP<V:100> _____ → Complete Adverse Events Form
- ☐ 4 Subject withdrew consent
- ☐ 5 MD decision
- ☐ 6 Lost to follow-up
- ☐ 98 Other *(specify)*: _____ TERMSP<V:100> (one specify)

2 Did the subject permanently discontinue study drug prior to Week 12 visit?

☐ 0 No DISCONTU<XYESNO>

☐ 1 Yes → If Yes: Date discontinued: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) DISCONDT

Reason for discontinuation *(check primary reason)*:

DISCREA<IPFDIS><I:3>

- ☐ 1 Subject withdrew consent for study drug
- ☐ 2 Adverse event *(specify)*: _____ AEVNTSP<V100> _____ → Complete Adverse Events Form
- ☐ 3 MD decision
- ☐ 98 Other

3 Was study drug unblinded?

☐ 0 No UNBLIND<XYESNO>

☐ 1 Yes → If Yes: Date unblinded: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) UNBLNDT

Reason unblinded: _____ UNBLINDR<V:100> _____

Investigator's Signature

I have reviewed all of the data recorded on these CRF pages and certify that they are accurate and complete to the best of my knowledge. SIGNATUR (TYPE 4)

Investigator: _____ INSIG<XYES> (Signature of investigator) Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) INVSIGDT

Site Personnel's Initials: ___ ___ ___

STEP-IPF IPFnet

FORM= WEEK13

NODATA<XYES>

Week 13

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Visit date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

SEE ANNOTATION P. 11

VISTDATE (TYPE 4)

Vital Signs

1 Weight: ___ ___ ___ ☐1 lb ☐2 kg

3 Heart rate: ___ ___ ___ bpm

2 Blood pressure: ___ ___ ___ / ___ ___ ___ mm Hg (systolic / diastolic)

SEE ANNOTATION P. 11

VITALS(TYPE 4)

GERD Substudy Review

Record all GERD related medications in the GERD Concomitant Medications log

1 Have there been any changes in the subject's GERD status since last visit?

☐0 No → Skip to question 3

☐1 Yes → If Yes: Check only one:

☐1 Newly diagnosed → Record on Adverse Event Log

How diagnosed *(check all that apply)*:

☐ 24 hr pH monitoring ☐ Endoscopy ☐ Upper GI/barium swallow test

☐ Symptoms of heartburn OR ☐ Unknown

☐2 Changes in non-pharmaceutical interventions

☐98 Other (including medications only) → Skip to question 3

SEE ANNOTATION P. 28

GERDSUB (TYPE 4)

2 If newly diagnosed GERD or changes in non-pharmaceutical interventions, answer all questions below:

Sleeping with the head end of the bed elevated with 6" to 8" blocks on the floor	☐0 No	☐1 Yes
Sleeping in a recliner	☐0 No	☐1 Yes
Limiting foods and beverages that cause symptoms	☐0 No	☐1 Yes
Avoiding lying down flat for 3 hours after a meal	☐0 No	☐1 Yes
Avoiding bedtime snacks	☐0 No	☐1 Yes
Eating small meals	☐0 No	☐1 Yes

3 Have there been any changes in the subject's obstructive sleep apnea status since last visit?

☐0 No → Skip to Safety Review

☐1 Yes → If Yes: Check only one:

☐1 Newly diagnosed → Record on Adverse Event Log

☐2 Changes in CPAP treatment

☐98 Other (including medications only) → Skip to Safety Review

4 If newly diagnosed sleep apnea or changes in CPAP treatment, specify current CPAP treatment:

☐0 None ☐1 Daily ☐2 Intermittent

Safety Review

SEE ANNOTATION P. 28

Has the subject experienced unexplained worsened dyspnea or cough since last visit, triggering unscheduled medical care *(e.g., clinic, study visit, hospitalization)*?

☐0 No ☐1 Yes → If Yes: Please send support materials for acute exacerbation review.

SAFETY (TYPE 4)

Record any new Adverse Events on the Adverse Event Log page.

Record any new or changed medications on the Concomitant Medications Log page.

Site Personnel's Initials: ___ ___ ___

Visit date: ___/___/___ (day/month/year) SEE ANNOTATION P.11 VISTDATE (TYPE 4)

Vital Signs

1 Weight: ___ ___ ___ ☐1 lb ☐2 kg

2 Blood pressure: ___ ___ ___/___ ___ ___ mm Hg (systolic/diastolic)

3 Heart rate: ___ ___ ___ bpm

VITALS (TYPE 4)

SEE ANNOTATION P.11
NOTE: EXCEPT NO HEIGHT or SPO2

NYHA Functional Class

Current NYHA heart failure classification *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

SEE ANNOTATION P.11

NYHA (TYPE 4)

Spirometry

Date of assessment: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year)

SPIROMET (TYPE 4)

1 FEV_1: Actual: ___ . ___ ___ liters

2 FEV_6: Actual: ___ . ___ ___ liters

3 FVC: Actual: ___ . ___ ___ liters

SEE ANNOTATION P.2
NOTE: DO NOT ADD QUESTIONS 4,5,6

Diffusing Capacity of the Lung for Carbon Monoxide (DLCO)

Date of assessment: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) SEE ANNOTATION P.12

DLCO (TYPE 4)

1 DLCO: Actual: ___ ___ . ___ ___ mL/min/mm Hg → Altitude-corrected DLCO *(National Jewish only)*: ___ ___ . ___ ___ mL/min/mm Hg

2 VI *(inspired volume)*: ___ . ___ ___ liters

3 VA *(alveolar volume)*: ___ . ___ ___ liters

6-Minute Walk Test (6MWT)

Date of assessment: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

WALK (TYPE4)

1 Pre-walk modified Borg Dyspnea Scale rating:
☐ 0 ☐ 0.5 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 97 Not done

2 Resting room air SpO_2: ___ ___ ___ %

3 Was supplemental O_2 used during walk? ☐ 0 No ☐ 1 Yes → If Yes: Specify: _____ liters/min
SpO_2 on Supplemental O_2 : ___ ___ ___ %

4 Was walk performed? ☐ 0 No → Provide reason: _____
☐ 1 Yes

5 Was a walking aid necessary to perform the 6MWT?
☐ 0 No
☐ 1 Yes → If Yes: Specify *(check only one)*: ☐ 1 Cane ☐ 2 Walker ☐ 98 Other *(specify)*: _____

WALKTIME(TYPE4)PS

6 Minutes	Heart Rate	SpO_2
Pre-walk	___ ___ ___ bpm	
1 minute	___ ___ ___ bpm	___ ___ ___ %
2 minutes	___ ___ ___ bpm	___ ___ ___ %
3 minutes	___ ___ ___ bpm	___ ___ ___ %
4 minutes	___ ___ ___ bpm	___ ___ ___ %
5 minutes	___ ___ ___ bpm	___ ___ ___ %
6 minutes	___ ___ ___ bpm	___ ___ ___ %
Three minutes of recovery after completion or stop of 6-Minute Walk Test		
1 minute	___ ___ ___ bpm	___ ___ ___ %
2 minutes	___ ___ ___ bpm	___ ___ ___ %
3 minutes	___ ___ ___ bpm	___ ___ ___ %

6 Did subject desaturate ($SpO_2 \leq 88\%$)? ☐ 0 No
☐ 1 Yes → If Yes: Walk duration at desaturation: _____ min / _____ sec
Walk distance at desaturation: ___ ___ ___ meters

Lowest SpO_2	Distance Walked	Did Subject Complete 6-Minute Walk?	If Stopped Early: Specify Reason (Check only one)
___ ___ ___ . ___ %	___ ___ ___ meters	☐ 0 No → If No: Duration: ___ / ___ (min / sec) ☐ 1 Yes	☐ 1 SpO_2 < 80% ☐ 2 Developed signs and symptoms requiring termination of test ☐ 98 Other *(specify)*: _____

7 Post-walk modified Borg Dyspnea Scale rating:
☐ 0 ☐ 0.5 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 97 Not done

Site Personnel's Initials: ___ ___ ___

Urgent or Inpatient Admissions

Has the subject been admitted to the hospital, emergency room/urgent care, assisted living/nursing facility, or rehabilitation center since the last study visit *(do not include protocol-specific study visits)*? ☐0 No ☐1 Yes → **If Yes: Provide details below.**

INPATNT (TYPE 4)R

	Reason for Admission	Major Procedures Performed	Discharge Destination *(check only one)*
1 **Admission date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Discharge date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Admission type** *(check only one)*: ☐1 Hospital ☐2 ER/urgent care ☐3 Assisted living/nursing facility ☐4 Rehabilitation center	☐1 Check if respiratory-related.		☐1 Home ☐2 Assisted living/nursing facility ☐3 Rehab center ☐4 Transfer to other hospital ☐5 Subject died ☐98 Other *(specify)*: _____ _____
2 **Admission date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Discharge date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Admission type** *(check only one)*: ☐1 Hospital ☐2 ER/urgent care ☐3 Assisted living/nursing facility ☐4 Rehabilitation center	☐1 Check if respiratory-related.		☐1 Home ☐2 Assisted living/nursing facility ☐3 Rehab center ☐4 Transfer to other hospital ☐5 Subject died ☐98 Other *(specify)*: _____ _____
3 **Admission date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Discharge date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Admission type** *(check only one)*: ☐1 Hospital ☐2 ER/urgent care ☐3 Assisted living/nursing facility ☐4 Rehabilitation center	☐1 Check if respiratory-related.		☐1 Home ☐2 Assisted living/nursing facility ☐3 Rehab center ☐4 Transfer to other hospital ☐5 Subject died ☐98 Other *(specify)*: _____ _____

Outpatient Visits

Has the subject required any non-urgent outpatient visits since the last study visit *(do not include protocol-specific study visits)*?

☐0 No ☐1 Yes → If Yes: Provide details below.

OUTPATNT (TYPE 4)R

Provider Type	No. of Respiratory-related Visits	No. of Non-respiratory-related Visits
1 Pulmonologist		
2 Cardiologist		
3 Other specialist: _____		
4 Primary care physician *(or NP or PA)*		
5 OT or PT		
6 Mental health provider		
7 Other *(specify)*: _____		

Self-administered Questionnaires

Date administered: ___/___/___ (day/month/year) SEE ANNOTATION P. 13 No GENDRPT

SELFREPT (TYPE 4)

1	EuroQol	☐ 1 Attached	☐ 97 Not done
2	SF-36	☐ 1 Attached	☐ 97 Not done
3	UCSD Shortness-of-Breath	☐ 1 Attached	☐ 97 Not done
4	St. George's Respiratory	☐ 1 Attached	☐ 97 Not done
5	ICECAP	☐ 1 Attached	☐ 97 Not done

GERD Substudy Review

Record all GERD related medications in the GERD Concomitant Medications log

GERDSUB (TYPE 4)

1 Have there been any changes in the subject's GERD status since last visit?

☐ 0 No → Skip to question 3

☐ 1 Yes → If Yes: Check only one: SEE ANNOTATION P. 28

- ☐ 1 Newly diagnosed → Record on Adverse Event Log
  - How diagnosed *(check all that apply)*:
    - ☐ 24 hr pH monitoring ☐ Endoscopy ☐ Upper GI/barium swallow test
    - ☐ Symptoms of heartburn OR ☐ Unknown
- ☐ 2 Changes in non-pharmaceutical interventions
- ☐ 98 Other (including medications only) → Skip to question 3

2 If newly diagnosed GERD or changes in non-pharmaceutical interventions, answer all questions below:

Sleeping with the head end of the bed elevated with 6" to 8" blocks on the floor	☐ 0 No	☐ 1 Yes
Sleeping in a recliner	☐ 0 No	☐ 1 Yes
Limiting foods and beverages that cause symptoms	☐ 0 No	☐ 1 Yes
Avoiding lying down flat for 3 hours after a meal	☐ 0 No	☐ 1 Yes
Avoiding bedtime snacks	☐ 0 No	☐ 1 Yes
Eating small meals	☐ 0 No	☐ 1 Yes

3 Have there been any changes in the subject's obstructive sleep apnea status since last visit?

☐ 0 No → Skip to Safety Review

☐ 1 Yes → If Yes: Check only one:

- ☐ 1 Newly diagnosed → Record on Adverse Event Log
- ☐ 2 Changes in CPAP treatment
- ☐ 98 Other (including medications only) → Skip to Safety Review

4 If newly diagnosed sleep apnea or changes in CPAP treatment, specify current CPAP treatment:

☐ 0 None ☐ 1 Daily ☐ 2 Intermittent

Safety Review

SEE ANNOTATION P. 28

SAFETY (TYPE 4)

Has the subject experienced unexplained worsened dyspnea or cough since last visit, triggering unscheduled medical care *(e.g., clinic, study visit, hospitalization)*?

☐ 0 No ☐ 1 Yes → If Yes: Please send support materials for acute exacerbation review.

Record any new Adverse Events on the Adverse Event Log page.

Record any new or changed medications on the Concomitant Medications Log page.

EuroQol Questionnaire EQ-5D English version for the U.S.

EUROQOL1 (TYPE 4)

By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.

1 Mobility:
- ☐1 I have no problems in walking about
- ☐2 I have some problems in walking about
- ☐3 I am confined to bed

2 Self-care:
- ☐1 I have no problems with self-care
- ☐2 I have some problems washing or dressing myself
- ☐3 I am unable to wash or dress myself

3 Usual activities (e.g., work, study, housework, family, or leisure activities):
- ☐1 I have no problems with performing my usual activities
- ☐2 I have some problems with performing my usual activities
- ☐3 I am unable to perform my usual activities

4 Pain/discomfort:
- ☐1 I have no pain or discomfort
- ☐2 I have moderate pain or discomfort
- ☐3 I have extreme pain or discomfort

5 Anxiety/depression:
- ☐1 I am not anxious or depressed
- ☐2 I am moderately anxious or depressed
- ☐3 I am extremely anxious or depressed

STOP.
Please let your study coordinator know that you are ready for the EuroQol Thermometer worksheet.

EuroQol Thermometer Response (Study staff use only)

Response to the EuroQol thermometer *(0–100)*: ___ ___ ___

EuroQol Questionnaire EQ-5D (continued)

EUROQOL2 (TYPE 4)

Because all replies are anonymous, it will help us to understand your answers better if we have a little background data from everyone, as covered in the following questions.

1 Have you experienced serious illness: ***in you yourself?*** ☐0 No ☐1 Yes
in your family? ☐0 No ☐1 Yes
in caring for others? ☐0 No ☐1 Yes

2 What is your age in years? _____

3 Are you *(please check appropriate box)*: ☐1 Male
☐2 Female

4 Are you *(please check only one)*: ☐1 A current smoker
☐2 An ex-smoker
☐3 A never smoker

5 Do you now, or did you ever, work in health or social services?
☐0 No
☐1 Yes → If Yes: In what capacity? _____

6 Which of the following best describes your main activity *(please check only one)*?
☐1 Employed (including self employment)
☐2 Retired
☐3 Keeping house
☐4 Student
☐5 Seeking work
☐98 Other (please specify): _____

7 What is the highest level of education you have completed *(please check only one)*?
☐1 Some high school or less
☐2 High school graduate or GED
☐3 Vocational college or some college
☐4 College degree
☐5 Professional or graduate degree

8 If you know your zip code, please write it here: ___ ___ ___ ___ ___

SF-36 Assessment

SF36_1 (TYPE 4)

1 In general, would you say your health is:

☐1 Excellent ☐2 Very good ☐3 Good ☐4 Fair ☐5 Poor

2 Compared to one year ago, how would you rate your health in general now?

☐1 Much better than one year ago ☐3 About the same as one year ago ☐5 Much worse now than one year ago

☐2 Somewhat better than one year ago ☐4 Somewhat worse than one year ago

3 The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. **Vigorous activities,** such as running, lifting heavy objects, participating in strenuous sports	☐1	☐2	☐3
b. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐1	☐2	☐3
c. Lifting or carrying groceries	☐1	☐2	☐3
d. Climbing **several** flights of stairs	☐1	☐2	☐3
e. Climbing **one** flight of stairs	☐1	☐2	☐3
f. Bending, kneeling or stooping	☐1	☐2	☐3
g. Walking **more than a mile**	☐1	☐2	☐3
h. Walking **several blocks**	☐1	☐2	☐3
i. Walking **one block**	☐1	☐2	☐3
j. Bathing or dressing yourself	☐1	☐2	☐3

4 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
a. Cut down on the **amount of time** you spend on work or other activities	☐1	☐2	☐3	☐4	☐5
b. **Accomplished less** than you would like	☐1	☐2	☐3	☐4	☐5
c. Were limited in the **kind** of work or other activities	☐1	☐2	☐3	☐4	☐5
d. Had **difficulty** performing the work or other activities *(for example, it took extra effort)*	☐1	☐2	☐3	☐4	☐5

5 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
a. Cut down on the **amount of time** you spend on work or other activities	☐1	☐2	☐3	☐4	☐5
b. **Accomplished less** than you would like	☐1	☐2	☐3	☐4	☐5
c. Did work or other activities **less carefully than usual**	☐1	☐2	☐3	☐4	☐5

SF-36 Assessment (continued)

SF36_2 (TYPE 4)

6 During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

☐1 Not at all ☐2 Slightly ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

7 How much bodily pain have you had during the past 4 weeks?

☐1 None ☐2 Very mild ☐3 Mild ☐4 Moderate ☐5 Severe ☐6 Very severe

8 During the past 4 weeks, how much did pain interfere with your normal work *(including both work outside the home and housework)*?

☐1 Not at all ☐2 Slightly ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

9 These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of life?	☐1	☐2	☐3	☐4	☐5
b. Have you been very nervous?	☐1	☐2	☐3	☐4	☐5
c. Have you felt so down in the dumps that nothing could cheer you up?	☐1	☐2	☐3	☐4	☐5
d. Have you felt calm and peaceful?	☐1	☐2	☐3	☐4	☐5
e. Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5
f. Have you felt downhearted and depressed?	☐1	☐2	☐3	☐4	☐5
g. Did you feel worn out?	☐1	☐2	☐3	☐4	☐5
h. Have you been happy?	☐1	☐2	☐3	☐4	☐5
i. Did you feel tired?	☐1	☐2	☐3	☐4	☐5

10 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities *(like visiting friends, relatives, etc.)*?

☐1 All of the time ☐2 Most of the time ☐3 Some of the time ☐4 A little of the time ☐5 None of the time

11 How **True** or **False** is each of the following statements for you?

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people	☐1	☐2	☐3	☐4	☐5
b. I am as healthy as anybody I know	☐1	☐2	☐3	☐4	☐5
c. I expect my health to get worse	☐1	☐2	☐3	☐4	☐5
d. My health is excellent	☐1	☐2	☐3	☐4	☐5

UCSD Shortness-of-Breath Questionnaire UCSD SOBQ

When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All				Severe	Maximal/ Unable To Do Because of Breathlessness
1 At rest	0	1	2	3	4	5
2 Walking on a level at your own pace	0	1	2	3	4	5
3 Walking on a level with others your age	0	1	2	3	4	5
4 Walking up a hill	0	1	2	3	4	5
5 Walking up stairs	0	1	2	3	4	5
6 While eating	0	1	2	3	4	5
7 Standing up from a chair	0	1	2	3	4	5
8 Brushing teeth	0	1	2	3	4	5
9 Shaving and/or brushing hair	0	1	2	3	4	5
10 Showering/bathing	0	1	2	3	4	5
11 Dressing	0	1	2	3	4	5
12 Picking up and straightening	0	1	2	3	4	5

UCSD Shortness-of-Breath Questionnaire UCSD SOBQ (continued)

When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All				Severe	Maximal/ Unable To Do Because of Breathlessness
13 Doing dishes	0	1	2	3	4	5
14 sweeping/vacuuming	0	1	2	3	4	5
15 Making bed	0	1	2	3	4	5
16 Shopping	0	1	2	3	4	5
17 Doing laundry	0	1	2	3	4	5
18 Washing car	0	1	2	3	4	5
19 Mowing lawn	0	1	2	3	4	5
20 Watering lawn	0	1	2	3	4	5
21 Sexual activities	0	1	2	3	4	5
How much do these limit you in your daily life?						
22 Shortness of breath	0	1	2	3	4	5
23 Fear of "hurting myself"	0	1	2	3	4	5
24 Fear of shortness of breath	0	1	2	3	4	5

St. George's Respiratory Questionnaire (SGRQ) (English for the United States)

STGRG1(TYPE 4)

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you the most problems, rather than what the doctors and nurses think your problems are.

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

Before completing the questionnaire:
Please check one box to show how you describe your current health:

- ☐ Very good
- ☐ Good
- ☐ Fair
- ☐ Poor
- ☐ Very poor

St. George's Respiratory Questionnaire Part 1

STGRG2 (TYPE 4)

Please describe how often your respiratory problems have affected you over the past 4 weeks.

Please check ☑ one box for each question.	Almost Every Day	Several Days a Week	A Few Days a Month	Only with Respiratory Infections	Not At All
1 Over the past 4 weeks, I have coughed:	☐	☐	☐	☐	☐
2 Over the past 4 weeks, I have brought up phlegm (sputum):	☐	☐	☐	☐	☐
3 Over the past 4 weeks, I have had shortness of breath:	☐	☐	☐	☐	☐
4 Over the past 4 weeks, I have had wheezing attacks:	☐	☐	☐	☐	☐

5 How many times during the past 4 weeks have you suffered from severe or very unpleasant respiratory attacks? Please check ☑ one:

- ☐ More than 3 times
- ☐ 3 times
- ☐ 2 times
- ☐ 1 time
- ☐ None of the time

6 How long did the worst respiratory attack last? Please check ☑ one:
(Go to question 7 if you did not have a severe attack)

- ☐ A week or more
- ☐ 3 or more days
- ☐ 1 or 2 days
- ☐ Less than a day

7 Over the past 4 weeks, in a typical week, how many good days (with few respiratory problems) have you had? Please check ☑ one:

- ☐ No good days
- ☐ 1 or 2 good days
- ☐ 3 or 4 good days
- ☐ Nearly every day was good
- ☐ Every day was good

8 If you wheeze, is it worse when you get up in the morning? Please check ☑ one:

- ☐$_0$ No
- ☐$_1$ Yes

St. George's Respiratory Questionnaire Part 2

Section 1

STGRG3 (TYPE 4)

9 How would you describe your respiratory condition? Please check ☑ one:

- ☐ The most important problem I have
- ☐ Causes me quite a lot of problems
- ☐ Causes me a few problems
- ☐ Causes me no problems

10 If you have ever held a job *(please check ☑ one)*:

- ☐ My respiratory problems made me stop working altogether
- ☐ My respiratory problems interfere with my job or made me change my job
- ☐ My respiratory problems do not affect my job

Section 2

These are questions about what activities usually make you feel short of breath these days.

For each statement, please check ☑ **the box** that applies to you **these days.**

11 Sitting or lying still	☐ 1 True	☐ 0 False
Washing or dressing yourself	☐ 1 True	☐ 0 False
Walking around the house	☐ 1 True	☐ 0 False
Walking outside on a level ground	☐ 1 True	☐ 0 False
Walking up a flight of stairs	☐ 1 True	☐ 0 False
Walking up hills	☐ 1 True	☐ 0 False
Playing sports or other physical activities	☐ 1 True	☐ 0 False

Section 3

12 These are more questions about your cough and shortness of breath these days.

For each statement, please check ☑ **the box** that applies to you **these days.**

Coughing hurts	☐ 1 True	☐ 0 False
Coughing makes me tired	☐ 1 True	☐ 0 False
I am short of breath when I talk	☐ 1 True	☐ 0 False
I am short of breath when I bend over	☐ 1 True	☐ 0 False
My coughing or breathing disturbs my sleep	☐ 1 True	☐ 0 False
I get exhausted easily	☐ 1 True	☐ 0 False

St. George's Respiratory Questionnaire Part 2 (continued)

STGRG4 (TYPE 4)

Section 4

13 These are questions about other effects that your respiratory problems may have on you <u>these days</u>.

For each statement, please check ☑ ***the box*** that applies to you ***these days.***

My cough or breathing is embarrassing in public	☐1 True	☐0 False
My respiratory problems are a nuisance to my family, friends or neighbors	☐1 True	☐0 False
I get afraid or panic when I cannot catch my breath	☐1 True	☐0 False
I feel that I am not in control of my respiratory problems	☐1 True	☐0 False
I do not expect my respiratory problems to get any better	☐1 True	☐0 False
I have become frail or an invalid because of my respiratory problems	☐1 True	☐0 False
Exercise is not safe for me	☐1 True	☐0 False
Everything seems too much of an effort	☐1 True	☐0 False

Section 5

14 These are questions about your respiratory treatment. If you are not receiving treatment, +go to Section 6.

For each statement, please check ☑ ***the box*** that applies to you ***these days.***

My treatment does not help me very much	☐1 True	☐0 False
I get embarrassed using my medication in public	☐1 True	☐0 False
I have unpleasant side effects from my medication	☐1 True	☐0 False
My treatment interferes with my life a lot	☐1 True	☐0 False

St. George's Respiration Questionnaire Part 2 (continued)

Section 6

STGRG5 (TYPE 4)

15 These are questions about how your activities might be affected by your respiratory problems.

For each statement, please check ☑ **the box** that applies to you ***because of your respiratory problems.***

I take a long time to get washed or dressed	☐1 True	☐0 False
I cannot take a bath or shower, or I take a long time to do it	☐1 True	☐0 False
I walk slower than other people my age, or I stop to rest	☐1 True	☐0 False
Jobs such as household chores take a long time, or I have to stop to rest	☐1 True	☐0 False
If I walk up one flight of stairs, I have to go slowly or stop	☐1 True	☐0 False
If I hurry or walk fast, I have to stop or slow down	☐1 True	☐0 False
My breathing makes it difficult to do things such as walk up hills, carry things up stairs, light gardening such as weeding, dance, bowl, or play	☐1 True	☐0 False
My breathing makes it difficult to do things such as carry heavy loads, dig in the garden or shovel snow, jog or walk briskly (5 miles per hour), play tennis or swim	☐1 True	☐0 False
My breathing makes it difficult to do things such as very heavy manual work, ride a bike, run, swim fast, or play competitive sports	☐1 True	☐0 False

SEE PAGE 24

SEE PAGE 24

SEE PAGE 24

Section 7

16 We would like to know how your respiratory problems <u>usually</u> affect your daily life.

For each statement, please check ☑ **the box** that applies to you ***because of your respiratory problems.***

I cannot play sports or do other physical activities	☐1 True	☐0 False
I cannot go out for entertainment or recreation	☐1 True	☐0 False
I cannot go out of the house to do the shopping	☐1 True	☐0 False
I cannot do household chores	☐1 True	☐0 False
I cannot move far from my bed or chair	☐1 True	☐0 False

St. George's Respiratory Questionnaire (continued)

STGRG6 (TYPE 4)

Here is a list of other activities that your respiratory problems may prevent you from doing. (You do not have to check these; they are just to remind you of ways your shortness of breath may affect you.)

- Going for walks or walking the dog
- Doing activities or chores at home or in the garden
- Sexual intercourse
- Going to a place of worship, or a place of entertainment
- Going out in bad weather or into smoky rooms
- Visiting family or friends or playing with children

Please write in any other important activities that your respiratory problems may stop you from doing:

_____

_____

_____

_____

_____

_____

_____

17 Now please check the box *(one only)* that you think best describes how your respiratory problems affect you:

- ☐ It does not stop me from doing anything I would like to do
- ☐ It stops me from doing one or two things I would like to do
- ☐ It stops me from doing most of the things I would like to do
- ☐ It stops me from doing everything I would like to do

Before you finish, would you please make sure that you have answered all the questions.

Thank you for completing this questionnaire.

ICECAP Questionnaire

ICECAP (TYPE 4)

By placing a check ☑ in one box in each group below, please indicate which statement best describes your quality of life at the moment.

Love and Friendship	☐1 I can have **all** of the love and friendship that I want ☐2 I can have **a lot** of the love and friendship that I want ☐3 I can have **a little** of the love and friendship that I want ☐4 I cannot have **any** of the love and friendship that I want
Thinking about the future	☐1 I can think about the future **without any** concern ☐2 I can think about the future with **only a little** concern ☐3 I can only think about the future with **some** concern ☐4 I can only think about the future with **a lot** of concern
Doing things that make you feel valued	☐1 I am able to do **all** of the things that make me feel valued ☐2 I am able to do **many** of the things that make me feel valued ☐3 I am able to do **a few** of the things that make me feel valued ☐4 I am unable to do **any** of the things that make me feel valued
Enjoyment and pleasure	☐1 I can have **all** of the enjoyment and pleasure that I want ☐2 I can have **a lot** of of the enjoyment and pleasure that I want ☐3 I can have **a little** of the enjoyment and pleasure that I want ☐4 I cannot have **any** of the enjoyment and pleasure that I want
Independence	☐1 I am able to be **completely** independent ☐2 I am able to be independent **in many things** ☐3 I am able to be independent in **a few things** ☐4 I am **unable** to be at all independent

STEP-IPF IPFnet

NODATA<XYES>

FORM=WEEK24

Week 24

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Visit date: ___/___/___ (day/month/year) Check if Early Termination visit for double-blind phase: ☐

EARLYTER <XYES>

SEE ANNOTATION P.11

VISTDATE (TYPE 4)

Vital Signs

1 Weight: ___ ___ ___ ☐1 lb ☐2 kg

2 Blood pressure: ___ ___ ___/___ ___ ___ mm Hg (systolic/diastolic)

3 Heart rate: ___ ___ ___ bpm

VITALS (TYPE 4)

SEE ANNOTATION P.11

NOTE: EXCEPT NO HEIGHT or SPO2

NYHA Functional Class

Current NYHA heart failure classification *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

SEE ANNOTATION P.11

NYHA (TYPE 4)

Spirometry

Date of assessment: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year)

1 FEV_1: Actual: ___ . ___ ___ liters

2 FEV_6: Actual: ___ . ___ ___ liters

3 FVC: Actual: ___ . ___ ___ liters

SPIROMET (TYPE 4)

SEE ANNOTATION P.2

NOTE: DO NOT ADD QUESTIONS 4,5,6

Diffusing Capacity of the Lung for Carbon Monoxide (DLCO)

Date of assessment: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year)

1 DLCO: Actual: ___ ___ . ___ ___ mL/min/mm Hg → Altitude-corrected DLCO *(National Jewish only)*: ___ ___ . ___ ___ mL/min/mm Hg

2 VI *(inspired volume)*: ___ . ___ ___ liters

3 VA *(alveolar volume)*: ___ . ___ ___ liters

DLCO (TYPE 4)

SEE ANNOTATION P.12

Arterial Blood Gas (ABG)

Date of assessment: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year)

SEE ANNOTATION P.12

ABG (TYPE 4)

1 Barometric pressure: ___ ___ ___ mm Hg

2 Clinic altitude *(check only one)*: ☐1 < 4000 ft ☐2 ≥ 4000 ft

3 FiO_2: ___ ___ ___ %

4 pH: ___ . ___ ___

5 PaO_2: ___ ___ ___ mm Hg

6 $PaCO_2$: ___ ___ ___ mm Hg

7 SaO_2: ___ ___ ___ %

6-Minute Walk Test (6MWT)

Date of assessment: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

WALK (TYPE4)

1 Pre-walk modified Borg Dyspnea Scale rating:
☐ 0 ☐ 0.5 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 97 Not done

2 Resting room air SpO_2: ___ ___ ___ %

3 Was supplemental O_2 used during walk? ☐ 0 No ☐ 1 Yes → If Yes: Specify: _____ liters/min
SpO_2 on Supplemental O_2 : ___ ___ ___ %

4 Was walk performed? ☐ 0 No → Provide reason: _____
☐ 1 Yes

5 Was a walking aid necessary to perform the 6MWT?
☐ 0 No
☐ 1 Yes → If Yes: Specify *(check only one)*: ☐ 1 Cane ☐ 2 Walker ☐ 98 Other *(specify)*: _____

WALKTIME(TYPE4)PS

6 Minutes	Heart Rate	SpO_2
Pre-walk	___ ___ ___ bpm	
1 minute	___ ___ ___ bpm	___ ___ ___ %
2 minutes	___ ___ ___ bpm	___ ___ ___ %
3 minutes	___ ___ ___ bpm	___ ___ ___ %
4 minutes	___ ___ ___ bpm	___ ___ ___ %
5 minutes	___ ___ ___ bpm	___ ___ ___ %
6 minutes	___ ___ ___ bpm	___ ___ ___ %
Three minutes of recovery after completion or stop of 6-Minute Walk Test		
1 minute	___ ___ ___ bpm	___ ___ ___ %
2 minutes	___ ___ ___ bpm	___ ___ ___ %
3 minutes	___ ___ ___ bpm	___ ___ ___ %

6 Did subject desaturate ($SpO_2 \leq 88\%$)? ☐ 0 No
☐ 1 Yes → If Yes: Walk duration at desaturation: _____ min / _____ sec
Walk distance at desaturation: ___ ___ ___ meters

Lowest SpO_2	Distance Walked	Did Subject Complete 6-Minute Walk?	If Stopped Early: Specify Reason (Check only one)
___ ___ ___ . ___ %	___ ___ ___ meters	☐ 0 No → If No: Duration: ___ / ___ (min / sec) ☐ 1 Yes	☐ 1 SpO_2 < 80% ☐ 2 Developed signs and symptoms requiring termination of test ☐ 98 Other *(specify)*: _____

7 Post-walk modified Borg Dyspnea Scale rating:
☐ 0 ☐ 0.5 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 97 Not done

Site Personnel's Initials: ___ ___ ___

Urgent or Inpatient Admissions

Has the subject been admitted to the hospital, emergency room/urgent care, assisted living/nursing facility, or rehabilitation center since the last study visit *(do not include protocol-specific study visits)*? ☐0 No ☐1 Yes → If Yes: Provide details below.

INPATNT (TYPE 4)R

	Reason for Admission	Major Procedures Performed	Discharge Destination *(check only one)*
1 **Admission date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Discharge date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Admission type** *(check only one)*: ☐1 Hospital ☐2 ER/urgent care ☐3 Assisted living/nursing facility ☐4 Rehabilitation center	☐1 Check if respiratory-related.		☐1 Home ☐2 Assisted living/nursing facility ☐3 Rehab center ☐4 Transfer to other hospital ☐5 Subject died ☐98 Other *(specify)*: _____ _____
2 **Admission date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Discharge date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Admission type** *(check only one)*: ☐1 Hospital ☐2 ER/urgent care ☐3 Assisted living/nursing facility ☐4 Rehabilitation center	☐1 Check if respiratory-related.		☐1 Home ☐2 Assisted living/nursing facility ☐3 Rehab center ☐4 Transfer to other hospital ☐5 Subject died ☐98 Other *(specify)*: _____ _____
3 **Admission date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Discharge date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **Admission type** *(check only one)*: ☐1 Hospital ☐2 ER/urgent care ☐3 Assisted living/nursing facility ☐4 Rehabilitation center	☐1 Check if respiratory-related.		☐1 Home ☐2 Assisted living/nursing facility ☐3 Rehab center ☐4 Transfer to other hospital ☐5 Subject died ☐98 Other *(specify)*: _____ _____

Outpatient Visits

Has the subject required any non-urgent outpatient visits since the last study visit *(do not include protocol-specific study visits)*?

☐0 No ☐1 Yes → If Yes: Provide details below.

OUTPATNT (TYPE 4)R

Provider Type	No. of Respiratory-related Visits	No. of Non-respiratory-related Visits
1 Pulmonologist		
2 Cardiologist		
3 Other specialist: _____		
4 Primary care physician *(or NP or PA)*		
5 OT or PT		
6 Mental health provider		
7 Other *(specify)*: _____		

Self-administered Questionnaires

Date administered: ___/___/___ (day/month/year) SEE ANNOTATION P. 13 No GENDRPT

SELFREPT (TYPE 4)

1	EuroQol	☐1 Attached	☐97 Not done
2	SF-36	☐1 Attached	☐97 Not done
3	UCSD Shortness-of-Breath	☐1 Attached	☐97 Not done
4	St. George's Respiratory	☐1 Attached	☐97 Not done
5	ICECAP	☐1 Attached	☐97 Not done

GERD Substudy Review

Record all GERD related medications in the GERD Concomitant Medications log

GERDSUB (TYPE 4)

1 Have there been any changes in the subject's GERD status since last visit?

☐0 No → Skip to question 3 SEE ANNOTATION P. 28

☐1 Yes → If Yes: Check only one:

- ☐1 Newly diagnosed → Record on Adverse Event Log
  - How diagnosed *(check all that apply)*:
    - ☐ 24 hr pH monitoring ☐ Endoscopy ☐ Upper GI/barium swallow test
    - ☐ Symptoms of heartburn OR ☐ Unknown
- ☐2 Changes in non-pharmaceutical interventions
- ☐98 Other (including medications only) → Skip to question 3

2 If newly diagnosed GERD or changes in non-pharmaceutical interventions, answer all questions below:

Sleeping with the head end of the bed elevated with 6" to 8" blocks on the floor	☐0 No	☐1 Yes
Sleeping in a recliner	☐0 No	☐1 Yes
Limiting foods and beverages that cause symptoms	☐0 No	☐1 Yes
Avoiding lying down flat for 3 hours after a meal	☐0 No	☐1 Yes
Avoiding bedtime snacks	☐0 No	☐1 Yes
Eating small meals	☐0 No	☐1 Yes

3 Have there been any changes in the subject's obstructive sleep apnea status since last visit?

☐0 No → Skip to Safety Review

☐1 Yes → If Yes: Check only one:

- ☐1 Newly diagnosed → Record on Adverse Event Log
- ☐2 Changes in CPAP treatment
- ☐98 Other (including medications only) → Skip to Safety Review

4 If newly diagnosed sleep apnea or changes in CPAP treatment, specify current CPAP treatment:

☐0 None ☐1 Daily ☐2 Intermittent

Safety Review

SEE ANNOTATION P. 28

SAFETY (TYPE 4)

Has the subject experienced unexplained worsened dyspnea or cough since last visit, triggering unscheduled medical care *(e.g., clinic, study visit, hospitalization)*?

☐0 No ☐1 Yes → If Yes: Please send support materials for acute exacerbation review.

Record any new Adverse Events on the Adverse Event Log page.

Record any new or changed medications on the Concomitant Medications Log page.

EuroQol Questionnaire EQ-5D English version for the U.S.

By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.

EUROQOL1 (TYPE 4)

1 Mobility:
- ☐1 I have no problems in walking about
- ☐2 I have some problems in walking about
- ☐3 I am confined to bed

2 Self-care:
- ☐1 I have no problems with self-care
- ☐2 I have some problems washing or dressing myself
- ☐3 I am unable to wash or dress myself

3 Usual activities (e.g., work, study, housework, family, or leisure activities):
- ☐1 I have no problems with performing my usual activities
- ☐2 I have some problems with performing my usual activities
- ☐3 I am unable to perform my usual activities

4 Pain/discomfort:
- ☐1 I have no pain or discomfort
- ☐2 I have moderate pain or discomfort
- ☐3 I have extreme pain or discomfort

5 Anxiety/depression:
- ☐1 I am not anxious or depressed
- ☐2 I am moderately anxious or depressed
- ☐3 I am extremely anxious or depressed

STOP.
Please let your study coordinator know that you are ready for the EuroQol Thermometer worksheet.

EuroQol Thermometer Response (Study staff use only)

Response to the EuroQol thermometer *(0–100)*: ___ ___ ___

EuroQol Questionnaire EQ-5D (continued)

EUROQOL2 (TYPE 4)

Because all replies are anonymous, it will help us to understand your answers better if we have a little background data from everyone, as covered in the following questions.

1 Have you experienced serious illness: *in you yourself?* ☐0 No ☐1 Yes
in your family? ☐0 No ☐1 Yes
in caring for others? ☐0 No ☐1 Yes

2 What is your age in years? _____

3 Are you *(please check appropriate box)*: ☐1 Male
☐2 Female

4 Are you *(please check only one)*: ☐1 A current smoker
☐2 An ex-smoker
☐3 A never smoker

5 Do you now, or did you ever, work in health or social services?
☐0 No
☐1 Yes → If Yes: In what capacity? _____

6 Which of the following best describes your main activity *(please check only one)*?
☐1 Employed (including self employment)
☐2 Retired
☐3 Keeping house
☐4 Student
☐5 Seeking work
☐98 Other (please specify): _____

7 What is the highest level of education you have completed *(please check only one)*?
☐1 Some high school or less
☐2 High school graduate or GED
☐3 Vocational college or some college
☐4 College degree
☐5 Professional or graduate degree

8 If you know your zip code, please write it here: ___ ___ ___ ___ ___

SF-36 Assessment

SF36_1(TYPE 4)

1 In general, would you say your health is:

☐1 Excellent ☐2 Very good ☐3 Good ☐4 Fair ☐5 Poor

2 Compared to one year ago, how would you rate your health in general now?

☐1 Much better than one year ago ☐3 About the same as one year ago ☐5 Much worse now than one year ago

☐2 Somewhat better than one year ago ☐4 Somewhat worse than one year ago

3 The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. **Vigorous activities,** such as running, lifting heavy objects, participating in strenuous sports	☐1	☐2	☐3
b. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐1	☐2	☐3
c. Lifting or carrying groceries	☐1	☐2	☐3
d. Climbing **several** flights of stairs	☐1	☐2	☐3
e. Climbing **one** flight of stairs	☐1	☐2	☐3
f. Bending, kneeling or stooping	☐1	☐2	☐3
g. Walking **more than a mile**	☐1	☐2	☐3
h. Walking **several blocks**	☐1	☐2	☐3
i. Walking **one block**	☐1	☐2	☐3
j. Bathing or dressing yourself	☐1	☐2	☐3

4 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
a. Cut down on the **amount of time** you spend on work or other activities	☐1	☐2	☐3	☐4	☐5
b. **Accomplished less** than you would like	☐1	☐2	☐3	☐4	☐5
c. Were limited in the **kind** of work or other activities	☐1	☐2	☐3	☐4	☐5
d. Had **difficulty** performing the work or other activities *(for example, it took extra effort)*	☐1	☐2	☐3	☐4	☐5

5 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
a. Cut down on the **amount of time** you spend on work or other activities	☐1	☐2	☐3	☐4	☐5
b. **Accomplished less** than you would like	☐1	☐2	☐3	☐4	☐5
c. Did work or other activities **less carefully than usual**	☐1	☐2	☐3	☐4	☐5

SF-36 Assessment (continued)

SF36_2(TYPE 4)

6 During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

☐1 Not at all ☐2 Slightly ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

7 How much bodily pain have you had during the past 4 weeks?

☐1 None ☐2 Very mild ☐3 Mild ☐4 Moderate ☐5 Severe ☐6 Very severe

8 During the past 4 weeks, how much did pain interfere with your normal work *(including both work outside the home and housework)*?

☐1 Not at all ☐2 Slightly ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

9 These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of life?	☐1	☐2	☐3	☐4	☐5
b. Have you been very nervous?	☐1	☐2	☐3	☐4	☐5
c. Have you felt so down in the dumps that nothing could cheer you up?	☐1	☐2	☐3	☐4	☐5
d. Have you felt calm and peaceful?	☐1	☐2	☐3	☐4	☐5
e. Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5
f. Have you felt downhearted and depressed?	☐1	☐2	☐3	☐4	☐5
g. Did you feel worn out?	☐1	☐2	☐3	☐4	☐5
h. Have you been happy?	☐1	☐2	☐3	☐4	☐5
i. Did you feel tired?	☐1	☐2	☐3	☐4	☐5

10 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities *(like visiting friends, relatives, etc.)*?

☐1 All of the time ☐2 Most of the time ☐3 Some of the time ☐4 A little of the time ☐5 None of the time

11 How **True** or **False** is each of the following statements for you?	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people	☐1	☐2	☐3	☐4	☐5
b. I am as healthy as anybody I know	☐1	☐2	☐3	☐4	☐5
c. I expect my health to get worse	☐1	☐2	☐3	☐4	☐5
d. My health is excellent	☐1	☐2	☐3	☐4	☐5

UCSD Shortness-of-Breath Questionnaire UCSD SOBQ

When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All				Severe	Maximal/ Unable To Do Because of Breathlessness
1 At rest	0	1	2	3	4	5
2 Walking on a level at your own pace	0	1	2	3	4	5
3 Walking on a level with others your age	0	1	2	3	4	5
4 Walking up a hill	0	1	2	3	4	5
5 Walking up stairs	0	1	2	3	4	5
6 While eating	0	1	2	3	4	5
7 Standing up from a chair	0	1	2	3	4	5
8 Brushing teeth	0	1	2	3	4	5
9 Shaving and/or brushing hair	0	1	2	3	4	5
10 Showering/bathing	0	1	2	3	4	5
11 Dressing	0	1	2	3	4	5
12 Picking up and straightening	0	1	2	3	4	5

UCSD Shortness-of-Breath Questionnaire UCSD SOBQ (continued)

When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All				Severe	Maximal/ Unable To Do Because of Breathlessness
13 Doing dishes	0	1	2	3	4	5
14 sweeping/vacuuming	0	1	2	3	4	5
15 Making bed	0	1	2	3	4	5
16 Shopping	0	1	2	3	4	5
17 Doing laundry	0	1	2	3	4	5
18 Washing car	0	1	2	3	4	5
19 Mowing lawn	0	1	2	3	4	5
20 Watering lawn	0	1	2	3	4	5
21 Sexual activities	0	1	2	3	4	5
How much do these limit you in your daily life?						
22 Shortness of breath	0	1	2	3	4	5
23 Fear of "hurting myself"	0	1	2	3	4	5
24 Fear of shortness of breath	0	1	2	3	4	5

St. George's Respiratory Questionnaire (SGRQ) (English for the United States)

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you the most problems, rather than what the doctors and nurses think your problems are.

STGRG1(TYPE 4)

Please read the instructions carefully and ask if you do not understand anything.
Do not spend too long deciding about your answers.

Before completing the questionnaire:
Please check one box to show how you describe your current health:

- ☐ Very good
- ☐ Good
- ☐ Fair
- ☐ Poor
- ☐ Very poor

St. George's Respiratory Questionnaire Part 1

Please describe how often your respiratory problems have affected you over the past 4 weeks.

STGRG2(TYPE 4)

Please check ☑ one box for each question.	Almost Every Day	Several Days a Week	A Few Days a Month	Only with Respiratory Infections	Not At All
1 Over the past 4 weeks, I have coughed:	☐	☐	☐	☐	☐
2 Over the past 4 weeks, I have brought up phlegm (sputum):	☐	☐	☐	☐	☐
3 Over the past 4 weeks, I have had shortness of breath:	☐	☐	☐	☐	☐
4 Over the past 4 weeks, I have had wheezing attacks:	☐	☐	☐	☐	☐

5 How many times during the past 4 weeks have you suffered from severe or very unpleasant respiratory attacks? Please check ☑ one:

- ☐ More than 3 times
- ☐ 3 times
- ☐ 2 times
- ☐ 1 time
- ☐ None of the time

6 How long did the worst respiratory attack last? Please check ☑ one:

(Go to question 7 if you did not have a severe attack)

- ☐ A week or more
- ☐ 3 or more days
- ☐ 1 or 2 days
- ☐ Less than a day

7 Over the past 4 weeks, in a typical week, how many good days (with few respiratory problems) have you had? Please check ☑ one:

- ☐ No good days
- ☐ 1 or 2 good days
- ☐ 3 or 4 good days
- ☐ Nearly every day was good
- ☐ Every day was good

8 If you wheeze, is it worse when you get up in the morning? Please check ☑ one:

- ☐$_0$ No
- ☐$_1$ Yes

SEE ANNOTATION P. 22

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

St. George's Respiratory Questionnaire Part 2

Section 1

9 How would you describe your respiratory condition? Please check ☑ one:

- ☐ The most important problem I have
- ☐ Causes me quite a lot of problems
- ☐ Causes me a few problems
- ☐ Causes me no problems

STGRG3(TYPE 4)

10 If you have ever held a job *(please check ☑ one)*:

- ☐ My respiratory problems made me stop working altogether
- ☐ My respiratory problems interfere with my job or made me change my job
- ☐ My respiratory problems do not affect my job

Section 2

These are questions about what activities usually make you feel short of breath these days.

For each statement, please check ☑ **the box** that applies to you **these days.**

11 Sitting or lying still	☐1 True	☐0 False
Washing or dressing yourself	☐1 True	☐0 False
Walking around the house	☐1 True	☐0 False
Walking outside on a level ground	☐1 True	☐0 False
Walking up a flight of stairs	☐1 True	☐0 False
Walking up hills	☐1 True	☐0 False
Playing sports or other physical activities	☐1 True	☐0 False

Section 3

12 These are more questions about your cough and shortness of breath these days.

For each statement, please check ☑ **the box** that applies to you **these days.**

Coughing hurts	☐1 True	☐0 False
Coughing makes me tired	☐1 True	☐0 False
I am short of breath when I talk	☐1 True	☐0 False
I am short of breath when I bend over	☐1 True	☐0 False
My coughing or breathing disturbs my sleep	☐1 True	☐0 False
I get exhausted easily	☐1 True	☐0 False

St. George's Respiratory Questionnaire Part 2 (continued)

Section 4

STGRG4(TYPE 4)

13 These are questions about other effects that your respiratory problems may have on you <u>these days</u>.

For each statement, please check ☑ ***the box*** that applies to you ***these days.***

My cough or breathing is embarrassing in public	☐1 True	☐0 False
My respiratory problems are a nuisance to my family, friends or neighbors	☐1 True	☐0 False
I get afraid or panic when I cannot catch my breath	☐1 True	☐0 False
I feel that I am not in control of my respiratory problems	☐1 True	☐0 False
I do not expect my respiratory problems to get any better	☐1 True	☐0 False
I have become frail or an invalid because of my respiratory problems	☐1 True	☐0 False
Exercise is not safe for me	☐1 True	☐0 False
Everything seems too much of an effort	☐1 True	☐0 False

Section 5

14 These are questions about your respiratory treatment. If you are not receiving treatment, +go to Section 6.

For each statement, please check ☑ ***the box*** that applies to you ***these days.***

My treatment does not help me very much	☐1 True	☐0 False
I get embarrassed using my medication in public	☐1 True	☐0 False
I have unpleasant side effects from my medication	☐1 True	☐0 False
My treatment interferes with my life a lot	☐1 True	☐0 False

St. George's Respiration Questionnaire Part 2 (continued)

Section 6

STGRG5(TYPE 4)

15 These are questions about how your activities might be affected by your respiratory problems.

For each statement, please check ☑ **the box** that applies to you ***because of your respiratory problems.***

I take a long time to get washed or dressed	☐1 True	☐0 False
I cannot take a bath or shower, or I take a long time to do it	☐1 True	☐0 False
I walk slower than other people my age, or I stop to rest	☐1 True	☐0 False
Jobs such as household chores take a long time, or I have to stop to rest	☐1 True	☐0 False
If I walk up one flight of stairs, I have to go slowly or stop	☐1 True	☐0 False
If I hurry or walk fast, I have to stop or slow down	☐1 True	☐0 False
My breathing makes it difficult to do things such as walk up hills, carry things up stairs, light gardening such as weeding, dance, bowl, or play	☐1 True	☐0 False
My breathing makes it difficult to do things such as carry heavy loads, dig in the garden or shovel snow, jog or walk briskly (5 miles per hour), play tennis or swim	☐1 True	☐0 False
My breathing makes it difficult to do things such as very heavy manual work, ride a bike, run, swim fast, or play competitive sports	☐1 True	☐0 False

SEE PAGE 24

SEE PAGE 24

SEE PAGE 24

Section 7

16 We would like to know how your respiratory problems usually affect your daily life.

For each statement, please check ☑ **the box** that applies to you ***because of your respiratory problems.***

I cannot play sports or do other physical activities	☐1 True	☐0 False
I cannot go out for entertainment or recreation	☐1 True	☐0 False
I cannot go out of the house to do the shopping	☐1 True	☐0 False
I cannot do household chores	☐1 True	☐0 False
I cannot move far from my bed or chair	☐1 True	☐0 False

St. George's Respiratory Questionnaire (continued)

Here is a list of other activities that your respiratory problems may prevent you from doing. (You do not have to check these; they are just to remind you of ways your shortness of breath may affect you.)

STGRG6(TYPE 4)

- Going for walks or walking the dog
- Doing activities or chores at home or in the garden
- Sexual intercourse
- Going to a place of worship, or a place of entertainment
- Going out in bad weather or into smoky rooms
- Visiting family or friends or playing with children

Please write in any other important activities that your respiratory problems may stop you from doing:

_____

_____

_____

_____

_____

_____

_____

17 Now please check the box *(one only)* that you think best describes how your respiratory problems affect you:

- ☐ It does not stop me from doing anything I would like to do
- ☐ It stops me from doing one or two things I would like to do
- ☐ It stops me from doing most of the things I would like to do
- ☐ It stops me from doing everything I would like to do

Before you finish, would you please make sure that you have answered all the questions.

Thank you for completing this questionnaire.

SEE ANNOTATION P. 26

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

ICECAP Questionnaire

By placing a check ☑ in one box in each group below, please indicate which statement best describes your quality of life at the moment.

ICECCAP(TYPE 4)

Love and Friendship	☐1 I can have **all** of the love and friendship that I want ☐2 I can have **a lot** of the love and friendship that I want ☐3 I can have **a little** of the love and friendship that I want ☐4 I cannot have **any** of the love and friendship that I want
Thinking about the future	☐1 I can think about the future **without any** concern ☐2 I can think about the future with **only a little** concern ☐3 I can only think about the future with **some** concern ☐4 I can only think about the future with **a lot** of concern
Doing things that make you feel valued	☐1 I am able to do **all** of the things that make me feel valued ☐2 I am able to do **many** of the things that make me feel valued ☐3 I am able to do **a few** of the things that make me feel valued ☐4 I am unable to do **any** of the things that make me feel valued
Enjoyment and pleasure	☐1 I can have **all** of the enjoyment and pleasure that I want ☐2 I can have **a lot** of of the enjoyment and pleasure that I want ☐3 I can have **a little** of the enjoyment and pleasure that I want ☐4 I cannot have **any** of the enjoyment and pleasure that I want
Independence	☐1 I am able to be **completely** independent ☐2 I am able to be independent **in many things** ☐3 I am able to be independent in **a few things** ☐4 I am **unable** to be at all independent

STEP-IPF IPFnet

SEE ANNOTATION P. 65

NODATA<XYES>

FORM=OL TERM

Study Drug Log Open-Label Phase

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

STYDRUG (TYPE 4)

Record of Study Drug Week 12 to Week 24

	Kit Number	Bottle Number (check only one)	Dispensed Date	Number of Pills Dispensed	Stop Date	Number of Pills Returned	Number of Pills Lost*
1	___ ___ ___ ___ ___	☐ #1 ☐ #2	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	150	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)		
2	___ ___ ___ ___ ___	☐ #1 ☐ #2	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	150	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)		
3	___ ___ ___ ___ ___	☐ #1 ☐ #2	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	150	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)		
4	___ ___ ___ ___ ___	☐ #1 ☐ #2	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	150	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)		

* Best estimate of number of pills not taken but not returned for any reason.

WHITE and YELLOW—Duke Clinical Research Institute • PINK—retain at site

Site Personnel's Initials: ___ ___ ___

NODATA<XYES>

STEP-IPF IPFnet

Study Completion/Termination Open-Label Phase (Weeks 12–24)

FORM=OL TERM

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Study Completion/Termination—Open-Label Phase

TERM (TYPE 4)

1 Did the subject terminate early from this phase?

☐ 0 No

☐ 1 Yes → If Yes: Date of study termination: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Reason *(check primary reason)*:

☐ 1 Death → Complete Death Form and Expedited Event Form.

☐ 2 Lung transplant

☐ 3 Adverse event *(specify)*: _____ → Complete Adverse Events Form

☐ 4 Subject withdrew consent

☐ 5 MD decision

☐ 6 Lost to follow-up

☐ 98 Other *(specify)*: _____

SEE ANNOTATION P. 66

EXCEPT EXCLUDE:

OPENLABL

NOCOUNTIN

UNBLIND

UNBLINDT

UNBLINDR

2 Did the subject permanently discontinue study drug prior to Week 24 visit?

☐ 0 No

☐ 1 Yes → If Yes: Date discontinued: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Reason for discontinuation *(check primary reason)*:

☐ 1 Subject withdrew consent for study drug

☐ 2 Adverse event *(specify)*: _____ → Complete Adverse Events Form

☐ 3 MD decision

☐ 98 Other *(specify)*: _____

Investigator's Signature

SIGNATUR (TYPE 4)

I have reviewed all of the data recorded on these CRF pages and certify that they are accurate and complete to the best of my knowledge.

Investigator: _____ (Signature of investigator) Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Follow-up Day 28

FOLLOWUP (TYPE 1)

1 Was the Follow-up Day 28 visit made? FUPVISIT<XYESNO>

☐0 No → If No: Specify reason: _____ NOFOLLOW<V:100>

☐1 Yes → If Yes: Date of visit: ___/___/___ (day / month / year) FOLLOWDT

If Yes: Check only one: ☐1 Telephone FUCOMMUM<IPFCOM><I:3>

☐2 In person

2 Were any adverse events reported? AEEVENTS<XYESNO>

☐0 No

☐1 Yes → If Yes: Complete Adverse Event form

NODATA<XYES>

FORM=DEATHPAGE

Death Form

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Death Form

DEATH (TYPE 1)

1 Check only one: ☐1 Inpatient ☐2 Outpatient DEATHLOC<IPFLOC><I:3>

2 Date of death: DEATHDT ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

3 Cause of death *(check only one)*:

☐1 Pulmonary death → **Check only one:**
- ☐1 Progression of IPF
- ☐2 Embolism
- ☐3 Lung infection
- ☐4 Lung cancer
- ☐98 Other *(specify)*: DEATHSP <V:100>

DEATHCAU<IPFCAU<I:3>

PULDEATH<IPFPUL><I:3>

☐2 Non pulmonary death → **Specify:** NONPULSP<V:100>

☐99 Unknown

Investigator's Signature

SIGNATUR (TYPE 4)

I have reviewed all of the data recorded on these CRF pages and certify that they are accurate and complete to the best of my knowledge.

Investigator: SAME AS P.64 _____ (Signature of investigator) Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Site Personnel's Initials: ___ ___ ___

STEP-IPF IPFnet

FORM=CONMEDS

NODATA<XYES>

Concomitant Medications Log

SEE ANNOTATION P.8

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Concomitant Medications

Record any new non-study medications taken during the course of the study, including over-the-counter and prescription drugs, and herbal remedies, with the exception of medications taken to treat gastrointestinal disorders, including GERD and Barrett's esophagus (record on GERD Concomitant Medications Log).

MEDLOG (TYPE 4)R

	Medication Name	Start Date	Stop Date OR ☑ if Continuing	Indication
1		___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 Continuing	
2		___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 Continuing	
3		___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 Continuing	
4		___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 Continuing	
5		___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 Continuing	
6		___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 Continuing	
7		___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 Continuing	
8		___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 Continuing	
9		___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 Continuing	
10		___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 Continuing	

FORM=GERD CONMEDS

NODATA<XYES>

THIS IS A REPEATING PAGE

SEE ANNOTATION P.9

STEP-IPF IPFnet

GERD Concomitant Medications Log

Subject ID: 02 - ___ ___ ___ (site #) - ___ ___ ___ (subject #) Subject Initials: ___ ___

GERDLOG (TYPE 4)R

GERD Concomitant Medications

Record any new or changed medications taken to treat gastroesophageal disorders, including GERD and Barrett's esophagus (e.g., proton pump inhibitors, antacids, H_2 receptor antagonists, metoclopramide), taken within 30 days of randomization, including over-the-counter and prescription drugs and herbal remedies.

Medication Name	Dose	Frequency (Check only one)	Start Date	Stop Date OR Check if Continuing	Indication (Check all that apply)
1 ☐ 1 Check if self-prescribed	___ ___ ___ ☐ 1 mg ☐ 2 tab ☐ 3 tsp ☐ 98 Other	☐ 1 QD ☐ 2 BID ☐ 3 TID ☐ 4 QID ☐ 5 PRN (≥ 1/wk) ☐ 6 PRN (< 1/wk)	___ ___/___ ___ ___/___ ___ ___ ___ day month year	___ ___/___ ___ ___/___ ___ ___ ___ day month year OR ☐ 1 Continuing	☐ IPF ☐ Heartburn symptoms ☐ Cough ☐ Hiatal hernia ☐ Barrett's esophagus ☐ Other (specify): ___
2 ☐ 1 Check if self-prescribed	___ ___ ___ ☐ 1 mg ☐ 2 tab ☐ 3 tsp ☐ 98 Other	☐ 1 QD ☐ 2 BID ☐ 3 TID ☐ 4 QID ☐ 5 PRN (≥ 1/wk) ☐ 6 PRN (< 1/wk)	___ ___/___ ___ ___/___ ___ ___ ___ day month year	___ ___/___ ___ ___/___ ___ ___ ___ day month year OR ☐ 1 Continuing	☐ IPF ☐ Heartburn symptoms ☐ Cough ☐ Hiatal hernia ☐ Barrett's esophagus ☐ Other (specify): ___
3 ☐ 1 Check if self-prescribed	___ ___ ___ ☐ 1 mg ☐ 2 tab ☐ 3 tsp ☐ 98 Other	☐ 1 QD ☐ 2 BID ☐ 3 TID ☐ 4 QID ☐ 5 PRN (≥ 1/wk) ☐ 6 PRN (< 1/wk)	___ ___/___ ___ ___/___ ___ ___ ___ day month year	___ ___/___ ___ ___/___ ___ ___ ___ day month year OR ☐ 1 Continuing	☐ IPF ☐ Heartburn symptoms ☐ Cough ☐ Hiatal hernia ☐ Barrett's esophagus ☐ Other (specify): ___
4 ☐ 1 Check if self-prescribed	___ ___ ___ ☐ 1 mg ☐ 2 tab ☐ 3 tsp ☐ 98 Other	☐ 1 QD ☐ 2 BID ☐ 3 TID ☐ 4 QID ☐ 5 PRN (≥ 1/wk) ☐ 6 PRN (< 1/wk)	___ ___/___ ___ ___/___ ___ ___ ___ day month year	___ ___/___ ___ ___/___ ___ ___ ___ day month year OR ☐ 1 Continuing	☐ IPF ☐ Heartburn symptoms ☐ Cough ☐ Hiatal hernia ☐ Barrett's esophagus ☐ Other (specify): ___
5 ☐ 1 Check if self-prescribed	___ ___ ___ ☐ 1 mg ☐ 2 tab ☐ 3 tsp ☐ 98 Other	☐ 1 QD ☐ 2 BID ☐ 3 TID ☐ 4 QID ☐ 5 PRN (≥ 1/wk) ☐ 6 PRN (< 1/wk)	___ ___/___ ___ ___/___ ___ ___ ___ day month year	___ ___/___ ___ ___/___ ___ ___ ___ day month year OR ☐ 1 Continuing	☐ IPF ☐ Heartburn symptoms ☐ Cough ☐ Hiatal hernia ☐ Barrett's esophagus ☐ Other (specify): ___

STEP_IPF VERSION 7.0 _17SEP2009

Site Personnel's Initials: ___ ___

STEP-IPF IPFnet

THIS IS A REPEATING PAGE

FORM=ADVERSE EVENT

NODATA<XYES>

Adverse Event Log

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Adverse Events

Did the subject have any adverse event(s) after first dose of study medication? ☐0 No ☐1 Yes → If Yes, provide details below:

ANYAE<XYESNO>

ADVERSE (TYPE 4)

AENUMBER<I:3> #	Adverse Event	Onset Date	End Date OR Check if Continuing	Hospitalized?	Maximum Intensity	Relationship to Study Drug	Actions Taken with Study Drug	Final Outcome	Was This Event Serious?
	AETERM<V:100>	AEONSTDT ___/___/___ (day/month/year)	AEENDDT ___/___/___ (day/month/year) OR ☐1 Ongoing	AEHOSP<XYESNO> ☐0 No ☐1 Yes	☐1 Mild ☐2 Moderate ☐3 Severe	AERELAT<IPFREL><I:3> ☐0 Not a reasonable possibility ☐1 Reasonable possibility	☐1 None ☐2 Interrupted ☐3 Discontinued ☐4 Dosage change	AEOUTCM<IPFOUT><I:3> ☐1 Subject died ☐2 Resolved no sequelae ☐3 Resolved with sequelae ☐4 Unresolved	AESERIUS<XYSNO> ☐0 No ☐1 Yes*
	MEDRA: MEDRCODE<V:8>	AECONTU<XYES> ___/___/___ (day/month/year)	___/___/___ (day/month/year) OR ☐1 Ongoing	☐0 No ☐1 Yes	AEINTENS<XINTNS><I:3> ☐1 Mild ☐2 Moderate ☐3 Severe	☐0 Not a reasonable possibility ☐1 Reasonable possibility	AEACTION<IPFATX><I:3> ☐1 None ☐2 Interrupted ☐3 Discontinued ☐4 Dosage change	☐1 Subject died ☐2 Resolved no sequelae ☐3 Resolved with sequelae ☐4 Unresolved	☐0 No ☐1 Yes*
	MEDRTEXT<V:100> WORKFLOW<V:5> CODETM<DATETIME> CODER<V:20>	___/___/___ (day/month/year)	___/___/___ (day/month/year) OR ☐1 Ongoing	☐0 No ☐1 Yes	☐1 Mild ☐2 Moderate ☐3 Severe	☐0 Not a reasonable possibility ☐1 Reasonable possibility	☐1 None ☐2 Interrupted ☐3 Discontinued ☐4 Dosage change	☐1 Subject died ☐2 Resolved no sequelae ☐3 Resolved with sequelae ☐4 Unresolved	☐0 No ☐1 Yes*
	MATCHES<V:4> CONFLVL<V:2>	___/___/___ (day/month/year)	___/___/___ (day/month/year) OR ☐1 Ongoing	☐0 No ☐1 Yes	☐1 Mild ☐2 Moderate ☐3 Severe	☐0 Not a reasonable possibility ☐1 Reasonable possibility	☐1 None ☐2 Interrupted ☐3 Discontinued ☐4 Dosage change	☐1 Subject died ☐2 Resolved no sequelae ☐3 Resolved with sequelae ☐4 Unresolved	☐0 No ☐1 Yes*
		___/___/___ (day/month/year)	___/___/___ (day/month/year) OR ☐1 Ongoing	☐0 No ☐1 Yes	☐1 Mild ☐2 Moderate ☐3 Severe	☐0 Not a reasonable possibility ☐1 Reasonable possibility	☐1 None ☐2 Interrupted ☐3 Discontinued ☐4 Dosage change	☐1 Subject died ☐2 Resolved no sequelae ☐3 Resolved with sequelae ☐4 Unresolved	☐0 No ☐1 Yes*

Investigator's Signature

I have reviewed all of the data recorded on these CRF pages and certify that they are accurate and complete to the best of my knowledge.

Investigator: _____ (Signature of investigator) Date: ___/___/___ (day/month/year)

SEE ANNOTATION P.64

SIGNATUR (TYPE 4)

*If serious and relationship to study drug is a reasonable possibility or death occurred, please submit Expedited Event (EE) Form.

*If serious, submit Pfizer Investigator Initiated Research SAE Form.

STEP-IPF IPFnet

NODATA<XYES>

FORM=MISSED VISIT

Missed Visit Form

THIS IS A REPEATING PAGE

Subject ID: 02 - ___ ___ ___ (site #) - ___ ___ ___ (subject #) Subject Initials: ___ ___ ___

Missed Visit

Instructions: Complete this form only if the subject missed an entire study visit but is continuing in the trial.
Complete one form per missed visit.
Do not send the CRF pages for this missed visit.

MVISITFM (TYPE 4)

Missed visit *(check only one)*:

- ☐ 1 Week 1
- ☐ 2 Week 6
- ☐ 3 Week 12
- ☐ 4 Week 13
- ☐ 5 Week 18
- ☐ 6 Week 24

MISVIS<IPFMIS><I:3>

Study Coordinator: Submit the original of each form to the DCRI with the next batch of CRF pages.
Maintain a copy in the subject's CRF binder in place of the scheduled visit pages.

STEP-IPF IPFnet

NODATA<XYES>

FORM=UNSCHEDULED

Unscheduled Visit

THIS IS A REPEATING PAGE

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Unscheduled Visit

SEE ANNOTATION P. 11

Visit date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

VISTDATE (TYPE 4)

Reason for unscheduled visit *(check all that apply)*: 1= ☐ Acute exacerbation follow-up

UNSCHREA<IPFUNS>

98= ☐ Other *(specify)*: ___UNSCHSP<V:100>_____

Vital Signs

1 Weight: ___ ___ ___ ☐1 lb ☐2 kg

2 Blood pressure: ___ ___ ___ / ___ ___ ___ mm Hg (systolic / diastolic)

3 Heart rate: ___ ___ ___ bpm

4 SpO_2: ___ ___ ___ %

VITALS (TYPE 4)

SEE ANNOTATION P.11
EXCEPT NO HEIGHT

Spirometry

SPIROMET (TYPE 4)

Date of assessment: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

1 FEV_1: Actual: ___ . ___ ___ liters

2 FEV_6: Actual: ___ . ___ ___ liters

3 FVC: Actual: ___ . ___ ___ liters

SEE ANNOTATION P.2
NOTE: DO NOT ADD QUESTIONS 4,5,6

Investigator's Signature

SIGNATUR(TYPE 4)

I have reviewed all of the data recorded on these CRF pages and certify that they are accurate and complete to the best of my knowledge.

Investigator: _____ SEE ANNOTATION P.64 _____ Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
(Signature of investigator) (day / month / year)

STEP-IPF IPFnet

NODATA<XYES>

FORM=EXACERBATION

Acute Exacerbation Identification Report

THIS IS A REPEATING PAGE

Subject ID: 02 - ___ ___ ___ (site #) - ___ ___ ___ (subject #) Subject Initials: ___ ___ ___

ACEXID (TYPE 4)

Acute Exacerbation Identification

Complete one form for each episode of acute worsening

1 Event description: EXACRBTN<V:100> _____

2 Date of event: EXACRBDT ___/___/___ (day/month/year)

3 Location of medical care (check only one): ☐1 Local physician/clinic ☐2 Local ER → If local, specify facility: LOCAL<V:100> _____
EXACRLOC<IPFEXA><I:3> ☐3 IPFnet clinic ☐4 IPFnet ER

4 Research blood obtained? BLOODOBT<XYESNO> ☐0 No ☐1 Yes → If Yes: Date: BLOODDT ___/___/___

5 Research BAL obtained? BLAOBT<XYESNO> ☐0 No ☐1 Yes → If If Yes: Date: BALDT ___/___/___

6 Outcome (check only one): ☐1 Treated as outpatient ☐2 Hospitalized, not mechanically ventilated ☐3 Hospitalized and mechanically ventilated
OUTCOME<IPFWHF><I:3>

7 During this episode of acute worsening, did the subject have (answer all questions): all have <XYNUNK>

COUGH Productive cough? ☐0 No ☐1 Yes ☐99 Unknown
CONGESTN Congestion? ☐0 No ☐1 Yes ☐99 Unknown
FEVER Fever? ☐0 No ☐1 Yes ☐99 Unknown
ACHINESS Achiness? ☐0 No ☐1 Yes ☐99 Unknown
HACHE Headache? ☐0 No ☐1 Yes ☐99 Unknown
SORETHOT Sore throat? ☐0 No ☐1 Yes ☐99 Unknown

ACEXTST (TYPE 4)PS

8 Reports collected: REPORTS<IPFTSX><I:3>	Not Performed	Performed But Unavailable	Performed and Report Attached	Date Performed
1= CT scan(s):	☐0	TESTPER <IPFPER> ☐1	☐2 →	TESTDT ___/___/___
2= Chest x-ray*: Prior to event	☐0	☐1	☐2 →	___/___/___
3= Chest x-ray Peri-event	☐0	☐1	☐2 →	___/___/___
4= Echocardiogram	☐0	☐1	☐2 →	___/___/___
5= Pulmonary function tests	☐0	☐1	☐2 →	___/___/___
6= Pulse oximetry and vital signs	☐0	☐1	☐2 →	___/___/___
7= Arterial blood gases	☐0	☐1	☐2 →	___/___/___
8= Respiratory cultures: Sputum	☐0	☐1	☐2 →	___/___/___
9= Respiratory cultures Endotracheal aspirate	☐0	☐1	☐2 →	___/___/___
10= Respiratory cultures Lavage	☐0	☐1	☐2 →	___/___/___
11= Bronchoscopy: Report	☐0	☐1	☐2 →	___/___/___
12= Bronchoscopy Cell count	☐0	☐1	☐2 →	___/___/___
13= Bronchoscopy Differential	☐0	☐1	☐2 →	___/___/___
14= Blood cultures	☐0	☐1	☐2 →	___/___/___
15= Clinic/hospital records related to the event	☐0	☐1	☐2 →	___/___/___

*Chest x-ray if no CT is available

9 Date this form and supporting materials sent to DCC for adjudication: SENTDT ___/___/___ (day/month/year)

Site Personnel's Initials: ___ ___ ___

STEP-IPF IPFnet

FORM=LOCAL LAB

NODATA<XYES>

Local Lab

THIS IS A REPEATING PAGE

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___

LOCLAB (TYPE 4)PS

Complete this form only if the Central Lab was not used for this visit.

LABVST<IPFLVT><V:3>

Check visit: 1 ☐1 Screening ☐2 Enrollment/Week 0 ☐3 Week 1 ☐4 Week 6 ☐5 Week 12 ☐6 Week 13 ☐7 Week 18 ☐8 Week 24

Date of assessment: ___/___/___ (day/month/year) LABDT

Labs

LABASSES<IPFLAB><I:3>

	Assessment	Not Done	Value	Units	LLN	ULN
1=	1 ALT/SGPT:	☐97	LABVAL<F:9:3> _____	☐1 U/L ☐2 IU/L LABND<XYES> LABUNT <IPFLUT>	LABLLN<F:9:3> _____	LABULN<F:9:3> _____
2=	2 AST/SGOT:	☐97	_____	☐1 U/L ☐2 IU/L	_____	_____
3=	3 Total bilirubin:	☐97	_____	☐3 mg/dL ☐4 µmol/L	_____	_____
4=	4 Creatinine	☐97	_____	☐3 mg/dL ☐4 µmol/L	_____	_____
5=	5 Hemoglobin *(Hgb)*:	☐97	_____	☐5 g/dL ☐6 g/L ☐7 mmol/L	_____	_____
6=	6 WBC:	☐97	_____	☐8 10^9/L OR 10^3/mm^3 ☐9 /mm^3	_____	_____
7=	7 BNP:	☐97	_____	☐10 pg/mL ☐11 ng/L	_____	_____

STEP-IPF IPFnet

NODATA<XYES>

FORM=EXACERBATION ADJ

Acute Exacerbation Adjudication Report

THIS IS A REPEATING PAGE

Subject ID: 02 - ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

ACEXADJ (TYPE 4)

Acute Exacerbation Adjudication

Complete one form for each episode of acute worsening.

1 Event description: EXACRBAJ<V:100>

2 Date of event: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) EXADJDT

The following three criteria will define acute exacerbation (AEx) in subjects with acute worsening of their respiratory condition:	Met	Not Met	Data Insufficient to Judge
3 Clinical *(all of the following must be met)*: CLINA<IPFXAJ><I:3>			
A Unexplained worsening of dyspnea or cough within 30 days, triggering unscheduled medical care *(e.g., clinic, study visit, hospitalization)*: CLINB<IPFXAJ><I:3>	☐1	☐2	☐3
B No clinical suspicious or overt evidence of cardiac event, pulmonary embolism, or deep venous thrombosis to explain acute worsening of dyspnea:	☐1	☐2	☐3
C No pneumothorax: CLINC<IPFXAJ><I:3>	☐1	☐2	☐3
4 Radiologic/Physiologic *(only one of the following must be met)*:			
A Radiographic change including new ground glass opacity or consolidation on chest X-ray or CT scan: RADLGA<IPFXAJ><I:3>	☐1	☐2	☐3
B Decline of ≥ 5% in resting room air SpO_2 from last recorded level OR decline of ≥ 8 mm Hg in resting room air PaO_2 from last recorded level: RADLGB<IPFXAJ><I:3>	☐1	☐2	☐3
5 Microbiologic *(all of the following must be met)*: MICROA<IPFXAJ><I:3>			
A No clinical evidence for infection *(i.e., absence of grossly purulent sputum, fever > 39°C orally)*:	☐1	☐2	☐3
B Lack of positive microbiological results from lower respiratory tract defined as (1) clinically significant bacterial growth on sputum or endotracheal aspirate cultures; (2) quantitative culture by protected brush specimen ≥10^3 cfu/mL or BAL ≥ 10^4 cfu/mL; (3) the presence of specific pathogens on stains of any of the above: MICROB<IPFXAJ><I:3>	☐1	☐2	☐3
C Lack of positive pathogen in blood cultures: MICROC<IPFXAJ><I:3>	☐1	☐2	☐3

6 Final diagnosis *(check only one)*: EXFNLDIG<IPFAJD><I:3>

- ☐1 Definite acute exacerbation *(all criteria met; no alternative etiology)*
- ☐2 Unclassifiable acute worsening *(Insufficient data to evaluate all criteria; no alternative etiology)*
- ☐3 Not acute exacerbation *(alternative etiology identified that explains acute worsening)* *(specify)*: FNDIGSP<V:100>
- ☐4 Other *(specify)*: _____

7 Date of final adjudication: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) FNLADJDT

Signature

Adjudication Committee Members involved in review *(check all who apply)*: All<I:1><XYES>

KANER ☐ Robert Kaner COLLARD ☐ Hal Collard SCHWARZ ☐ Marvin Schwarz ☐ Tom Colby COLBY ☐ David Lynch LYNCH ☐ Joao de Andrade ANDRADE ☐ Kevin Anstrom ANSTROM

☐ Other: ADJMBRSP<V:100> AJOTHR<XYES>

I have reviewed all of the data recorded on this CRF page and certify that they are accurate and complete to the best of my knowledge.

Adjudication Committee member: EXADJSIG _____ (Signature of adjudication committee member) Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) EXCADJDT

Site Personnel's Initials: ___ ___ ___

STEP-IPF IPFnet

NODATA<XYES>

FORM=BIOLOGICAL SAMPLES

Biological Sample Collection

THIS IS A REPEATING PAGE

Subject ID: 02 - ___ ___ ___ - ____ (site # / subject #) Subject Initials: ____

BIOSAMP (TYPE 4) PS

Biological Sample Collections

Complete this form for each visit biological sample collection is expected or an Acute Exacerbation, and submit it with the next batch of CRFs. Keep copy in subject file.

1 Check visit: ☐1 Enrollment ☐2 Week 6 ☐3 Week 12 ☐4 Week 18 ☐5 Week 24 ☐6 Acute Exacerbation ☐7 Other

BIOVISIT<IPFBVT>

2 Were any biological samples collected during this visit?

☐0 No BIOCOL <XYESNO>

☐1 Yes → If Yes: Date of collection: BIOCOLDT <XYESNO> __ __ / __ __ __ / __ __ __ __ (day / month / year)

Attach form label here: BIOLABEL<V:15>

	Sample		Was sample drawn and appropriately labeled and stored?	
1=	001	(0.5 ml Serum) BIOSAMP <IPFBSM>	☐0 No ☐1 Yes	BIOSMDON<XYESNO>
2=	002	(0.5 ml Serum)	☐0 No ☐1 Yes	
3=	003	(0.5 ml Serum)	☐0 No ☐1 Yes	
4=	004	(0.5 ml Serum)	☐0 No ☐1 Yes	
5=	005	(4.0 ml Serum)	☐0 No ☐1 Yes	
6=	006	(2.0 ml Serum)	☐0 No ☐1 Yes	
7=	007	(0.5 ml Plasma)	☐0 No ☐1 Yes	
8=	008	(0.5 ml Plasma)	☐0 No ☐1 Yes	
9=	009	(0.5 ml Plasma)	☐0 No ☐1 Yes	
10=	010	(0.5 ml Plasma)	☐0 No ☐1 Yes	
11=	011	(4.0 ml Plasma)	☐0 No ☐1 Yes	
12=	012	(2.0 ml Plasma)	☐0 No ☐1 Yes	
13=	013	013 (8.5 ml DNA) (8.5 ml DNA Enrollment/Acute Exacerbation only)	☐0 No ☐1 Yes	
14=	014	014 (8.5 ml DNA) (8.5 ml DNA Enrollment/Acute Exacerbation only)	☐0 No ☐1 Yes	
15=	015	(5.0 ml Urine)	☐0 No ☐1 Yes	
16=	016	(5.0 ml Urine)	☐0 No ☐1 Yes	
17=	017	(5.0 ml Urine)	☐0 No ☐1 Yes	
18=	018	(5.0 ml Urine)	☐0 No ☐1 Yes	