Patient Initials: ____ ____ ____ INITIALS<V:3> Patient Study #: ____ ____ ____—____ ____ ____ SUBJNO <V:10> Date of Randomization: ____/____/____ VISDT
mo day yr

Sudden Cardiac Death

SCD HeFT

Heart Failure Trial

Baseline Case Report Form

DEMOGRAPHICS

Date of birth: _____/_____/_____ BDOB
mo day yr

Gender: BGENDER<ZSEX> 1 ☐ Male 2 ☐ Female

Handedness: BHAND<SCBHAN> 1 ☐ Right 2 ☐ Non-right (left or ambidextrous)

*(To check **Right**, the right hand must have been used since birth for writing, throwing, and using toothbrush, knife and spoon.)*

BCRDEMO TYPE=1

GENERAL MEDICAL HISTORY

	No	Yes	N/A
Thyroid disease MTHYR <ZYESNO>	0 ☐	1 ☐	
Pulmonary disease MPULM <ZYESNO>	0 ☐	1 ☐	
Diabetes MDIAB <ZYESNO>	0 ☐	1 ☐	
Hepatitis MHEPA <ZYESNO>	0 ☐	1 ☐	
Post menopausal MMENO<SCNA>	0 ☐	1 ☐	2 ☐
Tremor MTREM<ZYESNO>	0 ☐	1 ☐	
Hysterectomy MHYST<SCNA>	0 ☐	1 ☐	2 ☐
Bilateral oophorectomy MBOOP<SCNA>	0 ☐	1 ☐	2 ☐
Ataxia MATAX<ZYESNO>	0 ☐	1 ☐	
Optic neuritis MOPTIC<ZYESNO>	0 ☐	1 ☐	

GMED TYPE=3

CARDIOVASCULAR SYMPTOMS

	No	Yes
Exertional angina EANG<ZYESNO>	0 ☐	1 ☐
Rest angina RANG<ZYESNO>	0 ☐	1 ☐
Dyspnea at rest RDYSP<ZYESNO>	0 ☐	1 ☐
Dyspnea on exertion EDYSP<ZYESNO>	0 ☐	1 ☐
Paroxysmal nocturnal dyspnea PND<ZYESNO>	0 ☐	1 ☐
Cough COUGH<ZYESNO>	0 ☐	1 ☐
Orthopnea ORTHOP<ZYESNO>	0 ☐	1 ☐
Fatigue FATIG<ZYESNO>	0 ☐	1 ☐
Palpitations PALP<ZYESNO>	0 ☐	1 ☐

(see follow-up p. 1)

CARDSYMP TYPE=3

All code lists are type < I:3>

NYHA CHF CLASS at time of randomization

	I	Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue or dyspnea. NYHA<SCNYHA>
☐ 2	**II**	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes fatigue or dyspnea.
☐ 3	**III**	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue or dyspnea.
	IV	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure may be present even at rest. If any physical activity is undertaken, symptoms are increased.

(see follow-up p. 2) NYHA TYPE=3

CHF AND SCD RISK FACTORS

History of cigarette smoking: BSMOKE<SCWHEN> 1 ☐ Never 2 ☐ Current 3 ☐ Past

History of hyperlipidemia: BHYPERL<ZYESNO> 0 ☐ No 1 ☐ Yes

History of hypertension: BHYPERT<ZYESNO> 0 ☐ No 1 ☐ Yes

History of alcohol abuse (past only): BPALCH <ZYESNO> 0 ☐ No 1 ☐ Yes

History of cocaine use (past only): BPCOCN <ZYESNO> 0 ☐ No 1 ☐ Yes

Family history of CAD: BHCAD<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Family history of sudden death: BHSDTH <SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Family history of CHF: BHCHF<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

History of rheumatic fever / rheumatic heart disease: BHRHEUM<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

BCRRISK TYPE=1

LEFT VENTRICULAR EJECTION FRACTION

Date of EF measurement: _____/_____/ LVEFDT
mo *day* *yr*

What is this patient's ejection fraction? _____ % LVEF<F:9.3>

How was the EF measured? EFMEAS<SCEF>
☐ 1 Nuclear (*preferred*)
☐ 2 Catheterization
☐ 3 Echo

(see follow-up p.7)

LVEF TYPE=3

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO ___ <V:10>

CAUSE OF HEART FAILURE

What is the cause of heart failure? *(check one)* BHFCAUSE <SCHFCA>

1 ☐ Non-ischemic cardiomyopathy **OR** 2 ☐ Ischemic cardiomyopathy

Ischemic cardiomyopathy is defined as:
1) ≥ 75% luminal narrowing in one or more major coronary arteries or ≥ 50% in the left main coronary artery
—OR—
2) insignificant CAD with definitive evidence of MI (e.g., ruptured plaque, acute thrombosis on modest plaque.)

➔ If **Non-ischemic cardiomyopathy**, primary etiology: (*check one*) BETIOL <SCETIO>

1 ☐ Idiopathic	2 ☐ Post-partum	3 ☐ Anthracycline induced
4 ☐ Alcoholic	5 ☐ Sarcoid	6 ☐ Radiation induced
7 ☐ End-stage valvular	8 ☐ Connective tissue disease	9 ☐ Giant cell myocarditis
10 ☐ Cocaine abuse	11 ☐ Familial	12 ☐ Chagasic
13 ☐ Other: BETIOLOT <V:30>		

➔ If **Ischemic cardiomyopathy**, complete the following:

Myocardial infarction? BMI <ZYESNO>	0 ☐ No 1 ☐ Yes	➔ If **Yes**, date of most recent: BMIM (mo) / BMIY (yr)
Coronary bypass grafting? BCABG <ZYESNO>	0 ☐ No 1 ☐ Yes	➔ If **Yes**, date of most recent: BCABGM (mo) / BCABGY (yr)
Percutaneous revascularization? *(angioplasty, atherectomy, stenting)* BPTCA <ZYESNO>	0 ☐ No 1 ☐ Yes	➔ If **Yes**, date of most recent: BPTCAM (mo) / BPTCAY (yr)
Vessels diseased: *(check if stenosis is greater than or equal to the indicated percent for each vessel affected)*	1 ☐ Left main ≥ 50% BLM50 <ZYES> 1 ☐ LAD ≥ 75% BLAD75 <ZYES> 1 ☐ Circumflex ≥ 75% BCIRC75 <ZYES> 1 ☐ Right coronary ≥ 75% BRCOR75 <ZYES>	

TYPE=1 BCRHFCAS

VALVULAR DISEASE

Valvular disease? VALVDZ<ZYESNO> 0 ☐ No 1 ☐ Yes (Don't check **Yes** for mild or 1+ MR or TR)

➔ If **Yes**, check all that apply: VALVAI 1 ☐ AI VALVAS 1 ☐ AS VALVMR 1 ☐ MR VALVMS 1 ☐ MS VALVTR 1 ☐ TR <ZYES>

Valvular repair? VALVRP <ZYESNO> 0 ☐ No 1 ☐ Yes <ZYES> ➔ If **Yes**: VALVRPA 1 ☐ AV VALVRPM 1 ☐ MV VALVRPT 1 ☐ TV VALVRPP 1 ☐ PV

Valvular replacement? VALVRL <ZYESNO> 0 ☐ No 1 ☐ Yes <ZYES> ➔ If **Yes**: VALVRLA 1 ☐ AV VALVRLM 1 ☐ MV VALVRLT 1 ☐ TV VALVRLP 1 ☐ PV

VALVDZ TYPE=3 (see follow-up p. 2)

VASCULAR DISEASE

History of stroke? STROKE <ZYESNO>	0 ☐ No 1 ☐ Yes	➔ If **Yes**, date of most recent: STROKEM (mo) / STROKEY (yr)
Transient ischemic attack? TIA <ZYESNO>	0 ☐ No 1 ☐ Yes	➔ If **Yes**, date of most recent: TIAM (mo) / TIAY (yr)
Peripheral arterial embolism? PAEMB <ZYESNO>	0 ☐ No 1 ☐ Yes	➔ If **Yes**, date of most recent: PAEMBM (mo) / PAEMBY (yr)
Deep venous thrombosis? DVT <ZYESNO>	0 ☐ No 1 ☐ Yes	➔ If **Yes**, date of most recent: DVTM (mo) / DVTY (yr)
Pulmonary embolism? PULEMB <ZYESNO>	0 ☐ No 1 ☐ Yes	➔ If **Yes**, date of most recent: PULEMBM (mo) / PULEMBY (yr)

VASCDZ TYPE=3 (see follow-up p.3)

ARRHYTHMIAS—ATRIAL FIBRILLATION/FLUTTER

Does this patient have a history of atrial fibrillation or atrial flutter (AF)? AF <ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, complete the following:

a. Date of first episode: AFM / AFY (mo / yr)

Permanent AF = completely refractory to cardioversion
Persistent AF = can be successfully cardioverted
Paroxysmal AF = terminates spontaneously

b. 1 ☐ Permanent
2 ☐ Persistent
3 ☐ Paroxysmal
AFTYP <SCAFTY>

c. 1 ☐ Asymptomatic
2 ☐ Symptomatic
AFSYMP <SCAFSY>

➔ If **Symptomatic** with AF, check all symptoms that apply:

1 ☐ Syncope AFSYNC<ZYES>
1 ☐ Near syncope AFNSYN<ZYES>
1 ☐ Fatigue AFFAT<ZYES>
1 ☐ Dyspnea AFDYSP<ZYES>
1 ☐ Palpitations AFPALP<ZYES>
1 ☐ Angina AFANG<ZYES>

AFIB1 TYPE=3

Has this patient ever had electrical cardioversion attempted for AF? AFCARD <ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, date of last cardioversion: AFCARDM / AFCARDY (mo / yr)

Has this patient ever had an ablation procedure for AV node interruption for AF? AFAVAB<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, date of last ablation: AFAVABM / AFAVABY (mo / yr)

Was the ablation procedure successful? 0 ☐ No 1 ☐ Yes AFAVYN <ZYESNO>

(see follow-up p. 4)

AFIB2 TYPE=3

Has this patient ever had a curative atrial ablation procedure for atrial **flutter?** AFFLAB <ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, date of last ablation: AFFLABM / AFFLABY (mo / yr)

Was the ablation procedure successful? 0 ☐ No 1 ☐ Yes AFFLYN <ZYESNO>

Has this patient ever had a curative atrial ablation procedure for focal atrial **fibrillation/tachycardia**? AFFTAB<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, date of last ablation: AFFTABM / AFFTABY (mo / yr)

Was the ablation procedure successful? 0 ☐ No 1 ☐ Yes AFFTYN <ZYESNO>

Has this patient ever had a catheter maze procedure for atrial **fibrillation**? AFFBAB <ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, date of last procedure: AFFBABM / AFFBABY (mo / yr)

Was the procedure successful? 0 ☐ No 1 ☐ Yes AFFBYN <ZYESNO>

Patient Initials: INITIALS <V:3> Patient Study #: SUBJNO __ <V:10>

ARRHYTHMIAS—NONSUSTAINED VT

Has this patient ever had a documented episode of spontaneous nonsustained ventricular tachycardia (≥ 3 beats @ ≥ 100 bpm)? 0 ☐ No 1 ☐ Yes BVTACH <ZYESNO>

NONSUSVT TYPE=1

ARRHYTHMIAS—EP STUDY

Has this patient ever had an EP study? 0 ☐ No 1 ☐ Yes EPSTUDY <ZYESNO>

➔ If **Yes,** has this patient ever had programmed electrical stimulation (PES) of the ventricle? 0 ☐ No 1 ☐ Yes PES <ZYESNO>

➔ If **Yes,** complete the following:

Date of most recent PES procedure: PESM / PESY
mo *yr*

Was this patient inducible into sustained VT/VF (i.e., shock or >30 sec. of VT/VF) 0 ☐ No 1 ☐ Yes PESIND <ZYESNO>

Reason for EP study: EPREAS <V:200>

(See follow-up p.5)

EPSTUDY TYPE=3

SYNCOPE

(Note: syncope of unknown etiology within 5 years is a SCD-HeFT exclusion criterion.)

Has this patient ever had syncope? SYNC <ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, complete the following:

a. Date of most recent syncopal event: SYNCM / SYNCY
mo *yr*

b. Was a tilt-table test performed? 0 ☐ No 1 ☐ Yes
SYNCTT <ZYESNO>

c. Indicate cause of syncope:
(check one)
SYNCC <SCSYNC>

2 ☐ Vasomotor *(e.g., vasovagal, vasodepressor, etc.)*
3 ☐ Orthostasic hypotension
4 ☐ Drug induced hypotension
5 ☐ Drug induced arrhythmia
6 ☐ Seizures
7 ☐ Other: SYNCCOTH <V:200>

(See follow-up p. 5)

SYNCOPE TYPE=3

6 MINUTE WALK

If this patient is unable to walk due to amputation, stroke, or similar disability, check this box ☐ 1
NOWALK <ZYES>

What is the distance walked in 6 minutes? WALKDIST ft <F:9.3>

(To do the 6 minute walk, choose a measured area, such as around the clinic area or hallway. Clock a time of 6 minutes and measure the distance, in feet, that the patient was able to walk. Do not encourage or otherwise influence the performance of the patient. See the SCD-HeFT Operations Manual for full instructions on how to perform a 6 minute walk.)

During 6 minute walk, was this patient? 1 ☐ Asymptomatic 2 ☐ Symptomatic
WALKSYM<SCAFSY>

➔ If **Symptomatic** during the 6 minute walk, check all symptoms that apply:

WKDYSP<ZYES>	WKANG<ZYES>	WKSYNC<ZYES>
1 ☐ Dyspnea	1 ☐ Angina	1 ☐ Syncope
1 ☐ Near syncope WKNSYNC<ZYES>	1 ☐ Lightheadedness WKLGHTHD<ZYES>	1 ☐ Other: WKSYMPTX<V:60> WKSYMPOT<ZYES>

(See follow-up p.6)

WALK TYPE=3

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO ___ <V:10>

PHYSICAL EXAM

Weight: PEWGHT lbs. <F:9.3>

Right Arm *(sitting)*: Blood pressure: PESYS <F:9.3> / PEDIAS <F:9.3> mmHg Pulse: PEPULSE <F:9.3> bpm

Was jugular venous pressure elevated: 0 ☐ No 1 ☐ Yes 2 ☐ Could not measure
PEPRESS<SCNOTM>
➔ If **Yes**, cm above the sternal notch PESTERN cm <F:9.3>

Rales: PERALES<SCRALE> 1 ☐ None 2 ☐ <1/3 3 ☐ 1/3-2/3 4 ☐ >2/3

Auscultation: S3: PES3 <ZYESNO> 0 ☐ No 1 ☐ Yes PEGRADE <SCGRAD>

MR murmur: PEMR <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**: Grade 1 ☐ 1 2 ☐ 2 3 ☐ 3 4 ☐ 4 5 ☐ 5 6 ☐ 6

Pericardial rub: PERUB <ZYESNO> 0 ☐ No 1 ☐ Yes

Hepatomegaly: PEHEPA <ZYESNO> 0 ☐ No 1 ☐ Yes

Assessment of peripheral edema:

	LOCATION	Absent	Mild	Moderate	Severe
PEPERA<SCASMT>	Right arm	0 ☐	1 ☐	2 ☐	3 ☐
PEPERL<SCASMT>	Right leg	0 ☐	1 ☐	2 ☐	3 ☐
PEPELA<SCASMT>	Left arm	0 ☐	1 ☐	2 ☐	3 ☐
PEPELL<SCASMT>	Left leg	0 ☐	1 ☐	2 ☐	3 ☐

PHYSICAL TYPE=3 (See follow-up p. 6)

$\dot{V}O_2$ MEASUREMENT

Has the patient had a $\dot{V}O_2$ measurement? 0 ☐ No 1 ☐ Yes HADVO2<ZYESNO>

➔ If **Yes**, when was $\dot{V}O_2$ measured? VO2M / VO2Y
mo / *yr*

➔ If **Yes**, what is the $\dot{V}O_2$? VO2 <F:9.3> ml/kg/min

(See follow-up p.8)

VO2 TYPE=3

CHEMISTRY PANEL

Date obtained: CHDT / ____ / ____
mo / *day* / *yr*

Sodium:	CHNA <F:9.3>	CHNAU<SCCHUA> 1 ☐ mEq/L	2 ☐ other units	CHNAUO<V:20>
Potassium:	CHK <F:9.3>	CHKU<SCCHUA> 1 ☐ mEq/L	2 ☐ other units	CHKUO<V:20>
Magnesium:	CHMG <F:9.3>	CHMGU<SCCHUA> 1 ☐ mEq/L	2 ☐ other units	CHMGUO<V:20>
BUN:	CHBUN <F:9.3>	CHBUNU<SCCHUB> 1 ☐ mg/dl	2 ☐ other units	CHBUNUO<V:20>
Creatinine:	CHCREAT <F:9.3>	CHCRU<SCCHUB> 1 ☐ mg/dl	2 ☐ other units	CHCRUO<V:20>

(See follow-up p. 7)

CHEMIST TYPE=3

THYROID

Date obtained: ____ / ____ / THYDT
mo / *day* / *yr*

TSH: TSH <F:9.3> TSHU<SCTHUT> 1 ☐ µU/ml 2 ☐ other units TSHUO <V:20>

(See follow-up p.7)

THYROID TYPE=3

Patient Initials: INITIALS <V:3> Patient Study #: SUBJNO ___ <V:10>

CURRENT MEDICATIONS

ACE inhibitor: ACE <ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**: ENAL <ZYES> 1 ☐ enalapril ENALDS <F:9.3> mg schedule: ENALSC<V:30>
CAPT 1 ☐ captopril CAPTDS <F:9.3> mg schedule: CAPTSC<V:30>
LISN 1 ☐ lisinopril LISNDS <F:9.3> mg schedule: LISNSC<V:30>
QUIN 1 ☐ quinapril QUINDS <F:9.3> mg schedule: QUINSC<V:30>
BENZ 1 ☐ benazepril BENZDS <F:9.3> mg schedule: BENZSC<V:30>
FOSN 1 ☐ fosinopril FOSNDS <F:9.3> mg schedule: FOSNSC<V:30>
AOTH 1 ☐ other: ACEOTH <V:60> AOTHDS <F:9.3> mg schedule: AOTHSC<V:30>

Date any ACE I started: ACEM (mo) / ACEY (yr)

MEDS1 TYPE=3

Losartan or other Angiotensin II inhibitor: 0 ☐ No 1 ☐ Yes LOSARTA <ZYESNO>

➔ If **Yes**: LOSAR <ZYES> 1 ☐ Losartan: LOSARDS<F:9.3> mg schedule: LOSARSC<V:30>

ANGI <ZYES> 1 ☐ Other: ANGIOTH<V:60> ANGIDS<F:9.3> mg schedule: ANGISC<V:30>

Date Angiotensin II inhibitor started: ANGIM (mo) / ANGIY (yr)

MEDS2 TYPE=3

Digoxin: DIG <ZYESNO> 0 ☐ No 1 ☐ Yes Refer to Section 7 of the SCD-HeFT Operations Manual for digoxin test schedule.

➔ If **Yes**, most recent level: DIGLVL <F:9.3> ng/ml Date level measured: DIGDT (mo) / _____ (day) / _____ (yr)

MEDS3 TYPE=3

Diuretic: (loop) LDIUR <ZYESNO> 0 ☐ No 1 ☐ Yes

<F:9.3> <V:30>

➔ If **Yes**: FURO <ZYES> 1 ☐ furosemide FURODS mg schedule: FUROSC
BUMT 1 ☐ bumetanide BUMTDS mg schedule: BUMTSC
TORS 1 ☐ torsemide TORSDS mg schedule: TORSSC
ETHC 1 ☐ ethacrynic acid ETHCDS mg schedule: ETHCSC
LDOTH 1 ☐ other: LDIUROT<V:60> LDOTHDS mg schedule: LDOTHSC

MEDS4 TYPE=3

Diuretic: (potassium sparing) PSDIUR<ZYESNO> 0 ☐ No 1 ☐ Yes

<F:9.3> <V:30>

➔ If **Yes**: SPIR <ZYES> 1 ☐ spironolactone SPIRDS mg schedule: SPIRSC
TRIA 1 ☐ triamterene TRIADS mg schedule: TRIASC
AMIL 1 ☐ amiloride AMILDS mg schedule: AMILSC
PSDOTH 1 ☐ other: PSDIURO<V:60> PSDOTDS mg schedule: PSDOTSC

MEDS5 TYPE=3

(See follow-up p. 12 & 13)

Diuretic: (thiazide) TDIUR <ZYESNO> 0 ☐ No 1 ☐ Yes

<F:9.3>

➔ If **Yes**: name: TDIUROT<V:60> TDIURDS mg schedule: TDIURSC<V:30>

MEDS6 TYPE=3

Warfarin: WARF <ZYESNO> 0 ☐ No 1 ☐ Yes Refer to Section 7 of the SCD-HeFT Operations Manual for warfarin test schedule.

➔ If **Yes**: INR: WARFINR<F:9.3> Date most recently measured: WARFDT (mo) / _____ (day) / _____ (yr)

MEDS7 TYPE=3

CURRENT MEDICATIONS *(cont.)*

Aspirin: ASA <ZYESNO> 0 ☐ No 1 ☐ Yes
(if taken daily)

Amlodipine: AMLDP <ZYESNO> 0 ☐ No 1 ☐ Yes
➔ If **Yes**: AMLDPDS<F:9.3> mg schedule: AMLDPSC<V:30>

MEDS8 TYPE=3

Other calcium channel blocker: CBLOCK <ZYESNO> 0 ☐ No 1 ☐ Yes

			<F:9.3>	<V:30>
➔ If **Yes**: <ZYES>	DILT 1	diltiazem	DILTDS mg	schedule: DILTSC
	VERA 1	verapamil	VERADS mg	schedule: VERASC
	NIFE 1	nifedipine	NIFEDS mg	schedule: NIFESC
	CCOTH 1	other: CBLOCKO<V:60>	CCOTHDS mg	schedule: CCOTHSC

MEDS9 TYPE=3

Beta blocker: BBLOCK <ZYESNO> 0 ☐ No 1 ☐ Yes

			<F:9.3>	<V:30>
➔ If **Yes**: <ZYES>	ATEN 1	atenolol	ATENDS mg	schedule: ATENSC
	CARV 1	carvedilol	CARVDS mg	schedule: CARVSC
	METO 1	metoprolol	METODS mg	schedule: METOSC
	PROP 1	propanolol	PROPDS mg	schedule: PROPSC
	BBOTH 1	other: BBLOCKO<V:60>	BBOTHDS mg	schedule: BBOTHSC

MEDS10 TYPE=3

(See follow-up p. 13)

Nitrate:	0 ☐ No	1 ☐ Yes	NITRATE <ZYESNO>
Hydralazine:	0 ☐ No	1 ☐ Yes	HYDRAL <ZYESNO>
Statins:	0 ☐ No	1 ☐ Yes	STATINS <ZYESNO>
Other lipid lowering agents:	0 ☐ No	1 ☐ Yes	LIPIDS <ZYESNO>
Potassium:	0 ☐ No	1 ☐ Yes	POTAS <ZYESNO>
Magnesium:	0 ☐ No	1 ☐ Yes	MAGNES <ZYESNO>
Estrogens:	0 ☐ No	1 ☐ Yes	ESTROG <ZYESNO>
Progesterone:	0 ☐ No	1 ☐ Yes	PROGST <ZYESNO>
Insulin:	0 ☐ No	1 ☐ Yes	INSULIN <ZYESNO>
Oral hypoglycemics:	0 ☐ No	1 ☐ Yes	ORALHYP <ZYESNO>
Thyroid replacement:	0 ☐ No	1 ☐ Yes	THYRPL <ZYESNO>

(See follow-up p.14)

MEDS11 TYPE=3

LIVING WITH HEART FAILURE QUESTIONNAIRE

Instructions for use

1. The following instructions should be given to the patient each time the questionnaire is completed.

   a. Read the introductory paragraph at the top of the questionnaire to the patient.

   b. Read the first question to the patient — "Did your heart failure prevent you from living as you wanted during the past month by causing swelling in your ankles or legs?" Tell the patient, "If you did not have any ankle or leg swelling during the past month you should circle the zero after this question to indicate that swelling was not a problem during the past month." Explain to the patient that if he or she did have swelling that was caused by a sprained ankle or some other cause that was definitely not related to heart failure he or she should also circle zero. Tell the patient "If you are not sure why you had the swelling or think it was related to your heart condition, then rate how much the swelling prevented you from doing things you wanted to do and from feeling the way you would like to feel." In other words, how bothersome was the swelling? Show the patient how to use the 1 to 5 scale to indicate how much the swelling affected his or her life during the past month — from very little to very much.

2. Let the patient read and respond to the other questions. The entire questionnaire may be read directly to the patient if one is careful not to influence responses by verbal or physical cues.

3. Check to make sure the patient has responded to each question and that there is only one answer clearly marked for each question.

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO ____ <V:10>

These questions concern how your heart failure (heart condition) has prevented you from living as you wanted during the last month. The items listed below describe different ways some people are affected. If you are sure an item does not apply to you or is not related to your heart failure then circle 0 (meaning "No") and go on to the next item. If an item does apply to you, then circle the number rating of how much it prevented you from living as you wanted. Remember to think about ONLY THE LAST MONTH.

Did your heart failure prevent you from living as you wanted during the last month by:

		No	Very Little →				Very Much
SWELL	1. causing swelling in your ankles, legs, etc?	0	1	2	3	4	5
WORK	2. making your working around the house or yard difficult?	0	1	2	3	4	5
FRIENDS	3. making your relating to or doing things with your friends difficult?	0	1	2	3	4	5
REST	4. making you sit or lie down to rest during the day?	0	1	2	3	4	5
ENERGY	5. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
DIFF	6. making your working to earn a living difficult?	0	1	2	3	4	5
WALKC	7. making your walking or climbing stairs difficult?	0	1	2	3	4	5
BREATH	8. making you short of breath?	0	1	2	3	4	5
SLEEP	9. making your sleeping well at night difficult?	0	1	2	3	4	5
EAT	10. making you eat less of the foods you like?	0	1	2	3	4	5
AWAY	11. making your going places away from home difficult?	0	1	2	3	4	5
SEX	12. making your sexual activities difficult?	0	1	2	3	4	5
HOBBIE	13. making your recreational pastimes, sports, or hobbies difficult?	0	1	2	3	4	5
REMEM	14. making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
EFFECT	15. giving you side effects from medications?	0	1	2	3	4	5
WORRY	16. making you worry?	0	1	2	3	4	5
DEPRS	17. making you feel depressed?	0	1	2	3	4	5
COST	18. costing you money for medical care?	0	1	2	3	4	5
LOSS	19. making you feel a loss of self-control in your life?	0	1	2	3	4	5
STAY	20. making you stay in a hospital?	0	1	2	3	4	5
BURDEN	21. making you feel you are a burden to your family or friends?	0 0	1 1	2 2	3 3	4 4	5 5

TYPE=3

(See follow-up p. 17)

LWHFQUES

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO <V:10>

RANDOMIZATION REVIEW

Treatment assigned: BTX <SCBTX>

1 ☐ ICD

➔ Date of ICD implantation: BIMPLDT _____/_____/_____ (mo / day / yr)

Please submit **ICD Implant Form**.

2 ☐ Drug therapy

➔ Date of drug therapy start: BDRUGDT _____/_____/_____ (mo / day / yr)

Kit # dispensed to patient: BKIT_INV<V:5> ____

BCRREV TYPE=3

Please forward this form to the Data Coordinating Center at Duke.

Coordinator signature: _____ Date: _____/_____/_____ (mo / day / yr)

SHSIG

Patient Initials: ____ ____ ____ INITIALS<V:3> Patient Study #: ____ ____ ____—____ ____ ____ SUBJNO<V:10>

Sudden Cardiac Death

SCD HeFT

Heart Failure Trial

Cardiac Arrest Survival Form

Complete this form for all patients who have a cardiac arrest during the study and survive for more than 48 hours. Cardiac arrest is defined as a loss of consciousness necessitating CPR and/or transthoracic defibrillation.

PERI-ARREST CIRCUMSTANCES

TYPE=3 EVENT1

Date of last patient visit: _____/_____/_____ LVISDT
mo day yr

Date of cardiac arrest: _____/_____/_____ EVENTDT
mo day yr

Time of cardiac arrest: _____:_____ EVENTTM with EVENTDT
(24 hour clock)
1 ☐ Known 2 ☐ Estimated 3 ☐ No data EVENTST <SCTMST>

Location of cardiac arrest: EVENTLOC <SCSHOC>
1 ☐ Hospital 2 ☐ Work 3 ☐ Home
4 ☐ En route to hospital 5 ☐ Other: EVENTLTX <V:200>

What was the patient's activity at the time of cardiac arrest? EVENTACT <SCACT>

1 ☐ Awake, no distress, no exercise 2 ☐ Sleeping 3 ☐ Exercising
4 ☐ Emotional distress 5 ☐ Eating 6 ☐ Sex
7 ☐ Bowel movement 8 ☐ Urinating
9 ☐ Other: EVENTATX <V:200>

TYPE=3 EVENT2

Was the cardiac arrest witnessed? 0 ☐ No 1 ☐ Yes 2 ☐ Unknown
(Event occurring within 1 minute of last contact) WITNESS <SCUNK>

Was the patient's ECG monitored 1 ☐ No 2 ☐ At onset of event 3 ☐ Only later after onset of event during the event? (*check one*) EVENTECG <SCECG>

➔ If ECG monitored, indicate rhythm when first monitored: *(check all that apply)*
All check boxes are <ZYES>

1 ☐ VF ECGVF
1 ☐ Polymorphic VT ECGPVT
1 ☐ Monomorphic VT ECGMVT
1 ☐ Asystole ECGASYS
1 ☐ Bradycardia (<50 bpm) ECGBRAD
1 ☐ AFib/Flutter ECGAFIB
1 ☐ Normal sinus rhythm ECGSINUS
1 ☐ Electromechanical dissociation ECGEMD
1 ☐ Other: ECGOTHTX <V:200> ECGOTH

Did this patient have progressive heart failure within 2 weeks prior to the cardiac arrest? 0 ☐ No 1 ☐ Yes 2 ☐ Unknown EVENTHF <SCUNK>

Did this patient have progressive ischemic heart disease within 2 weeks prior to the cardiac arrest? 0 ☐ No 1 ☐ Yes 2 ☐ Unknown EVENTIHD <SCUNK>

Patient Initials: ____ ____ ____ Patient Study #: ____ ____ ____—____ ____ ____

MEDIC AND PHYSICIAN DATA

How was the cardiac arrest documented? *(check all that apply)*

Family interview EVTFAM<ZYESNO>	0☐ No	1☐ Yes
Physician interview EVTPHYS<ZYESNO>	0☐ No	1☐ Yes
Hospital medical record review EVTMEDR <ZYESNO>	0☐ No	1☐ Yes
Medic report EVTMEDIC <ZYESNO>	0☐ No	1☐ Yes
Hospital Discharge summary EVTDISC <ZYESNO>	0☐ No	1☐ Yes
EVTOTH1 <ZYESNO> Other: EVTOTHT1 <V:200>	0☐ No	1☐ Yes

Please include all supporting documentation with this Cardiac Arrest Survival Form.

EVENT3 TYPE=3

RANDOMIZATION AND THERAPY DATA

1. Was the patient randomized to drug therapy? EVTDRUG <ZYESNO> 0☐ No 1☐ Yes

   ➔ If **Yes**, was the cardiac arrest considered to be related to the study drug? EVTRDRUG <SCUNK> 0☐ No 1☐ Yes 2☐ Unknown

   ➔ If **Yes**, indicate reason: EVTREAS <V:200> _____

2. Did the patient have an ICD at the time of cardiac arrest? EVTICD <ZYESNO> 0☐ No 1☐ Yes

   ➔ If **Yes**, answer the following:

   a. Did the patient receive an ICD shock? EVTICDSH <SCUNK> 0☐ No 1☐ Yes 2☐ Unknown

   b. Was the cardiac arrest caused by failure to pace or shock? EVTFPACE <SCUNK> 0☐ No 1☐ Yes 2☐ Unknown

   c. Was the cardiac arrest considered to be caused by **inappropriate** pacing or shock therapy? EVTIPACE <SCUNK> 0☐ No 1☐ Yes 2☐ Unknown

      ➔ If **Yes**, what was the probable cause of the inappropriate pace or shock therapy?

(check all that apply)

All check boxes are <ZYES>

- EVTSVT 1☐ SVT
- EVTOVS 1☐ Oversensing
- EVTLFRAC 1☐ Lead fracture
- EVTEMI 1☐ Electromechanical interference (EMI)
- EVTLSET 1☐ Loose set screw
- EVTLEAD 1☐ Lead dislodgement
- EVTOTH2 1☐ Other: EVTOTHT2 <V:200> _____

EVENT4 TYPE=3

Please forward this form to the Data Coordinating Center at Duke.

Coordinator signature: _____ Date: _____/_____/_____ *mo day yr*

SHSIG

INITIALS SUBJNO

Patient Initials: ___ ___ ___ Patient Study #: ___ ___ ___ - ___ ___ ___

Sudden Cardiac Death

SCDHeFT

Heart Failure Trial

Clinical Events Classification

Death/Cardiac Arrest Data Entry Form PANEL=CECDEATH TYPE=2

Event adjudicated: 1 ☐ **I. Cardiac Arrest ⇒ Date:** ____/____/____ **Time:**____:____
mo day year 24 hour

CECEVENT <SCEVT> CECEVDT CECEVTM

2 ☐ **II. Death ⇒ Date:** ____/____/____ **Time:**____:____
mo day year 24 hour

CLASSIFICATION

Witnessed/ Unwitnessed	Cardiac / Noncardiac	Subclass			
CECWIT <V:3>	CECTYPE <V:3>	CECSUB1 <V:3>	CECSUB2 <V:3>	CECSUB3 <V:3>	CECSUB4 <V:3>

DEGREE OF CERTAINTY

CECDEG <SCDEG>

1 ☐ **VERY** (excellent documentation / consistent data)
2 ☐ **REASONABLY** (good documentation / generally consistent data)
3 ☐ **SOMEWHAT** (missing documentation / inconsistent data)
4 ☐ **UNCERTAIN** (fragmented documentation / conflicting data)

1 ☐ **Independent Physician Review**
CECREV <SCREV>

2 ☐ **Adjudication Committee Review**

CECREVCM <V:200>

_____

CEC Coordinator_____ ***Date***____/____/____
Mo Day Year

K: cec/trials/SCD-HeFT/formsworks/erf-def/deathdef
Revised: 03/08/99
Revised: 05/15/2000

Sudden Cardiac Death

SCD HeFT

Heart Failure Trial

Comments Form

Patient Study Number: STUDYNO ____ ____ ____ — <V:10> ____ ____ ____

Patient Initials: PATINIT<V:3> ____ ____ ____

Please check **one** box below to indicate to which form/visit the attached comments pertain. If the form/visit is not listed below, please check the **Other** box and specify the form/visit. If this is a general comment about the patient, please check the **Other** box and indicate 'general' as the specific text.

COMFORM<SCVISI>

30 ☐ Randomization Form

31 ☐ Baseline Case Report Form

32 ☐ ICD Implant Form

Follow-up Form ➔ Date of Contact: ____/____/COMFUDT
mo day yr

1 ☐ 1 week 2 ☐ 1 mo. 3 ☐ 3 mo. 4 ☐ 6 mo. 5 ☐ 9 mo. 6 ☐ 12 mo. 7 ☐ 15 mo.
8 ☐ 18 mo. 9 ☐ 21 mo. 10 ☐ 24 mo. 11 ☐ 27 mo. 12 ☐ 30 mo. 13 ☐ 33 mo. 14 ☐ 36 mo.
15 ☐ 39 mo. 16 ☐ 42 mo. 17 ☐ 45 mo. 18 ☐ 48 mo. 19 ☐ 51 mo. 20 ☐ 54 mo. 21 ☐ 57 mo.
22 ☐ 60 mo. 99 ☐ unscheduled 24 ☐ 66 mo. 26 ☐ 72 mo.

33 ☐ Death Report Form

34 ☐ Cardiac Arrest Survival Form ➔ Date of Cardiac Arrest: ____/____/COMCADT
mo day yr

35 ☐ Other (specify): COMOTH <V:60>

TYPE=2 COMMENT1

Please type or attach a typewritten sheet. If more space is required, please attach any additional pages.

COMM <V:200>

TYPE=4 COMMENT2

Please forward this form to the Data Coordinating Center at Duke.

Coordinator signature: _____ Date: ____/____/____
mo day yr

SHSIG

Annotation Date = 9/27/02

Sudden Cardiac Death

SCD HeFT

Heart Failure Trial

Notification of Patient Death Form

Please complete and FAX this form to the Data Coordinating Center at Duke **IMMEDIATELY** after the death of a patient enrolled in SCD-HeFT or **IMMEDIATELY** after notification of a patient's death from an outside source.

Patient Study Number: STUDYNO ____ ____ ____ — <V:10> ____ ____ ____

Patient Initials: PATINIT <V:3> ____ ____ ____

Date of death: _____ / _____ / DEATHDT _____
mo *day* *yr*

Location of death: *(check one)*

DEATHLOC <SCDEAT>

1 ☐ Home

2 ☐ Hospital ➔ DTHHOSP <V:200>
(hospital name and location)

3 ☐ Other: DTHOTH <V:200>

TYPE=1

DEATH

Please complete the SCD-HeFT **Death Report Form** and mail to the Data Coordinating Center at Duke within one week after the submission of this form.

Attach all available source documentation of the event using only the appropriate SCD-HeFT source document labels included in each patient binder to identify all medical records.

Coordinator signature: _____ Date: _____/_____/_____
mo *day* *yr*

SHSIG

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO __ <V:10>

Sudden Cardiac Death

SCD HeFT

Heart Failure Trial

Death Report Form

Complete this form for all patients who die during the study.

DEATH CIRCUMSTANCES

Date of last patient visit: ____/____/ LVISDT
mo day yr

Date of death: ____/____/ EVENTDT
mo day yr

Time of death: ____ : EVENTTM 1☐ Known 2☐ Estimated 3☐ No data
(24 hour clock) (associate w/ EVENTDT) EVENTST<SCTMST>

Location of death: 1☐ Hospital 2☐ Work 3☐ Home
EVENTLOC <SCSHOC> 4☐ En route to hospital 5☐ Other: EVENTLTX<V:200>

What was the patient's activity at the time of death? EVENTACT <SCACT>

1☐ Awake, no distress, no exercise 2☐ Sleeping 3☐ Exercising
4☐ Emotional distress 5☐ Eating 6☐ Sex
7☐ Bowel movement 8☐ Urinating
9☐ Other: EVENTATX<V:200>

TYPE=3 EVENT1

Was the death witnessed? 0☐ No 1☐ Yes 2☐ Unknown
(Event occurring within 1 minute of last contact) WITNESS <SCUNK>

Death was: 1☐ Sudden, within 1 hour of symptom onset
DEATHC <SCDTYP> 2☐ Nonsudden
3☐ Unknown

TYPE=3 EVENT2

Was the patient's ECG monitored during the event? (*check one*) EVENTECG<SCECG> 1☐ No 2☐ At onset of event 3☐ Only later after onset of event

➔ If ECG monitored, indicate rhythm when first monitored: *(check all that apply)* ALL <ZYES>

1☐ VF ECGVF
1☐ Polymorphic VT ECGPVT
1☐ Monomorphic VT ECGMVT
1☐ Asystole ECGASYS
1☐ Bradycardia (<50 bpm) ECGBRAD
1☐ AFib/Flutter ECGAFIB
1☐ Normal sinus rhythm ECGSINUS
1☐ Electromechanical dissociation ECGEMD
ECGOTH 1☐ Other: ECGOTHTX<V:200>

Did this patient have progressive heart failure within 2 weeks prior to death? EVENTHF <SCUNK> 0☐ No 1☐ Yes 2☐ Unknown

Did this patient have progressive ischemic heart disease within 2 weeks prior to death? EVENTIHD <SCUNK> 0☐ No 1☐ Yes 2☐ Unknown

Patient Initials: ____ ____ ____ Patient Study #: ____ ____ ____—____ ____ ____

CAUSE OF DEATH

In the opinion of the investigator, what was the primary cause of death? _____

DTHCAUSE <V:200>

_____

CDEATH1 TYPE=2

Please classify the cause of death as one of the following:

DTHCLASS <SCCLAS>

1 ☐ CARDIAC ➔ Check one: DTHCARD <SCCARD>
- 1 ☐ Primary arrhythmic (without worsening LV function)
- 2 ☐ Ischemic/infarction
- 3 ☐ Left Ventricular Dysfunction
  - ➔ 1 ☐ Without end-stage VT/VF DTHCRDLV<SCCRLV>
  - 2 ☐ With end-stage VT/VF
  - 3 ☐ Unknown
- 4 ☐ Other: DTHCARDO <V:200>

2 ☐ NONCARDIAC ➔ Check one: DTHNCARD <SCNAR>
- 1 ☐ Vascular (e.g., pulmonary embolus, stroke, aneurysm)
- 2 ☐ Nonvascular (e.g., trauma, cancer, renal failure, suicide, sepsis, lung disease)

3 ☐ UNKNOWN

CDEATH2 TYPE=1

DOCUMENTATION OF DEATH

How was the cause of death determined? *(check all that apply)*

all <ZYESNO>

Autopsy report EVTAUT	0 ☐ No	1 ☐ Yes	
Family interview EVTFAM	0 ☐ No	1 ☐ Yes	
Physician interview EVTPHYS	0 ☐ No	1 ☐ Yes	
Hospital medical record review EVTMEDR	0 ☐ No	1 ☐ Yes	
Medic report EVTMEDIC	0 ☐ No	1 ☐ Yes	
Hospital Discharge summary EVTDISC	0 ☐ No	1 ☐ Yes	
EVTOTH1 Other: EVTOTHT1<V:200>	0 ☐ No	1 ☐ Yes	

Please include all supporting documentation with this Death Report Form.

EVENT3 TYPE=3

RANDOMIZATION AND THERAPY DATA

1. Was the patient randomized to study drug? 0 ☐ No 1 ☐ Yes
   EVTDRUG <ZYESNO>

   ➔ If **Yes**, was this death considered to be related to the study drug? 0 ☐ No 1 ☐ Yes 2 ☐ Unknown
   EVTRDRUG <SCUNK>

   ➔ If **Yes**, indicate reason: EVTREAS <V:200> _____

   _____

2. Did the patient have an ICD at the time of death? 0 ☐ No 1 ☐ Yes
   EVTICD <ZYESNO>

   ➔ If **No**, go to the **HEART TRANSPLANT SINCE LAST CONTACT** section on page 7.

   ➔ If **Yes**, was this death considered to be caused by ICD surgery? 0 ☐ No 1 ☐ Yes
   EVTICDSG <ZYESNO>

   Please continue with **POSTMORTEM ICD INTERROGATION** section on page 4.

TYPE=3

EVENT4

Patient Initials: ____ ____ ____ Patient Study #: ____ ____ ____—____ ____ ____

POSTMORTEM ICD INTERROGATION

Date of ICD interrogation: _____/_____/ ICDINTDT
mo day yr

FUICD1 TYPE=3

Was an ICD interrogation of the entire ICD memory saved-to-disk and forwarded (electronically or via mail) to the ICD Memory Log Core Laboratory? FICDSENT <ZYESNO> 0 ☐ No 1 ☐ Yes

FUICD2 TYPE=3

Was VT/VF detected by the ICD at the time of death? FICDDET <SCUNK> 0 ☐ No 1 ☐ Yes

Was VT/VF treated by the ICD at the time of death? FICDTRT <SCUNK> 0 ☐ No 1 ☐ Yes

➔ If **Yes** to either question above, was "VT/VF" ICD electrogram consistent with:

True VF? FVTVF<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Polymorphic VT? FVPMVT<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Monomorphic VT? FVMOVT<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

➔ If **Yes**, monomorphic VT cycle length, if present: FVMOVTN<F:9.3> ms

Nonsustained VT? FVNSVT<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Sinus tachycardia? FVSTACH<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Atrial fibrillation? FVAFIB<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Atrial flutter? FVAFL<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Other? FVOTH<V:200> FVOT<ZYESNO> 0 ☐ No 1 ☐ Yes

FUICD3 TYPE=1

If the patient was shocked by the ICD at the time of death, was therapy considered **APPROPRIATE**? DTHICDAP<ZYESNO> 0 ☐ No 1 ☐ Yes

If the patient was shocked by ICD at the time of death, was therapy considered **INAPPROPRIATE**? DTHICDNP<ZYESNO> 0 ☐ No 1 ☐ Yes

(Note: You may indicate both APPROPRIATE and INAPPROPRIATE if both indeed apply.)

➔ If a therapy was inappropriate, what was the probable cause? *(check all that apply)*

all <ZYES>

1 ☐ SVT DTHSVT
1 ☐ Lead dislodgement DTHLEAD
1 ☐ Lead fracture DTHLFRAC
1 ☐ Loose set screw DTHLSET
1 ☐ Electromechanical interference (EMI) DTHEMI
1 ☐ Oversensing DTHOVS
1 ☐ Other: DTHOTHTX<V:200> DTHOTHI

Patient Initials: ____ ____ ____ Patient Study #: ____ ____ ____—____ ____ ____

ICD COMPLICATIONS SINCE LAST CONTACT

Were there any complications of ICD therapy since the last contact? FCOMPLIC <ZYESNO>

0 ☐ No ➔If **No**, go to Page 7 1☐ Yes ➔If **Yes**, check below all that apply and give dates of first occurrence.

FUICDC1 TYPE=3

FUICDC2 TYPE=4

FCOMP<SCCOMP>

		FCOMPM / FCOMPY
1. 1	☐ Pneumothorax, observation only	____/____ mo yr
2. 2	☐ Pneumothorax, chest tube required	____/____ mo yr
3. 3	☐ Pneumothorax, surgical repair required	____/____ mo yr
4. 4	☐ Hemothorax, observation only	____/____ mo yr
5. 5	☐ Hemothorax, chest tube required	____/____ mo yr
6. 6	☐ Hemothorax, surgical repair required	____/____ mo yr
7. 7	☐ ICD pocket hematoma, observation only	____/____ mo yr
8. 8	☐ ICD pocket hematoma requiring change in anticoagulation therapy	____/____ mo yr
9. 9	☐ ICD pocket hematoma requiring hospitalization	____/____ mo yr
10. 10	☐ ICD pocket hematoma requiring needle aspiration	____/____ mo yr
11. 11	☐ ICD pocket hematoma requiring surgical drainage	____/____ mo yr
12. 12	☐ Superficial ICD pocket infection, observation only	____/____ mo yr
13. 13	☐ Superficial ICD pocket infection requiring oral antibiotics	____/____ mo yr
14. 14	☐ Superficial ICD pocket infection requiring IV antibiotics	____/____ mo yr
15. 15	☐ Deep ICD pocket infection requiring oral antibiotics	____/____ mo yr
16. 16	☐ Deep ICD pocket infection requiring IV antibiotics	____/____ mo yr
17. 17	☐ Deep ICD pocket infection requiring pocket revision	____/____ mo yr
18. 18	☐ Deep ICD pocket infection requiring system removal	____/____ mo yr
19. 19	☐ Cardiac perforation, no effusion, observation only	____/____ mo yr
20. 20	☐ Cardiac perforation with effusion, no tamponade	____/____ mo yr

ICD COMPLICATIONS SINCE LAST CONTACT *(cont.)*

21.21☐	Cardiac perforation with tamponade, needle aspirate	_____/_____ mo yr
22.22☐	Cardiac perforation with tamponade, surgical drainage	_____/_____ mo yr
23.23☐	Minor lead dislodgment requiring observation only	_____/_____ mo yr
24.24☐	Minor lead dislodgment requiring generator reprogramming only	_____/_____ mo yr
25.25☐	Lead dislodgment requiring lead repositioning	_____/_____ mo yr
26.26☐	Lead fracture, no action	_____/_____ mo yr
27.27☐	Lead fracture with system revision	_____/_____ mo yr
28.28☐	"Twiddler's Syndrome" without surgical intervention	_____/_____ mo yr
29.29☐	"Twiddler's Syndrome" with surgical intervention	_____/_____ mo yr
30.30☐	ICD migration, observation only	_____/_____ mo yr
31.31☐	ICD migration requiring ICD reprogramming only	_____/_____ mo yr
32.32☐	ICD migration requiring ICD repositioning	_____/_____ mo yr
33.33☐	Impending ICD pocket erosion, observation only	_____/_____ mo yr
34.34☐	Impending ICD pocket erosion, leading to ICD pocket revision	_____/_____ mo yr
35.35☐	ICD pocket erosion requiring ICD explantation	_____/_____ mo yr
36.36☐	Other FCOMPOTH <V:200> _____	_____/_____ mo yr

_____

_____

FUICDC2 (CONTINUED)

Patient Initials: ____ ____ ____ Patient Study #: ____ ____ ____—____ ____ ____

HEART TRANSPLANT SINCE LAST CONTACT

Has this patient received a heart transplant since last contact? FTPLANT<ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**, date : FTPLANTM ____/FTPLANTY (mo/yr)

FTPLANT TYPE=3

ISCHEMIC HEART DISEASE SINCE LAST CONTACT

New myocardial infarction? FMI <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**, date of last: FMIM/FMIY (mo/yr)

New coronary bypass graft? FCABG <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**, date of last: FCABGM ____/FCABGY (mo/yr)

New LV aneurysmectomy or LV reduction surgery? FLVSURG <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**, date of last: FLVSURGM ____/FLVSURGY (mo/yr)

FUISCH1 TYPE=3

Catheterization or percutaneous revascularization (PTCA, stent, atherectomy)? FINTV<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, How many catheterizations? FCATHN<I:3>

How many percutaneous revascularizations? FPTCAN<I:3>

Complete the following table:

Procedure		Date *(mo/day/yr)*
FCATH 1 ☐ Cath	1 ☐ PTCA/stent/atherectomy FPTCA <ZYES>	____/____/FINTVDT
<ZYES> ☐ Cath	☐ PTCA/stent/atherectomy	____/____/____
☐ Cath	☐ PTCA/stent/atherectomy	____/____/____

FUISCH2 TYPE=4

VALVULAR DISEASE SINCE LAST CONTACT

New diagnosis of valvular disease? VALVDZ <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**: VALVAI 1 ☐ AI VALVAS 1 ☐ AS VALVMR 1 ☐ MR VALVMS 1 ☐ MS VALVTR 1 ☐ TR (all <ZYES>)

Date: FVALVDZM ____/FVALVDZY (mo/yr)

New valvular repair? VALVRP <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**: VALVRPA 1 ☐ AV VALVRPM 1 ☐ MV VALVRPT 1 ☐ TV VALVRPP 1 ☐ PV (all <ZYES>)

Date: FVALVRPM ____/FVALVRPY (mo/yr)

New valvular replacement? VALVRL <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**: VALVRLA 1 ☐ AV VALVRLM 1 ☐ MV VALVRLT 1 ☐ TV VALVRLP 1 ☐ PV (all<ZYES>)

Date: FVALVRLM ____/FVALVRLY (mo/yr)

VALVDZ TYPE=3

VASCULAR DISEASE SINCE LAST CONTACT

New vascular disease? VASC<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**: new stroke? STROKE<ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**, date of last: STROKEM ____/STROKEY (mo/yr)

new pulmonary embolism? PULEMB<ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**, date of last: PULEMBM ____/PULEMBY (mo/yr)

VASCDZ TYPE=3

NON-SCD-HeFT ICD IMPLANT SINCE LAST CONTACT

Was a non SCD-HeFT protocol ICD implanted in this patient since the last contact? FNPICD<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, complete the following:

a. Date of ICD implant: FNPICDM _____ / FNPICDY _____
mo *yr*

b. Type of ICD: FNPICDTP<SCIMP> 1 ☐ Single chamber 2 ☐ Dual chamber

c. Reason for ICD implantation:
(check all that apply) all <ZYES>

1 ☐ Atrial fibrillation/flutter FNPICDAF
1 ☐ Ventricular fibrillation FNPICDVF
1 ☐ Ventricular tachycardia FNPICDVT
FNPICDOT 1 ☐ Other: FNPICDO <V:200> _____

FUNPICD TYPE=3

ATRIAL FIBRILLATION/FLUTTER SINCE LAST CONTACT

Has this patient had atrial fibrillation/flutter (AF) since the last contact? AF <ZYESNO> 0 ☐ No 1 ☐ Yes

➔If **Yes,** complete the following:

a. Date of most recent episode: AFM / AFY (mo / yr)

Permanent AF = completely refractory to cardioversion
Persistent AF = can be successfully cardioverted
Paroxysmal AF = terminates spontaneously

b. AFTYP <SCAFTY>
1 ☐ Permanent
2 ☐ Persistent
3 ☐ Paroxysmal

c. AFSYMP <SCAFSY>
1 ☐ Asymptomatic
2 ☐ Symptomatic

➔ If **Symptomatic** with AF, check all symptoms that apply: all <ZYES>

AFSYNC 1 ☐ Syncope
AFNSYN 1 ☐ Near syncope
AFFAT 1 ☐ Fatigue
1 ☐ Dyspnea AFDYSP
AFPALP 1 ☐ Palpitations
1 ☐ Angina AFANG

TYPE=3 AFIB1

Has this patient been cardioverted for AF since the last contact? AFCARD <ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, date of last cardioversion: AFCARDM / AFCARDY (mo / yr)

Was an ablation procedure for AV node interruption for AF done since the last contact? AFAVAB<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, date of last ablation: AFAVABM / AFAVABY (mo / yr)

Was the ablation procedure successful? AFAVYN<ZYESNO> 0 ☐ No 1 ☐ Yes

Was a curative atrial ablation procedure for atrial **flutter** done since the last contact? AFFLAB<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, date of last ablation: AFFLABM / AFFLABY (mo / yr)

Was the ablation procedure successful? AFFLYN <ZYESNO> 0 ☐ No 1 ☐ Yes

Was a curative atrial ablation procedure for focal atrial **fibrillation/tachycardia** done since the last contact? AFFTAB <ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, date of last ablation: AFFTABM / AFFTABY (mo / yr)

Was the ablation procedure successful? AFFTYN<ZYESNO> 0 ☐ No 1 ☐ Yes

Was a catheter maze procedure for atrial **fibrillation** done since the last contact? AFFBAB<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, date of last procedure: AFFBABM / AFFBABY (mo / yr)

Was the procedure successful? AFFBYN<ZYESNO> 0 ☐ No 1 ☐ Yes

TYPE=3 AFIB2

Patient Initials: ____ ____ ____ Patient Study #: ____ ____ ____—____ ____ ____

ARRHYTHMIAS—VT/VF SINCE LAST CONTACT

Has this patient had ventricular fibrillation since the last contact? FVFIB <ZYESNO> 0 ☐ No 1 ☐ Yes

Has this patient had spontaneous sustained VT (≥30 sec. at >100 bpm) since the last contact? FSVT<ZYESNO> 0 ☐ No 1 ☐ Yes

Was this patient cardioverted out of VT since the last contact? FSVTCARD<ZYESNO> 0 ☐ No 1 ☐ Yes

Was an ablation for VT done since the last contact? FSVTABL<ZYESNO> 0 ☐ No 1 ☐ Yes

FVTVF TYPE=3

CARDIAC ARREST SINCE LAST CONTACT

Has this patient had a cardiac arrest since the last contact? FCARDA<ZYESNO> 0 ☐ No 1 ☐ Yes

(Cardiac arrest is defined as a loss of consciousness necessitating CPR and/or transthoracic defibrillation.)

➔ If **Yes:**

Number of cardiac arrests: FCARDAN<I:3>

Date of most recent: ____/____/FCARDADT
mo day yr

For each cardiac arrest that the patient survived at least 48 hours, submit a **Cardiac Arrest Survival Form**.

FUCARDA TYPE=3

SYNCOPE SINCE LAST CONTACT

Has this patient had syncope since the last contact? SYNC <ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, complete the following:

a. Date of most recent syncopal event: SYNCM____/SYNCY____
mo yr

SYNCTT<ZYESNO>

b. Was a tilt-table test performed? 0 ☐ No 1 ☐ Yes

SYNCOPE TYPE=3

PERMANENT PACEMAKER IMPLANT SINCE LAST CONTACT

Was a permanent pacemaker implanted in this patient since the last contact? FPCIMP<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, complete the following:

a. Date of pacemaker implant: FPCIMPM____/FPCIMPY____
mo yr

b. Type of pacemaker: FPCTYPE<SCIMP> 1 ☐ Single chamber 2 ☐ Dual chamber

FUPACE TYPE=3

Patient Initials: ____ ____ ____ Patient Study #: ____ ____ ____—____ ____ ____

EP STUDY SINCE LAST CONTACT

Has this patient had an EP study since the last contact? 0 ☐ No 1 ☐ Yes
EPSTUDY <ZYESNO>

➔ If **Yes,** did this patient have programmed electrical stimulation (PES) of the ventricle? 0 ☐ No 1 ☐ Yes
PES <ZYESNO>

➔ If **Yes,** complete the following:

Date of most recent PES procedure: PESM / PESY
mo *yr*

Was this patient inducible into sustained VT/VF 0 ☐ No 1 ☐ Yes
(i.e., defib. shock or >30 sec. of VT/VF) PESIND<ZYESNO>

Reason for EP study: EPREAS <V:200>

EPSTUDY TYPE=3

MEDICATIONS

ACE inhibitor:	0 ☐ No	1 ☐ Yes	ACE <ZYESNO>
Losartan or other Angiotensin II inhibitor:	0 ☐ No	1 ☐ Yes	LOSARTA <ZYESNO>
Digoxin:	0 ☐ No	1 ☐ Yes	DIG <ZYESNO>
Diuretic:	0 ☐ No	1 ☐ Yes	DIUR <ZYESNO>
Warfarin:	0 ☐ No	1 ☐ Yes	WARF <ZYESNO>
Aspirin: *(if taken daily)*	0 ☐ No	1 ☐ Yes	ASA <ZYESNO>
Amlodipine:	0 ☐ No	1 ☐ Yes	AMLDP <ZYESNO>
Other calcium channel blocker:	0 ☐ No	1 ☐ Yes	CBLOCK <ZYESNO>
Carvedilol:	0 ☐ No	1 ☐ Yes	CARVED <ZYESNO>
Other beta blocker:	0 ☐ No	1 ☐ Yes	OBETAB <ZYESNO>

MEDS1 TYPE=3
MEDS2 TYPE=3
MEDS3 TYPE=3
DIURET TYPE=1
MEDS7 TYPE=3
MEDS8 TYPE=3
MEDS9 TYPE=3
BETABL TYPE=1

Antiarrhythmic drug other than study drug 0 ☐ No 1 ☐ Yes
OANTIAR <ZYESNO>

➔ If **Yes**: *(check all that apply)*
ALL <ZYES>

- CIA ☐ Class IA *(quinidine, procainamide, disopyramide)*
- CIB ☐ Class IB *(mexiletine)*
- CIC ☐ Class IC (*propafenone, flecainide)*
- AMIO ☐ amiodarone *(open label)*
- SOTL ☐ sotalol
- AAOTH ☐ other: OANTIOT <V:60>

MEDS12 TYPE=3

NON-SCD-HeFT OUTPATIENT VISITS

SINCE THE LAST CONTACT, how many non-SCD-HeFT outpatient (office or clinic) visits has the patient made to... List number of visits: (0, 1, 2,...)

...any physician visit FANYPHYS <I:5>

...any emergency department visit FEMERN <I:5>

FUOUTPAT TYPE=3

INTERVAL HOSPITALIZATION SINCE LAST CONTACT

Was this patient hospitalized at any time since the DATE OF LAST CONTACT including the time of death? FRHOSP <ZYESNO>

0 ☐ No 1 ☐ Yes

Note: If there were more than three hospitalizations, add additional pages.

➔ If **Yes**, how many times? FRHOSPN <I:4>

Complete resource utilization grid below.

Hospitalization dates	Hospital/Rehabilitation Institution/Nursing Home (name/location)	Reason for rehospitalization
From: ____ / ____ / FHADMDT (mo / day / yr) To: ____ / ____ / FHDISCDT (mo / day / yr)	Hospital: FHNAME<V:200> City: FHCITY<V:200> State/Prov.: FHSTATE<V:50> Country: FHCOUNTR<V:50>	FHREAS <V:200>
From: ____ / ____ / ____ (mo / day / yr) To: ____ / ____ / ____ (mo / day / yr)	Hospital: _____ City: _____ State/Prov.: _____ Country: _____	
From: ____ / ____ / ____ (mo / day / yr) To: ____ / ____ / ____ (mo / day / yr)	Hospital: _____ City: _____ State/Prov.: _____ Country: _____	

Patient Initials: _____ Patient Study #: _____

Patient Initials: ____ ____ ____ Patient Study #: ____ ____ ____—____ ____ ____

THERAPY COMPLIANCE SINCE LAST CONTACT

Was the patient randomized to ICD therapy? 0 ☐ No 1 ☐ Yes
FICDTHER <ZYESNO>

➔ If **Yes**, answer the following:

1. Was the ICD replaced prior to death? 0 ☐ No 1 ☐ Yes
   FICDREP <ZYESNO>
   ➔ If **Yes**, submit **ICD Replacement Form**
2. Was the ICD removed prior to death? 0 ☐ No 1 ☐ Yes
   FICDREM <ZYESNO>
   ➔ If **Yes**, reason: FICDREMR <V:200> _____
3. Was the ICD system revised prior to death? 0 ☐ No 1 ☐ Yes
   FICDREV <ZYESNO>
   ➔ If **Yes**, reason: FICDREVR <V:200> _____

FUTHERC1 TYPE=3

Was the patient randomized to drug therapy? 0 ☐ No 1 ☐ Yes
FDRAND <ZYESNO>

➔ If **Yes**, answer the following:

1. Was the patient still on study drug at the time of death? 0 ☐ No 1 ☐ Yes ➔ If **No**, reason: _____
   FONDRUG <ZYESNO> FNODRGRS <V:200>
   ➔ If **Yes**, answer the following:
2. How many tablets had the patient previously been instructed to take each day? 1 ☐ 1 2 ☐ 1½ 3 ☐ 2 4 ☐ other: FTABCNTO _____
   FTABCNT <SCTAB> <F:9.3>

FUTHERC2 TYPE=3

DOCUMENTATION

Submit to the Data Coordinating Center at Duke:

1. A <u>detailed</u> letter explaining the circumstances leading up to the patient's death or cardiac arrest. This must be sufficiently detailed to allow us to determine time and mode of the event, as well as determine whether it was witnessed or unwitnessed, arrhythmic, ischemic, or due to left ventricular dysfunction, whether there had been a change in the patient's status prior to the death. This summary should not disclose the therapeutic group to which the patient was randomized. If information available to the principal investigator does not agree with available hospital, ER, or paramedic notes, sufficient detail should be available to support his/her point of view.
2. Medical notes.
3. Ambulance notes.
3. Emergency room notes.
4. Hospital notes, including physician progress notes.
5. Nurses notes.
6. MD orders and drug administration notes.
7. All relevant ECGs, rhythm strips, enzymes, and other lab tests.
8. Discharge summary.
9. Autopsy report (if available.)

Please forward this form to the Data Coordinating Center at Duke.

Coordinator signature: _____ Date: _____/_____/_____
mo day yr

SHSIG

Sudden Cardiac Death
SCDHeFT
Heart Failure Tri l

Heart Transplant Notification Form

Please complete and FAX this form to the Data Coordinating Center at Duke ((919) 668-7100) immediately upon learning that a SCD-HeFT patient has received a heart transplant. All dates should be in MM/DD/YYYY format.

Site #: ___ ___ ___

Patient Study #: ___ ___ ___ - ___ ___ ___

Patient Initials: ___ ___ ___

Please complete the following information post-transplant

Date of heart transplant: _____/_____/_____ HTPDT

HTPFORM T=3

Please fax this form to the Data Coordinating Center at Duke

Coordinator Signature:_____ Date: _____/_____/_____

SHSIG

Sudden Cardiac Death

SCDHeFT

Heart Failure Tri l

Vital Status Summary Form

This form is to be used to assess the vital status of patients for which there is no current vital status information. All dates should be in MM/DD/YYYY format.

Site #: ___ ___ ___

Patient Study #: ___ ___ ___ - ___ ___ ___

Patient Initials: ___ ___ ___

Please assess the following information

Is the patient alive:

PTALIVE<SCUNK>

VSTATDT

❑ No Date of death: _____/_____/_____

❑ Yes Date last known alive: _____/_____/_____

❑ Unknown Date last known alive: _____/_____/_____

VSTATUS T=3

Please fax this form to the Data Coordinating Center at Duke at (919) 668-7100

Coordinator Signature:_____ Date: _____/_____/_____

SHSIG

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO ____ <V:10> Date of Contact: ____/____/VISDT
mo day yr

Sudden Cardiac Death

SCD HeFT

Heart Failure Trial

Follow-up Form

This form is to be completed at all scheduled and unscheduled visits.

Is this patient alive? FUSTAT <ZYESNO>

0 ☐ No ➔ If **No**, fax **NOTIFICATION OF PATIENT DEATH FORM** within 24 hours of notification. Submit **DEATH REPORT FORM** and provide complete medical report within 1 month. Do not proceed with this Follow-up Form.

1 ☐ Yes ➔ If **Yes**, complete this form based on any clinical changes between the last contact date and today.

TYPE=3

TYPE OF VISIT

FUVIS

FVISTYP<SCVTYP> 1 ☐ Unscheduled 2 ☐ Scheduled

Check follow-up interval below if visit is scheduled: FVIS (codelist name=<scvisi>)

1 ☐ 1 week 2 ☐ 1 mo. 3 ☐ 3 mo. 4 ☐ 6 mo. 5 ☐ 9 mo. 6 ☐ 12 mo. 7 ☐ 15 mo.
8 ☐ 18 mo. 9 ☐ 21 mo. 10 ☐ 24 mo. 11 ☐ 27 mo. 12 ☐ 30 mo. 13 ☐ 33 mo. 14 ☐ 36 mo.
15 ☐ 39 mo. 16 ☐ 42 mo. 17 ☐ 45 mo. 18 ☐ 48 mo. 19 ☐ 51 mo. 20 ☐ 54 mo. 21 ☐ 57 mo.
22 ☐ 60 mo. 24 ☐ 66 mo. 26 ☐ 72 mo.

INTERVAL MEDICAL HISTORY

GMED TYPE=3 (See baseline CRF p. 1)

	No	Yes
Pulmonary disease MPULM<ZYESNO>	0 ☐	1 ☐
Hepatitis MHEPA<ZYESNO>	0 ☐	1 ☐
Tremor MTREM<ZYESNO>	0 ☐	1 ☐
Ataxia MATAX<ZYESNO>	0 ☐	1 ☐
Optic neuritis MOPTIC<ZYESNO>	0 ☐	1 ☐

INTERVAL CARDIOVASCULAR SYMPTOMS

CARDSYMP TYPE=3

	No	Yes
Exertional angina EANG<ZYESNO>	0 ☐	1 ☐
Rest angina RANG<ZYESNO>	0 ☐	1 ☐
Dyspnea at rest RDYSP<ZYESNO>	0 ☐	1 ☐
Dyspnea on exertion EDYSP<ZYESNO>	0 ☐	1 ☐
Paroxysmal nocturnal dyspnea PND <ZYESNO>	0 ☐	1 ☐
Cough COUGH<ZYESNO>	0 ☐	1 ☐
Orthopnea ORTHOP<ZYESNO>	0 ☐	1 ☐
Fatigue FATIG<ZYESNO>	0 ☐	1 ☐
Palpitations PALP<ZYESNO>	0 ☐	1 ☐

Annotation Date = 9/27/02

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO <V:10> Date of Contact: ___/___/VISDT
mo day yr

NYHA CHF CLASS at time of this contact NYHA<SCNYHA>

NYHA TYPE=3

☐ 1	**I**	Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue or dyspnea.
☐ 2	**II**	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes fatigue or dyspnea.
☐ 3	**III**	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue or dyspnea.
☐ 4	**IV**	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure may be present even at rest. If any physical activity is undertaken, symptoms are increased.

HEART TRANSPLANT SINCE LAST CONTACT

FTPLANT TYPE=3

Has this patient received a heart transplant since last contact? FTPLANT<ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**, date : FTPLANTM___/FTPLANTY___ (mo / yr)

ISCHEMIC HEART DISEASE SINCE LAST CONTACT

FUISCH1 TYPE=3

New myocardial infarction? FMI <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**, date of last: FMIM___/FMIY___ (mo / yr)

New coronary bypass graft? FCABG <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**, date of last: FCABGM___/FCABGY___ (mo / yr)

New LV aneurysmectomy or LV reduction surgery? FLVSURG <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**, date of last: FLVSURGM___/FLVSURGY___ (mo / yr)

Catheterization or percutaneous revascularization (PTCA, stent, atherectomy)? FINTV <ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**,
How many catheterizations? FCATHN<I:3>
How many percutaneous revascularizations? FPTCAN<I:3>

FUISCH2 TYPE=4

Complete the following table:

	Procedure	Date (mo/day/yr)
FCATH <ZYES> 1	☐ Cath 1 ☐ PTCA/stent/atherectomy FPTCA<ZYES>	___/___/FINTVDT
	☐ Cath ☐ PTCA/stent/atherectomy	___/___/___
	☐ Cath ☐ PTCA/stent/atherectomy	___/___/___

VALVULAR DISEASE SINCE LAST CONTACT

VALVDZ TYPE=3

New diagnosis of valvular disease? VALVDZ<ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**: ☐ 1 AI VALVAI ☐ 1 AS VALVAS ☐ 1 MR VALVMR ☐ 1 MS VALVMS ☐ 1 TR VALVTR <ZYES>
Date: FVALVDZM___/FVALVDZY___ (mo / yr)

New valvular repair? VALVRP <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**: ☐ 1 AV VALVRPA ☐ 1 MV VALVRPM ☐ 1 TV VALVRPT ☐ 1 PV VALVRPP <ZYES>
Date: FVALVRPM___/FVALVRPY___ (mo / yr)

New valvular replacement? VALVRL <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**: ☐ 1 AV VALVRLA ☐ 1 MV VALVRLM ☐ 1 TV VALVRLT ☐ 1 PV VALVRLP <ZYES>
Date: FVALVRLM___/FVALVRLY___ (mo / yr)

Annotation Date = 9/27/02

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO <V:10> Date of Contact: ____/____/VISDT
mo day yr

VASCULAR DISEASE SINCE LAST CONTACT

New vascular disease? VASC<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**:

new stroke? STROKE <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**, date of last: STROKEM ____/STROKEY (mo/yr)

new transient ischemic attack? TIA <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**, date of last: TIAM / TIAY (mo/yr)

new peripheral arterial embolism? PAEMB <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**, date of last: PAEMBM ____/PAEMBY (mo/yr)

new deep venous thrombosis? DVT <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**, date of last: DVTM / DVTY (mo/yr)

new pulmonary embolism? PULEMB <ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**, date of last: PULEMBM ____/PULEMBY (mo/yr)

TYPE=3 VASCDZ

CARDIAC ARREST SINCE LAST CONTACT

Has this patient had a cardiac arrest since the last contact? FCARDA<ZYESNO> 0 ☐ No 1 ☐ Yes

(Cardiac arrest is defined as a loss of consciousness necessitating CPR and/or transthoracic defibrillation.)

➔ If **Yes:**

Number of cardiac arrests: FCARDAN<I:3>

Date of most recent: ____/____/FCARDADT (mo/day/yr)

Please submit **Cardiac Arrest Survival Form** for each episode that the patient survived 48 hours or more.

TYPE=3 FUCARDA

ARRHYTHMIAS—VT/VF SINCE LAST CONTACT

Has this patient had spontaneous ventricular fibrillation since the last contact? FVFIB<ZYESNO> 0 ☐ No 1 ☐ Yes

Has this patient had spontaneous sustained VT since the last contact (≥30 sec. at >100 bpm)? 0 ☐ No 1 ☐ Yes FSVT<ZYESNO>

➔ If **Yes**, was patient: FSVTSYMP <SCAFSY> 1 ☐ Asymptomatic 2 ☐ Symptomatic

➔ If **Symptomatic:** *(check all that apply)* <ZYES>

- FSVTSYN 1 ☐ Syncope
- FSVTNSYN 1 ☐ Near syncope
- FSVTFAT 1 ☐ Fatigue
- FSVTDYSP 1 ☐ Dyspnea
- FSVTPALP 1 ☐ Palpitations
- FSVTANG 1 ☐ Angina

Was this patient cardioverted out of VT since the last contact? FSVTCARD <ZYESNO> 0 ☐ No 1 ☐ Yes

Was an ablation for VT done since the last contact? FSVTABL <ZYESNO> 0 ☐ No 1 ☐ Yes

TYPE=3 FVTVF

Annotation Date = 9/27/02

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO ____ <V:10> Date of Contact: ____/____/VISDT
mo day yr

ATRIAL FIBRILLATION/FLUTTER SINCE LAST CONTACT

Has this patient had atrial fibrillation/flutter (AF) since the last contact? AF <ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes,** complete the following:

a. Date of most recent episode: AFM / AFY
mo yr

Permanent AF = completely refractory to cardioversion
Persistent AF = can be successfully cardioverted
Paroxysmal AF = terminates spontaneously

AFTYP <SCAFTY>

b. 1 ☐ Permanent
2 ☐ Persistent
3 ☐ Paroxysmal

AFSYMP <SCAFSY>

c. 1 ☐ Asymptomatic
2 ☐ Symptomatic

➔ If **Symptomatic** with AF, check all symptoms that apply: <ZYES>

AFSYNC 1 ☐ Syncope
AFNSYN 1 ☐ Near syncope
AFFAT 1 ☐ Fatigue
1 ☐ Dyspnea AFDYSP
AFPALP 1 ☐ Palpitations
1 ☐ Angina AFANG

TYPE=3 AFIB1

Has this patient been cardioverted for AF since the last contact? AFCARD <ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, date of last cardioversion: AFCARDM / AFCARDY
mo yr

Was an ablation procedure for AV node interruption for AF done since the last contact? AFAVAB<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, date of last ablation: AFAVABM / AFAVABY
mo yr

Was the ablation procedure successful? 0 ☐ No 1 ☐ Yes AFAVYN<ZYESNO>

Was a curative atrial ablation procedure for atrial **flutter** done since the last contact? AFFLAB<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, date of last ablation: AFFLABM / AFFLABY
mo yr

Was the ablation procedure successful? 0 ☐ No 1 ☐ Yes AFFLYN<ZYESNO>

Was a curative atrial ablation procedure for focal atrial **fibrillation/tachycardia** done since the last contact? AFFTAB<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, date of last ablation: AFFTABM / AFFTABY
mo yr

Was the ablation procedure successful? 0 ☐ No 1 ☐ Yes AFFTYN <ZYESNO>

Was a catheter maze procedure for atrial **fibrillation** done since the last contact? AFFBAB<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, date of last procedure: AFFBABM / AFFBABY
mo yr

Was the procedure successful? 0 ☐ No 1 ☐ Yes AFFBYN<ZYESNO>

TYPE=3 AFIB2

EP STUDY SINCE LAST CONTACT

Has this patient had an EP study since the last contact? 0 ☐ No 1 ☐ Yes
EPSTUDY<ZYESNO>

➔ If **Yes,** did this patient have programmed electrical stimulation (PES) of the ventricle? 0 ☐ No 1 ☐ Yes
PES<ZYESNO>

➔ If **Yes,** complete the following:

Date of most recent PES procedure: PESM / PESY
mo yr

Was this patient inducible into sustained VT/VF (i.e., defib. shock or >30 sec. of VT/VF) 0 ☐ No 1 ☐ Yes
PESIND<ZYESNO>

Reason for EP study: EPREAS <V:200>

EPSTUDY TYPE=3

SYNCOPE SINCE LAST CONTACT

Has this patient had syncope since the last contact? 0 ☐ No 1 ☐ Yes
SYNC<ZYESNO>

➔ If **Yes**, complete the following:

a. Date of most recent syncopal event: SYNCM / SYNCY
mo yr

b. Was a tilt-table test performed? 0 ☐ No 1 ☐ Yes
SYNCTT<ZYESNO>

c. Indicate cause of syncope:
(check one)
SYNCC<SCSYNC>

1 ☐ Cardiac arrest
2 ☐ Vasomotor *(e.g., vasovagal, vasodepressor, etc.)*
3 ☐ Orthostasic hypotension
4 ☐ Drug induced hypotension
5 ☐ Drug induced arrhythmia
6 ☐ Seizures
7 ☐ Other: SYNCCOTH<V:200>

SYNCOPE TYPE=3

NON-SCD-HeFT ICD IMPLANT SINCE LAST CONTACT

Was a non SCD-HeFT protocol ICD implanted in this patient since the last contact? 0 ☐ No 1 ☐ Yes
FNPICD <ZYESNO>

➔ If **Yes**, complete the following:

a. Date of ICD implant: FNPICDM / FNPICDY
mo yr

b. Type of ICD: FNPICDTP <SCIMP> 1 ☐ Single chamber 2 ☐ Dual chamber

c. Reason for ICD implantation:
(check all that apply)
<ZYES>

FNPICDAF 1 ☐ Atrial fibrillation/flutter
FNPICDVF 1 ☐ Ventricular fibrillation
FNPICDVT 1 ☐ Ventricular tachycardia
FNPICDOT 1 ☐ Other: FNPICDO <V:200>

FUNPICD TYPE=3

Annotation Date = 9/27/02

Patient Initials: INITIALS <V:3> Patient Study #: SUBJNO ___ — ___ <V:10> Date of Contact: ___/___/VISDT
mo day yr

PERMANENT PACEMAKER IMPLANT SINCE LAST CONTACT

Was a permanent pacemaker implanted in this patient since the last contact? FPCIMP<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, complete the following:

a. Date of pacemaker implant: FPCIMPM ___ / FPCIMPY ___
mo yr

b. Type of pacemaker: FPCTYPE<SCIMP> 1 ☐ Single chamber 2 ☐ Dual chamber

c. Cause of bradycardia: *(check all that apply)* <ZYES>

FPCIHDBC 1 ☐ Intrinsic heart disease related bradycardia
FPCDIBC 1 ☐ Drug induced bradycardia (non-study drug)
FPCNDIBC 1 ☐ Drug induced bradycardia (study drug)
FPCOT 1 ☐ Other: FPCOTH<V:200>

FUPACE TYPE=3

PHYSICAL EXAM

Weight: PEWGHT lbs. <F:9.3>

Right Arm *(sitting)*: Blood pressure: PESYS / PEDIAS mmHg <F:9.3> Pulse: PEPULSE bpm <F:9.3>

Was jugular venous pressure elevated: 0 ☐ No 1 ☐ Yes 2 ☐ Could not measure PEPRESS<SCNOTM>

➔ If **Yes**, cm above the sternal notch: PESTERN cm <F:9.3>

Rales: PERALES<SCRALE> 1 ☐ None 2 ☐ <1/3 3 ☐ 1/3-2/3 4 ☐ >2/3

Auscultation: S3: PES3 0 ☐ No 1 ☐ Yes <ZYESNO>

MR murmur: PEMR<ZYESNO> 0 ☐ No 1 ☐ Yes ➔ If **Yes**: Grade 1 ☐ 1 2 ☐ 2 3 ☐ 3 4 ☐ 4 5 ☐ 5 6 ☐ 6

Assessment of peripheral edema: PEGRADE<SCGRAD>

LOCATION	Absent	Mild	Moderate	Severe
PEPERA<SCASMT> Right arm	0 ☐	1 ☐	2 ☐	3 ☐
PEPERL<SCASMT> Right leg	0 ☐	1 ☐	2 ☐	3 ☐
PEPELA<SCASMT> Left arm	0 ☐	1 ☐	2 ☐	3 ☐
PEPELL<SCASMT> Left leg	0 ☐	1 ☐	2 ☐	3 ☐

PHYSICAL TYPE=3

6 MINUTE WALK

Complete only for the follow-up visits listed below.

1 ☐ Test not required for this visit WKNOTEST<ZYES>

FWKVISIT
(code list name= <SCVISI>)

4 ☐ 6 month 6 ☐ 12 month 8 ☐ 18 month 10 ☐ 24 month 12 ☐ 30 month
14 ☐ 36 month 16 ☐ 42 month 18 ☐ 48 month 20 ☐ 54 month 22 ☐ 60 month 99 ☐ Unscheduled
24 ☐ 66 mo. 26 ☐ 72 mo.

If this patient is unable to walk due to amputation, stroke, or similar disability, check this box 1 ☐ NOWALK<ZYES>

What is the distance walked in 6 minutes? WALKDIST ft <F:9.3>

(To do the 6 minute walk, choose a measured area, such as around the clinic area or hallway. Clock a time of 6 minutes and measure the distance, in feet, that the patient was able to walk. Do not encourage or otherwise influence the performance of the patient. See the SCD-HeFT Operations Manual for full instructions on how to perform a 6 minute walk.)

During 6 minute walk, was this patient? WALKSYM<SCAFSY> 1 ☐ Asymptomatic 2 ☐ Symptomatic

➔ If **Symptomatic** during the 6 minute walk, check all symptoms that apply:

WKDYSP<ZYES> 1 ☐ Dyspnea
WKANG<ZYES> 1 ☐ Angina
WKSYNC<ZYES> 1 ☐ Syncope
WKNSYNC<ZYES> 1 ☐ Near syncope
WKLGHTHD<ZYES> 1 ☐ Lightheadedness
WKSYMPOT<ZYES> 1 ☐ Other: WKSYMPTX<V:60>

WALK TYPE=3

Annotation Date = 9/27/02

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO ___ <V:10> Date of Contact: ___/___/VISDT
mo day yr

LEFT VENTRICULAR EJECTION FRACTION

Complete only for the follow-up visits listed below.

1 ☐ Test not required for this visit LVNTEST<ZYES>

6 ☐ 12 month 12 ☐ 30 month 99 ☐ Unscheduled FLVVISIT (code list name=<SCVISI>)

Date of EF measurement: ___/___/LVEFDT
mo day yr

What is this patient's ejection fraction? LVEF % <F:9.3>

How was the EF measured? EFMEAS<SCEF>
1 ☐ Nuclear (*preferred*)
2 ☐ Catheterization
3 ☐ Echo

TYPE=3 LVEF

CHEMISTRY PANEL

Complete only for the follow-up visits listed below.

1 ☐ Test not required for this visit FCHNTEST<ZYES>

3 ☐ 3 month 4 ☐ 6 month 6 ☐ 12 month 8 ☐ 18 month 10 ☐ 24 month 12 ☐ 30 month
14 ☐ 36 month 16 ☐ 42 month 18 ☐ 48 month 20 ☐ 54 month 22 ☐ 60 month 99 ☐ Unscheduled
24 ☐ 66 mo. 26 ☐ 72 mo. FUCHEMVS (codelist name=<SCVISI>)

Date obtained: CHDT/___/___
mo day yr

CHNAU<SCCHUA>
Sodium: CHNA<F:9.3> 1 ☐ mEq/L 2 ☐ other units CHNAUO<V:20>

CHKU<SCCHUA>
Potassium: CHK<F:9.3> 1 ☐ mEq/L 2 ☐ other units CHKUO<V:20>

CHMGU<SCCHUA>
Magnesium: CHMG<F:9.3> 1 ☐ mEq/L 2 ☐ other units CHMGUO<V:20>

CHBUNU<SCCHUB>
BUN: CHBUN<F:9.3> 1 ☐ mg/dl 2 ☐ other units CHBUNUO<V:20>

CHCRU<SCCHUB>
Creatinine: CHCREAT<F:9.3> 1 ☐ mg/dl 2 ☐ other units CHCRUO<V:20>

TYPE=3 CHEMIST

THYROID

Complete only for the follow-up visits listed below.

1 ☐ Test not required for this visit FTHNTEST<ZYES>

4 ☐ 6 month 6 ☐ 12 month 8 ☐ 18 month 10 ☐ 24 month 12 ☐ 30 month
14 ☐ 36 month 16 ☐ 42 month 18 ☐ 48 month 20 ☐ 54 month 22 ☐ 60 month 99 ☐ Unscheduled
24 ☐ 66 mo. 26 ☐ 72 mo. FTHVISIT (codelist name = <SCVISI>)

Date obtained: ___/___/THYDT
mo day yr

TSHU<SCTHUT>
TSH: TSH<F:9.3> 1 ☐ µU/ml 2 ☐ other units TSHUO<V:20>

TYPE=3 THYROID

Annotation Date = 9/27/02

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO <V:10> Date of Contact: ___/___/VISDT
mo day yr

$\dot{V}O_2$ MEASUREMENT

Complete only for the follow-up visits listed below.

Note: A $\dot{V}O_2$ measurement is requested, but is not a required test.

1 ☐ Test not requested for this visit FVONTEST <ZYES>

6 ☐ 12 month 12 ☐ 30 month 99 ☐ Unscheduled FVOVISIT (codelist name=<SCVISI>)

Date of $\dot{V}O_2$ measurement VO2M / VO2Y
mo yr

What is the $\dot{V}O_2$? VO2 <F:9.3> ml/kg/min

TYPE=3 VO2

ICD THERAPY SINCE LAST CONTACT

This section should be completed for patients who were randomized to receive ICDs as well as those patients who received a non-SCD-HeFT ICD after they were randomized. If the patient has a non SCD-HeFT ICD, some items in this section will not be applicable, but an effort should be made to complete this section as thoroughly as is possible.

Does this patient have an ICD? 0 ☐ No 1 ☐ Yes
FICD<ZYESNO>

➔ If **No,** go to Page 12

➔ If **Yes**, perform an initial and final interrogation of the ICD and forward ICD Save-to-Disk diskette (electronically or via mail) to the ICD Memory Log Core Laboratory at the University of Washington and keep a second diskette copy of the saved-to-disk interrogations with the patient's records.

Pacing threshold via ICD @ 4V: FICDTHRS ms <F:9.3>

Electrogram (EGM) amplitude measured from ICD programmer hardcopy:

True bipolar *(P-/S to P+/S)* FICDTB<F:9.3> mV @ 1 mV/mm
(baseline-to-peak)

Far-field *(HVA to HVB)* FICDFF<F:9.3> mV @ 1 mV/mm
(baseline-to-peak)

TYPE=3 FUICD1

Since the last contact:

Has this patient perceived being shocked? 0 ☐ No 1 ☐ Yes ➔ If **Yes**, how many times? FICDPN <I:10>
FICDSHKP<ZYESNO>

Has this patient indeed been shocked? 0 ☐ No 1 ☐ Yes ➔ If **Yes**, how many times? FICDIN <I:10>
FICDSHKI<ZYESNO>

➔ If **Yes**, complete the following series of questions

Were the initial and final ICD interrogations of the entire ICD memory saved-to-disk and forwarded (electronically or via mail) to the ICD Memory Log Core Laboratory at the University of Washington? 0 ☐ No 1 ☐ Yes FICDSENT<ZYESNO>

Location of patient when first shocked: FICDLOC<SCSHOC>

1 ☐ Hospital 2 ☐ Work 3 ☐ Home
4 ☐ En route to hospital 5 ☐ Other: FICDLOCO<V:200>

Annotation Date = 9/27/02

ICD THERAPY SINCE LAST CONTACT *(cont.)*

What was the patient's activity at the time of first shock? FICDACTV<SCACT>

1 ☐ Awake, no distress, no exercise 2 ☐ Sleeping 3 ☐ Exercising
4 ☐ Emotional distress 5 ☐ Eating 6 ☐ Sex
7 ☐ Bowel movement 8 ☐ Urination
9 ☐ Other: FICDACTO<V:200>

Did this patient have progressive heart failure within 2 weeks prior to the first shock? FICDHF<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Did this patient have progressive ischemic heart disease within 2 weeks prior to the first shock? FICDHD<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Was VT/VF detected by the ICD? FICDDET<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Was VT/VF treated by the ICD? FICDTRT<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

➔ If **Yes** to either question above, was VT/VF ICD electrogram consistent with:

True VF? FVTVF<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Polymorphic VT? FVPMVT<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Monomorphic VT? FVMOVT<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

➔ If Yes, monomorphic VT cycle length, if known FVMOVTN ms <F:9.3>

Nonsustained VT? FVNSVT<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Sinus tachycardia? FVSTACH<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Atrial fibrillation? FVAFIB<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

Atrial flutter? FVAFL<SCUNK> 0 ☐ No 1 ☐ Yes 2 ☐ Unknown

FVOT<ZYESNO>
Other? FVOTH<V:200> 0 ☐ No 1 ☐ Yes

TYPE=3

FUICD2

Annotation Date = 9/27/02

ICD COMPLICATIONS SINCE LAST CONTACT

Were there any complications of ICD therapy since the last contact?
FCOMPLIC<ZYESNO>

0 ☐ No ➔If **No**, go to Page 12

1 ☐ Yes ➔If **Yes**, check below all that apply and give dates of first occurrence.

FCOMP <SCCOMP>

FUICDC1 TYPE=3

FUICDC2 TYPE=4

		FCOMPM / FCOMPY
1. 1	☐ Pneumothorax, observation only	____/____ mo yr
2. 2	☐ Pneumothorax, chest tube required	____/____ mo yr
3. 3	☐ Pneumothorax, surgical repair required	____/____ mo yr
4. 4	☐ Hemothorax, observation only	____/____ mo yr
5. 5	☐ Hemothorax, chest tube required	____/____ mo yr
6. 6	☐ Hemothorax, surgical repair required	____/____ mo yr
7. 7	☐ ICD pocket hematoma, observation only	____/____ mo yr
8. 8	☐ ICD pocket hematoma requiring change in anticoagulation therapy	____/____ mo yr
9. 9	☐ ICD pocket hematoma requiring hospitalization	____/____ mo yr
10. 10	☐ ICD pocket hematoma requiring needle aspiration	____/____ mo yr
11. 11	☐ ICD pocket hematoma requiring surgical drainage	____/____ mo yr
12. 12	☐ Superficial ICD pocket infection, observation only	____/____ mo yr
13. 13	☐ Superficial ICD pocket infection requiring oral antibiotics	____/____ mo yr
14. 14	☐ Superficial ICD pocket infection requiring IV antibiotics	____/____ mo yr
15. 15	☐ Deep ICD pocket infection requiring oral antibiotics	____/____ mo yr
16. 16	☐ Deep ICD pocket infection requiring IV antibiotics	____/____ mo yr
17. 17	☐ Deep ICD pocket infection requiring pocket revision	____/____ mo yr
18. 18	☐ Deep ICD pocket infection requiring system removal	____/____ mo yr
19. 19	☐ Cardiac perforation, no effusion, observation only	____/____ mo yr
20. 20	☐ Cardiac perforation with effusion, no tamponade	____/____ mo yr

Annotation Date = 9/27/02

ICD COMPLICATIONS SINCE LAST CONTACT *(cont.)*

21.21	☐ Cardiac perforation with tamponade, needle aspirate	____/____ mo yr
22.22	☐ Cardiac perforation with tamponade, surgical drainage	____/____ mo yr
23.23	☐ Minor lead dislodgment requiring observation only	____/____ mo yr
24.24	☐ Minor lead dislodgment requiring generator reprogramming only	____/____ mo yr
25.25	☐ Lead dislodgment requiring lead repositioning	____/____ mo yr
26.26	☐ Lead fracture, no action	____/____ mo yr
27.27	☐ Lead fracture with system revision	____/____ mo yr
28.28	☐ "Twiddler's Syndrome" without surgical intervention	____/____ mo yr
29.29	☐ "Twiddler's Syndrome" with surgical intervention	____/____ mo yr
30.30	☐ ICD migration, observation only	____/____ mo yr
31.31	☐ ICD migration requiring ICD reprogramming only	____/____ mo yr
32.32	☐ ICD migration requiring ICD repositioning	____/____ mo yr
33.33	☐ Impending ICD pocket erosion, observation only	____/____ mo yr
34.34	☐ Impending ICD pocket erosion, leading to ICD pocket revision	____/____ mo yr
35.35	☐ ICD pocket erosion requiring ICD explantation	____/____ mo yr
36.36	☐ Other FCOMPOTH <V:200>	____/____ mo yr

FUICDC2 (continued)

Annotation Date = 9/27/02

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO ___ <V:10> Date of Contact: ___/___/VISDT
mo day yr

CURRENT MEDICATIONS

ACE inhibitor: ACE <ZYESNO> 0 ☐ No 1 ☐ Yes

			<F:9.3>		<V:30>
➔ If **Yes**:	ENAL 1 ☐	enalapril	ENALDS	mg	schedule: ENALSC
	CAPT 1 ☐	captopril	CAPTDS	mg	schedule: CAPTSC
<ZYES>	LISN 1 ☐	lisinopril	LISNDS	mg	schedule: LISNSC
	QUIN 1 ☐	quinapril	QUINDS	mg	schedule: QUINSC
	BENZ 1 ☐	benazepril	BENZDS	mg	schedule: BENZSC
	FOSN 1 ☐	fosinopril	FOSNDS	mg	schedule: FOSNSC
	AOTH 1 ☐	other: ACEOTH<V:60>	AOTHDS	mg	schedule: AOTHSC

MEDS1 TYPE=3

Losartan or other Angiotensin II inhibitor: LOSARTA<ZYESNO> 0 ☐ No 1 ☐ Yes

			<F:9.3>		<V:30>
➔ If **Yes**:	LOSAR 1 ☐	Losartan:	LOSARDS	mg	schedule: LOSARSC
<ZYES>	ANGI 1 ☐	Other: ANGIOTH<V:60>	ANGIDS	mg	schedule: ANGISC

MEDS2 TYPE=3

Digoxin: DIG <ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **Yes**, obtain digoxin level only for the follow-up visits listed below.

1 ☐ Test not required for this visit FDIGNTST<ZYES>

FDIGVIS (codelist name=<SCVISI>)

2 ☐ 1 month 4 ☐ 6 month 6 ☐ 12 month 8 ☐ 18 month 10 ☐ 24 month 12 ☐ 30 month
14 ☐ 36 month 16 ☐ 42 month 18 ☐ 48 month 20 ☐ 54 month 22 ☐ 60 month 99 ☐ Unscheduled
24 ☐ 66 mo. 26 ☐ 72 mo.

Digoxin level: DIGLVL ng/ml <F:9.3> Date level measured: DIGDT/___/___
mo day yr

MEDS3 TYPE=3

Diuretic: LDIUR (loop) <ZYESNO> 0 ☐ No 1 ☐ Yes

			<F:9.3>		<V:30>
➔ If **Yes**:	FURO 1 ☐	furosemide	FURODS	mg	schedule: FUROSC
	BUMT 1 ☐	bumetanide	BUMTDS	mg	schedule: BUMTSC
<ZYES>	TORS 1 ☐	torsemide	TORSDS	mg	schedule: TORSSC
	ETHC 1 ☐	ethacrynic acid	ETHCDS	mg	schedule: ETHCSC
	LDOTH 1 ☐	other: LDIUROT<V:60>	LDOTHDS	mg	schedule: LDOTHSC

MEDS4 TYPE=3

Diuretic: (potassium sparing) PSDIUR<ZYESNO> 0 ☐ No 1 ☐ Yes

			<F:9.3>		<V:30>
➔ If **Yes**:	SPIR 1 ☐	spironolactone	SPIRDS	mg	schedule: SPIRSC
	TRIA 1 ☐	triamterene	TRIADS	mg	schedule: TRIASC
<ZYES>	AMIL 1 ☐	amiloride	AMILDS	mg	schedule: AMILSC
	PSDOTH 1 ☐	other: PSDIURO<V:60>	PSDOTDS	mg	schedule: PSDOTSC

MEDS5 TYPE=3

Diuretic: TDIUR (thiazide) <ZYESNO> 0 ☐ No 1 ☐ Yes

		<F:9.3>		<V:30>
➔ If **Yes**:	name: TDIUROT<V:60>	TDIURDS	mg	schedule: TDIURSC

MEDS6 TYPE=3

Annotation Date = 9/27/02

CURRENT MEDICATIONS *(cont.)*

Refer to the Section 7 of the SCD-HeFT Operations Manual for warfarin test schedule.

Warfarin: WARF <ZYESNO> 0 ☐ No 1 ☐ Yes
➔ If **Yes**: INR: WARFINR<F:9.3> Date most recently measured: WARFDT ___/___/___ mo day yr

MEDS7 TYPE=3

Aspirin: ASA<ZYESNO> 0 ☐ No 1 ☐ Yes
(if taken daily)

MEDS8 TYPE=3

Amlodipine: AMLDP <ZYESNO> 0 ☐ No 1 ☐ Yes
➔ If **Yes**: AMLDPDS mg<F:9.3> schedule: AMLDPSC<V:30>

MEDS9 TYPE=3

Other calcium channel blocker: CBLOCK<ZYESNO> 0 ☐ No 1 ☐ Yes

				<F:9.3>		<V:30>
➔ If **Yes**:	DILT	1 ☐	diltiazem	DILTDS mg	schedule:	DILTSC
<ZYES>	VERA	1 ☐	verapamil	VERADS mg	schedule:	VERASC
	NIFE	1 ☐	nifedipine	NIFEDS mg	schedule:	NIFESC
	CCOTH	1 ☐	other: CBLOCKO<V:60>	CCOTHDS mg	schedule:	CCOTHSC

MEDS10 TYPE=3

Beta blocker: BBLOCK <ZYESNO> 0 ☐ No 1 ☐ Yes

				<F:9.3>		<V:30>
➔ If **Yes**:	ATEN	1 ☐	atenolol	ATENDS mg	schedule:	ATENSC
	CARV	1 ☐	carvedilol	CARVDS mg	schedule:	CARVSC
<ZYES>	METO	1 ☐	metoprolol	METODS mg	schedule:	METOSC
	PROP	1 ☐	propanolol	PROPDS mg	schedule:	PROPSC
	BBOTH	1 ☐	other: BBLOCKO<V:60>	BBOTHDS mg	schedule:	BBOTHSC

MEDS12 TYPE=3

Antiarrhythmic drug other than study drug OANTIAR<ZYESNO> 0 ☐ No 1 ☐ Yes

				<F:9.3>		<V:30>
➔ If **Yes**:	CIA	1 ☐	Class IA *(quinidine, procainamide, disopyramide)*	CIADS mg	schedule:	CIASC
(check all that apply)	CIB	1 ☐	Class IB *(mexiletine)*	CIBDS mg	schedule:	CIBSC
<ZYES>	CIC	1 ☐	Class IC *(propafenone, flecainide)*	CICDS mg	schedule:	CICSC
	AMIO	1 ☐	amiodarone *(open label)*	AMIODS mg	schedule:	AMIOSC

Reason: AMIOREA <V:200>

<ZYES>	SOTL	1 ☐	sotalol	SOTLDS mg	schedule:	SOTLSC
	AAOTH	1 ☐	other: OANTIOT<V:60>	AAOTHDS mg	schedule:	AAOTHSC

➔ If **Yes**: indicate reason: *(check all that apply)*

<ZYES>

ANTISVT	1 ☐	sustained VT	1 ☐	VF	ANTIVF
ANTISYN	1 ☐	syncope	1 ☐	cardiac arrest	ANTICA
ANTIAF	1 ☐	atrial fibrillation	1 ☐	frequent ICD shocks	
ANTIOTH	1 ☐	other: OANTIOR<V:200>			ANTIIS

CURRENT MEDICATIONS *(cont.)*

TYPE=3 MEDS11

Nitrate: NITRATE<ZYESNO>	0 No	1 Yes	
Hydralazine: HYDRAL<ZYESNO>	0 No	1 Yes	
Statins: STATINS<ZYESNO>	0 No	1 Yes	
Other lipid lowering agents:	0 No	1 Yes	LIPIDS<ZYESNO>
Potassium: POTAS<ZYESNO>	0 No	1 Yes	
Magnesium: MAGNES<ZYESNO>	0 No	1 Yes	
Estrogens: ESTROG<ZYESNO>	0 No	1 Yes	
Progesterone: PROGST<ZYESNO>	0 No	1 Yes	
Insulin: INSULIN<ZYESNO>	0 No	1 Yes	
Oral hypoglycemics:	0 No	1 Yes	ORALHYP<ZYESNO>
Thyroid replacement:	0 No	1 Yes	THYRPL<ZYESNO>

NON-SCD-HeFT OUTPATIENT VISITS

TYPE=3 FUOUTPAT

SINCE THE LAST CONTACT, how many non-SCD-HeFT outpatient (office or clinic) visits has the patient made to... List number of visits: (0, 1, 2,...)

...a cardiologist	FCARDION<I:5>
...an internist	FINTERNN<I:5
...a family or general practitioner	FFAMLYN<I:5>
...a heart surgeon	FHEARTN<I:5>
...a psychiatrist or psychologist	FPSYCHN<I:5>
...emergency department (non admission)	FEMERN<I:5>
...home doctor visit	FHOMEDN<I:5>
...home nurse visit	FHOMEN<I:5>
...cardiac rehabilitation program	FREHABN<I:5>
...physical, occupational, or speech therapist	FTHERN<I:5>
...any other medical doctor or medical care facility	FOTHDOCN<I:5>
➔ Specify: FODOCSP <V:200>	
...any other health provider	FOHPROVN<I:5>
➔ Specify: FOHPSP <V:200>	

Annotation Date = 9/27/02

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Follow-up Form
FUHOSPI TYPE=3

INTERVAL HOSPITALIZATION

Has this patient been hospitalized at any time since the DATE OF LAST CONTACT?
FRHOSP <ZYESNO>

0 ☐ No 1 ☐ Yes

➔ If **Yes**, how many times? _____ FRHOSPN<I:4>

Complete resource utilization grid below.

Note: If there were more than three hospitalizations, add additional pages.

FUHOSP2

Hospitalization dates	Hospital/Rehabilitation Institution/Nursing Home (name/location)	Reason for rehospitalization
From: ____ / ____ / FHADMDT (mo / day / yr) To: FHDISCDT ____ / ____ / ____ (mo / day / yr) FHSTILLH<ZYES> 1 ☐ Still hospitalized	Hospital: FHNAME<V:200> City: FHCITY<V:200> State/Prov.: FHSTATE<V:50> Country: FHCOUNTR<V:50>	FHREAS<V:200>
From: ____ / ____ / ____ (mo / day / yr) To: ____ / ____ / ____ (mo / day / yr) ☐ Still hospitalized	Hospital: _____ City: _____ State/Prov.: _____ Country: _____	
From: ____ / ____ / ____ (mo / day / yr) To: ____ / ____ / ____ (mo / day / yr) ☐ Still hospitalized	Hospital: _____ City: _____ State/Prov.: _____ Country: _____	

LIVING WITH HEART FAILURE QUESTIONNAIRE

Instructions for use

1. The following instructions should be given to the patient each time the questionnaire is completed.

   a. Read the introductory paragraph at the top of the questionnaire to the patient.

   b. Read the first question to the patient — “Did your heart failure prevent you from living as you wanted during the past month by causing swelling in your ankles or legs?” Tell the patient, “If you did not have any ankle or leg swelling during the past month you should circle the zero after this question to indicate that swelling was not a problem during the past month.” Explain to the patient that if he or she did have swelling that was caused by a sprained ankle or some other cause that was definitely not related to heart failure he or she should also circle zero. Tell the patient “If you are not sure why you had the swelling or think it was related to your heart condition, then rate how much the swelling prevented you from doing things you wanted to do and from feeling the way you would like to feel.” In other words, how bothersome was the swelling? Show the patient how to use the 1 to 5 scale to indicate how much the swelling affected his or her life during the past month — from very little to very much.

2. Let the patient read and respond to the other questions. The entire questionnaire may be read directly to the patient if one is careful not to influence responses by verbal or physical cues.

3. Check to make sure the patient has responded to each question and that there is only one answer clearly marked for each question.

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO <V:10> Date of Contact: ____/____/VISDT
mo day yr

These questions concern how your heart failure (heart condition) has prevented you from living as you wanted during the last month. The items listed below describe different ways some people are affected. If you are sure an item does not apply to you or is not related to your heart failure then circle 0 (meaning "No") and go on to the next item. If an item does apply to you, then circle the number rating of how much it prevented you from living as you wanted. Remember to think about ONLY THE LAST MONTH.

Did your heart failure prevent you from living as you wanted during the last month by:

		No	Very Little →				Very Much
SWELL	1. causing swelling in your ankles, legs, etc?	0	1	2	3	4	5
WORK	2. making your working around the house or yard difficult?	0	1	2	3	4	5
FRIENDS	3. making your relating to or doing things with your friends difficult?	0	1	2	3	4	5
REST	4. making you sit or lie down to rest during the day?	0	1	2	3	4	5
ENERGY	5. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
DIFF	6. making your working to earn a living difficult?	0	1	2	3	4	5
WALKC	7. making your walking or climbing stairs difficult?	0	1	2	3	4	5
BREATH	8. making you short of breath?	0	1	2	3	4	5
SLEEP	9. making your sleeping well at night difficult?	0	1	2	3	4	5
EAT	10. making you eat less of the foods you like?	0	1	2	3	4	5
AWAY	11. making your going places away from home difficult?	0	1	2	3	4	5
SEX	12. making your sexual activities difficult?	0	1	2	3	4	5
HOBBIE	13. making your recreational pastimes, sports, or hobbies difficult?	0	1	2	3	4	5
REMEM	14. making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
EFFECT	15. giving you side effects from medications?	0	1	2	3	4	5
WORRY	16. making you worry?	0	1	2	3	4	5
DEPRS	17. making you feel depressed?	0	1	2	3	4	5
COST	18. costing you money for medical care?	0	1	2	3	4	5
LOSS	19. making you feel a loss of self-control in your life?	0	1	2	3	4	5
STAY	20. making you stay in a hospital?	0	1	2	3	4	5
BURDEN	21. making you feel you are a burden to your family or friends?	0	1	2	3	4	5
		(0	1	2	3	4	5)

TYPE=3

LWHFQUES

Annotation Date = 9/27/02

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO <V:10> Date of Contact: ___/___/ VISDT
mo day yr

THERAPY COMPLIANCE

Was the patient randomized to ICD therapy? 0 ☐ No 1 ☐ Yes
FICDTHER<ZYESNO>

➔ If **Yes**, answer the following:

1. Has the ICD been replaced? 0 ☐ No 1 ☐ Yes ➔ If **Yes**, submit **ICD Replacement Form**
   FICDREP<ZYESNO>
2. Has the ICD been removed? 0 ☐ No 1 ☐ Yes ➔ If **Yes**, reason: _____
   FICDREM<ZYESNO> FICDREMR<V:200>
3. Has the ICD been revised? 0 ☐ No 1 ☐ Yes ➔ If **Yes**, reason: _____
   FICDREV<ZYESNO> FICDREVR<V:200>

TYPE=3 FUTHERC1

Was the patient randomized to drug therapy? 0 ☐ No 1 ☐ Yes
FDRAND<ZYESNO>

➔ If **Yes**, answer the following:

1. Is the patient still on study drug? 0 ☐ No 1 ☐ Yes ➔ If **No**, reason: _____
   FONDRUG<ZYESNO> FNODRGRS<V:200>

➔ If **Yes**, answer the following:

2. How many tablets had the patient previously been instructed to take each day? 1 ☐ 1 2 ☐ 1½ 3 ☐ 2 4 ☐ other: FTABCNTO <F:9.3>
   FTABCNT<SCTAB>
3. How many tablets did the patient return to clinic today? FTABRTN <F:9.3> tablets 1 ☐ Patient did not bring tablets
   FNOTABS<ZYES>
4. How many bottles of study drug were dispensed today? FBOTTLE <I:3> bottles ➔ Kit #: FKIT_INV<V:5>
5. Will the patient's study drug dosing regimen be changed at this contact? 0 ☐ No 1 ☐ Yes
   FDOSCHG<ZYESNO>

   ➔ If **Yes**, answer the following:

   a. How many tablets will the patient be instructed to take each day? 1 ☐ 1 2 ☐ 1½ 3 ☐ 2 4 ☐ other: FNTABCNO <F:9.3>
      FNTABCNT<SCTAB>

   b. What is the reason for the change?
      FWGHTCHG 1 ☐ Weight change
      FSIDEFF 1 ☐ Side effects: FSIDEFFO<V:200>
      <ZYES>
      FOTHRS 1 ☐ Other: FOTHRSTX<V:200>

TYPE=3 FUTHERC2

Please forward this form to the Data Coordinating Center at Duke.

Coordinator signature: COORDSIG (Yes Only) <ZYES> Date: COORDDT ___/___/___
mo day yr

SHSIG TYPE=4

Annotation Date = 9/27/02

ScdHeft

CODELIST NAME=SCVISI

1 = 1 week
2 = 1 mo.
3 = 3 mo.
4 = 6 mo.
5 = 9 mo.
6 = 12 mo.
7 = 15 mo.
8 = 18 mo.
9 = 21 mo.
10 = 24 mo.
11 = 27 mo.
12 = 30 mo.
13 = 33 mo.
14 = 36 mo.
15 = 39 mo.
16 = 42 mo.
17 = 45 mo.
18 = 48 mo.
19 = 51 mo.
20 = 54 mo.
21 = 57 mo.
22 = 60 mo.
24 = 66 mo.
26 = 72 mo.
30 = Randomization Form
31 = Baseline Case Report Form
32 = ICD Implant Form
33 = Death Report Form
34 = Cardiac Arrest Survival Form
35 = Other

99 = Unscheduled

Annotation Date = 9/27/02

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO <V:10> Date of Randomization ___/___/VISDT
mo day yr

Sudden Cardiac Death

SCD HeFT

Heart Failure Trial

ICD Implant Form

Did the patient leave the procedure with an ICD? ICDPROC<ZYESNO>
0 ☐ No 1 ☐ Yes

➔ If **No**, go to Page 2

ICD GENERATOR & LEAD SYSTEM

ICD Serial Number: ICDSNUM<V:10>
☐☐☐☐☐☐☐☐☐☐

ICD placement ➔ ICDPLACE <SCPLAC>
1 ☐ Sub-cutaneous
2 ☐ Sub-muscular

ICD location ➔ ICDLOC <SCLOC>
1 ☐ Left pectoral
2 ☐ Right pectoral

RV lead Serial Number: ICDRVSNM<V:10>
☐☐☐☐☐☐☐☐☐☐

RV lead insertion site ➔ ICDRVIST<SCRVIS>
1 ☐ Subclavian vein 2 ☐ Axillary vein
3 ☐ Cephalic vein 4 ☐ Internal jugular vein

Other lead Serial Number: *(if used)* ICDOSNUM<V:10>
☐☐☐☐☐☐☐☐☐☐

Other lead insertion site ➔ ICDOTIST<SCOTIS>
1 ☐ Subclavian vein 2 ☐ Subcutaneous patch
3 ☐ Cephalic vein

Other lead location ➔ ICDOTLL<SCOTLL>
1 ☐ Superior Vena Cava 2 ☐ Coronary sinus
3 ☐ Inferior Vena Cava 4 ☐ Subcutaneous patch

Pacing threshold via ICD @ 4V: ICDPACE<F:9.3> ms

Electrogram (EGM) amplitude measured from ICD programmer hardcopy:

True bipolar *(P-/S to P+/S)* ICDEGMTB<F:9.3> mV @ 1 mV/mm
(baseline-to-peak)

Far-field *(HVA to HVB)* ICDEGMFF<F:9.3> mV @ 1 mV/mm
(baseline-to-peak)

TYPE=1

ICDIF1

Patient Initials: ____ ____ ____ Patient Study #: ____ ____ ____—____ ____ ____

ICD PROCEDURE

Where was the procedure performed? *(check one)* ICDPERF <SCPERF>

- 1 ☐ EP Lab
- 2 ☐ Cath Lab
- 3 ☐ Operating room
- 4 ☐ Other: ICDPEROT <V:60>

Who performed the actual surgery of lead and generator placement? *(check one)* ICDWHO<SCWHO>

- 1 ☐ EP physician alone
- 2 ☐ Cardiac surgeon alone
- 3 ☐ Non-cardiac surgeon alone
- 4 ☐ Both EP physician and cardiac surgeon
- 5 ☐ Both EP physician and non-cardiac surgeon
- 6 ☐ Other: ICDWHOOT<V:60>

ANESTHESIA PROVIDER

Who provided anesthesia? *(check all that apply)*

- ICDANES<ZYES> 1 ☐ Anesthesiologist
- ICDNA<ZYES> 1 ☐ Nurse anesthetist
- ICDLN<ZYES> 1 ☐ Cath/EP lab nurse
- ICDLT<ZYES> 1 ☐ Cath/EP lab tech
- ICDANOT<ZYES> 1 ☐ Other: ICDANESO<V:60>

TYPE=1 ICDIF2

ENDOTRACHEAL INTUBATION

Was endotracheal intubation used? ICDENDOT <ZYESNO> 0 ☐ No 1 ☐ Yes

TYPE OF ANESTHESIA

What type of anesthesia was used? *(check all that apply)* <ZYES>

- ICDTYPGN 1 ☐ General anesthesia
- ICDTYPCS 1 ☐ "Conscious sedation"
- ICDTYANO 1 ☐ other: ICDTYPOT<V:60>

ANTIBIOTICS

Was a pre-operative antibiotic administered? 0 ☐ No 1 ☐ Yes ICDPOANT<ZYESNO>

➔ If **Yes**,

- 1 ☐ cefazolin 1gm IV ICDCEFAZ<ZYES>
- 1 ☐ vancomycin 1 gm IV ICDVANCO<ZYES>
- ICDPOAOT<ZYES> 1 ☐ other: ICDPOATX<V:30>

Was a post-operative antibiotic administered? 0 ☐ No 1 ☐ Yes ICDPANT<ZYESNO>

➔ If **Yes**,

- 1 ☐ cefazolin 1gm IV ICDPCEFZ<ZYES>
- 1 ☐ vancomycin 1 gm IV ICDPVANC<ZYES>
- ICDPOST <ZYES> 1 ☐ other: ICDPOSTX<V:30>

TYPE=1 ICDIF3

Patient Initials: ____ ____ ____ Patient Study #: ____ ____ ____—____ ____ ____

PROCEDURAL COMPLICATIONS OF ICD IMPLANTATION *(day of implant)*

Were there any complications of ICD implantation? FCOMPLIC <ZYESNO>

0 ☐ No ➔If **No**, go to next section on Page 4 (Duration of Procedure & In-Hospital Time)
1 ☐ Yes ➔If **Yes**, check below all that apply.

FCOMP<SCCOMP>

FUICDC1 TYPE=3

FUICDC2 TYPE=4

41	1. ☐ Death (Please submit **DEATH REPORT FORM**)
42	2. ☐ Unable to defibrillate by ICD at maximum output after all methods tried
43	3. ☐ Unable to place RV lead in heart (no venous access)
1	4. ☐ Pneumothorax, observation only
2	5. ☐ Pneumothorax, chest tube required
3	6. ☐ Pneumothorax, surgical repair required
4	7. ☐ Hemothorax, observation only
5	8. ☐ Hemothorax, chest tube required
6	9. ☐ Hemothorax, surgical repair required
7	10. ☐ ICD pocket hematoma, observation only
8	11. ☐ ICD pocket hematoma requiring change in anticoagulation therapy
9	12. ☐ ICD pocket hematoma requiring hospitalization
10	13. ☐ ICD pocket hematoma requiring needle aspiration
11	14. ☐ ICD pocket hematoma requiring surgical drainage
12	15. ☐ Superficial ICD pocket infection, observation only
13	16. ☐ Superficial ICD pocket infection requiring oral antibiotics
14	17. ☐ Superficial ICD pocket infection requiring IV antibiotics
15	18. ☐ Deep ICD pocket infection requiring oral antibiotics
16	19. ☐ Deep ICD pocket infection requiring IV antibiotics
17	20. ☐ Deep ICD pocket infection requiring ICD pocket revision
18	21. ☐ Deep ICD pocket infection requiring ICD system removal
40	22. ☐ Bleeding requiring blood transfusion or major surgical intervention
19	23. ☐ Cardiac perforation, no effusion, observation only
20	24. ☐ Cardiac perforation with effusion, no tamponade
21	25. ☐ Cardiac perforation with tamponade, needle aspirate
22	26. ☐ Cardiac perforation with tamponade, surgical drainage

Patient Initials: ____ ____ ____ Patient Study #: ____ ____ ____—____ ____ ____

PROCEDURAL COMPLICATIONS OF ICD IMPLANTATION *(cont.)*

Check all that apply if there were any complications of ICD implantation.

23 27. ☐ Minor lead dislodgment, observation only

24 28. ☐ Minor lead dislodgment requiring ICD reprogramming only

25 29. ☐ Lead dislodgment requiring lead repositioning

30 30. ☐ ICD migration, observation only

31 31. ☐ ICD migration requiring ICD reprogramming only

32 32. ☐ ICD migration requiring ICD repositioning

33 33. ☐ Impending ICD pocket erosion, observation only

34 34. ☐ Impending ICD pocket erosion requiring ICD pocket revision

37 35. ☐ Exacerbation of CHF not requiring hospitalization

38 36. ☐ Exacerbation of CHF requiring hospitalization

39 37. ☐ Any complication requiring hospitalization or prolonging hospital stay

36 38. ☐ Other: FCOMPOTH <V:200>

FUICDC2 (continued)

DURATION OF PROCEDURE & IN-HOSPITAL TIME *(use 24 hour clock)*

Time of hospital entry: ICDHOSTM :____ on date: ICDHOSDT ____/____/____ *mo day yr*

Time in to procedure/operating room: ICDOPTM :____ on date: ICDOPDT ____/____/____ *mo day yr*

Time of incision: ICDINCTM :____

Time of incision closure: ICDNCLTM :____

Time out of procedure/operating room: ICDOUTTM :____

all times use ICDOPDT as the date

Time of hospital discharge: ICDHDSTM :____ on date: ICDHDSDT ____/____/____ *mo day yr*

TYPE=1

ICDIF6

Please forward this form to the Data Coordinating Center at Duke.

Coordinator signature: _____ Date: ____/____/____ *mo day yr*

SHSIG

Sudden Cardiac Death

SCD HeFT

Heart Failure Trial

Missed Visit Notification Form

If the patient has missed a scheduled visit and it will not be made up in that scheduling interval, please complete this form.

Patient Study Number: STUDYNO ____ — <V:10> ____

Patient Initials: PATINIT<V:3>

Check follow-up visit that was missed: *(check one box only)* MISVIS <SCVISI>

1 ☐ 1 week	2 ☐ 1 mo.	3 ☐ 3 mo.	4 ☐ 6 mo.	5 ☐ 9 mo.	6 ☐ 12 mo.	7 ☐ 15 mo.
8 ☐ 18 mo.	9 ☐ 21 mo.	10 ☐ 24 mo.	11 ☐ 27 mo.	12 ☐ 30 mo.	13 ☐ 33 mo.	14 ☐ 36 mo.
15 ☐ 39 mo.	16 ☐ 42 mo.	17 ☐ 45 mo.	18 ☐ 48 mo.	19 ☐ 51 mo.	20 ☐ 54 mo.	21 ☐ 57 mo.
22 ☐ 60 mo.	24 ☐ 66 mo.	26 ☐ 72 mo.				

Please provide reason for no scheduled visit: MISVISRS<V:200>

MISVISIT TYPE=2

MISSREAS TYPE=4

Please FAX this form to the Data Coordinating Center at Duke.

Coordinator signature: _____ Date: ____/____/____ *mo day yr*

SHSIG

Annotation Date = 9/27/02

Sudden Cardiac Death

SCD HeFT

Heart Failure Trial

Patient Discontinuation Form

<SCPTDS>

Patient Study Number: STUDYNO ____ — <V:10> ____

Patient Initials: PATINIT <V:3>

Why is this patient no longer in the study? *(check one)*

PTDSCRSN

1 ☐ Consent withdrawn after randomization but prior to treatment. Date: PTDSCDT _____/_____/_____ (mo / day / yr)

2 ☐ Consent withdrawn during follow-up. Date: _____/_____/_____ (mo / day / yr)

3 ☐ Patient lost to follow-up. Date patient last known alive: _____/_____/_____ (mo / day / yr)

Please attach documentation of events leading up to patient discontinuation and provide a detailed description of all efforts made to contact patient.

TYPE=2

PATDISC

Please forward this form to the Data Coordinating Center at Duke.

Coordinator signature: _____ Date: _____/_____/_____ (mo / day / yr)

SHSIG

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO <V:10>

Sudden Cardiac Death

SCD HeFT

Heart Failure Trial

Randomization Form

Thank you for considering a patient for enrollment in SCD-HeFT. If this patient meets the enrollment criteria and has signed the informed consent form, obtain a 12-lead ECG and answer the following questions. FAX this form to the Data Coordinating Center at Duke within 2 working days of randomization.

Enrolling Center Name: RCENTER <V:200>

Patient Initials: RPATINIT <V:3>

Randomization Date: RRANDDT _____/_____/_____ (mo / day / yr)

RGENDER <ZSEX>
Gender: 1 ☐ Male 2 ☐ Female

Date of Birth: RDOB _____/_____/_____ (mo / day / yr)

Weight: RWEIGHT lbs.<F:9.3>

Race: RACE <SCRACE>
5 ☐ Asian 2 ☐ African American
4 ☐ Latin American 3 ☐ Native American
1 ☐ Caucasian 6 ☐ Pacific Islander

TYPE=1

INCLUSION CRITERIA

1. Has this patient had a diagnosis of CHF for at least 3 months prior to the day of randomization? INCL1<ZYESNO> 0 ☐ No 1 ☐ Yes

2. Does this patient have NYHA CHF Class II or Class III on date of randomization as defined below? INCL2<ZYESNO> 0 ☐ No 1 ☐ Yes

I Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue or dyspnea.

(This NYHA class is not eligible for enrollment.)

II Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes fatigue or dyspnea.

III Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue or dyspnea.

IV Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure may be present even at rest. If any physical activity is undertaken, symptoms are increased.

(This NYHA class is not eligible for enrollment.)

RDEMOG

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO <V:10>

INCLUSION CRITERIA *(cont.)*

	No	Yes	N/A
3. Is this patient's LVEF ≤ 35%, as measured within last 6 months? Date of EF measurement: REFMESDT _____/_____/_____ (mo / day / yr) INCL3 <ZYESNO> What is this patient's ejection fraction? REJFR _____ % <F:9.3> How was the EF measured? REFMEAS <SCEF> 1 ☐ Nuclear (*preferred*) 2 ☐ Catheterization 3 ☐ Echo	0 ☐	1 ☐	
4. Has this patient had a coronary angiogram? INCL4 <ZYESNO> RCATHDT	0	1	Not Required
5. Has this patient been on ACE Inhibitor therapy prior to randomization? INCL5 <ZYESNO> *ACE I is required unless the patient is intolerant to the drug. Nitrates and hydralazine, and angiotensin II receptor blockers, have not been proven to be of similar value, and should only be used if the patient is absolutely intolerant to ACE I. Appropriate ACE I dosing (e.g., enalapril 10 mg BID) should be attempted ultimately either before or shortly after randomization.*	0 ☐	1 ☐	
6. If this patient has chronic atrial fibrillation, has he/she been consistently anticoagulated at an INR ≥ 2.0 for at least 21 days prior to randomization? INCL6<SCNA>	0 ☐	1 ☐	2 ☐
7. If female, is this patient post-menopausal, surgically sterile **or** using adequate contraception and has a negative serum pregnancy test within 1 week prior to randomization and has no intentions of becoming pregnant? INCL7<SCNA>	0 ☐	1 ☐	2 ☐
8. Has this patient performed a 6 minute walk at the time of randomization? *(If this patient is unable to walk due to amputation, stroke, or other disability, then check N/A.)* INCL8<SCNA>	0 ☐	1 ☐	2 ☐
9. Has this patient had a 24 hour Holter recording within 1 week prior to randomization? **DO NOT READ HOLTER!** Forward Holter recording using supplied envelope to the Data Coordinating Center at Duke. INCL9<ZYESNO>	0 ☐	1 ☐	
10. Has a 12-lead ECG been obtained for this patient on the day of randomization? Submit a copy of the baseline 12-lead ECG that was obtained on the day of randomization to the Data Coordinating Center at Duke. INCL10<ZYESNO>	0 ☐	1 ☐	

RINCL1 TYPE=1

RINCL2 TYPE=1

If the answer to any question above is No,
then this patient is *CURRENTLY INELIGIBLE* for this study.

Patient Initials: ___ ___ ___ Patient Study #: ___ ___ ___ ___ ___ ___ ___

EXCLUSION CRITERIA

	No	Yes
1. Has this patient had a cardiac arrest or a spontaneous episode of sustained ventricular tachycardia (≥30 sec) not associated with an acute Q-wave MI? EXCL1<ZYESNO>	0 ☐	1 ☐
2. Does this patient have surgically correctable valvular heart disease; inoperable obstructive valvular heart disease; constrictive, restrictive, infiltrative, and/or hypertrophic cardiomyopathy; acute myocarditis; and/or congenital heart disease? EXCL2<ZYESNO>	0 ☐	1 ☐
3. Is this patient younger than 18 years of age? EXCL3<ZYESNO>	0 ☐	1 ☐
4. Is this patient likely to die from any non-cardiac cause within 12 months? EXCL4<ZYESNO>	0 ☐	1 ☐
5. Is this patient likely to receive a heart transplant within 12 months? EXCL5<ZYESNO>	0 ☐	1 ☐
6. Does this patient have a history of a major psychiatric disorder, active drug/alcohol abuse, or non-compliance? EXCL6<ZYESNO>	0 ☐	1 ☐
7. Is amiodarone contraindicated for any reason? EXCL7<ZYESNO>	0 ☐	1 ☐
8. Is this patient currently taking amiodarone? EXCL8<ZYESNO>	0 ☐	1 ☐
9. Does this patient require antiarrhythmic drug therapy (Class I or III) for any arrhythmia? EXCL9<ZYESNO> *(calcium channel blockers, beta blockers, and digoxin are allowed)*	0 ☐	1 ☐
10. Does this patient require catheter ablation of the AV conduction system to control atrial fibrillation? EXCL10<ZYESNO>	0 ☐	1 ☐
11. Is there new onset AF on today's 12-lead ECG? EXCL11<ZYESNO>	0 ☐	1 ☐
12. Does this patient have a pacemaker? EXCL12<ZYESNO>	0 ☐	1 ☐
13. Does this patient have a history of unexplained syncope within the last 5 years? EXCL13<ZYESNO>	0 ☐	1 ☐
14. Is this patient unable to accommodate ICD placement in the left infraclavicular region? EXCL14<ZYESNO>	0 ☐	1 ☐
15. Has this patient had a myocardial infarction, unstable angina, PTCA, CABG or CVA within the last 30 days? EXCL15<ZYESNO>	0 ☐	1 ☐
16. Does this patient have a mechanical heart valve? EXCL16<ZYESNO>	0 ☐	1 ☐
17. Does this patient have liver function tests ≥ 2.5 times normal or a serum creatinine >2.5 mg/dl at the time of randomization? EXCL17<ZYESNO>	0 ☐	1 ☐
18. Is this patient currently enrolled in another investigational study? EXCL18<ZYESNO>	0 ☐	1 ☐
19. Is this patient currently receiving antibiotics? EXCL19<ZYESNO>	0 ☐	1 ☐
20. Is this patient unable to give informed consent? EXCL20<ZYESNO>	0 ☐	1 ☐

REXCL1 TYPE=1

REXCL2 TYPE=1

If the answer to any question above is Yes, then this patient is *CURRENTLY INELIGIBLE* for this study.

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO <V:10>

ENROLLMENT DATA

RENROLL TYPE=1

1. What is the cause of this patient's heart failure? RHFCAUSE<SCHFCA>

1 ☐ Non-ischemic cardiomyopathy **OR** 2 ☐ Ischemic cardiomyopathy

Ischemic cardiomyopathy is defined as:
1) ≥ 75% luminal narrowing in one or more major coronary arteries or ≥ 50% in the left main coronary artery
—OR—
2) insignificant CAD with definitive evidence of MI (e.g., ruptured plaque, acute thrombosis on modest plaque.)

2. When was this patient's CHF first diagnosed? RFDCHFM / RFDCHFY
mo *yr*

3. What is this patient's NYHA CHF functional class on the day of randomization?

RNYHA <SCNYHA> 2 ☐ II **OR** 3 ☐ III

WALK TYPE=3 (see follow-up p. 6)

4. What is the distance this patient walked in 6 minutes? WALKDIST ft <F:9.3>

If this patient is unable to walk due to amputation, stroke, or similar disability, check this box ☐1
NOWALK<ZYES>

(To do the 6 minute walk, choose a measured area, such as around the clinic area or hallway. Clock a time of 6 minutes and measure the distance, in feet, that the patient was able to walk. Do not encourage or otherwise influence the patient's performance. See the SCD-HeFT Operations Manual for full instructions on how to perform a 6 minute walk.)

WALKSYM <SCAFSY>
During 6 minute walk, was this patient? 1 ☐ Asymptomatic 2 ☐ Symptomatic

➔ If **Symptomatic** during the 6 minute walk, check all symptoms that apply:

WKDYSP <ZYES> 1☐ Dyspnea
WKANG <ZYES> 1☐ Angina
WKSYNC <ZYES> 1☐ Syncope
WKNSYNC <ZYES> 1☐ Near syncope
WKLGHTHD <ZYES> 1☐ Lightheadedness
WKSYMPOT <ZYES> 1☐ Other: WKSYMPTX <V:60>

Patient Initials: INITIALS<V:3> Patient Study #: SUBJNO <V:10>

Before you call the randomization hotline:

(1) Make certain that this patient has given written informed consent.
(2) Have this patient's completed **Randomization Form** on hand.
(3) Know your SCD-HeFT site name and number.
(4) Be prepared to start therapy within 3 working days.

RANDOMIZATION

Dial the Randomization Hotline at Duke anytime (24 hours/day, 365 days/year)

(800) 545-3853

You will be given the patient's Study ID # and treatment assignment over the telephone.

Fill in the following information AFTER the patient has been randomized.

1. PATIENT STUDY NUMBER: STUDYNO <V:10>

2. TREATMENT ASSIGNMENT: *(check Drug Therapy or ICD Therapy)*

2 ☐ **Drug Therapy**

If this patient was assigned to receive drug therapy,
the starting study drug kit # is: BKIT_INV <V:5>

BTX <SCBTX> Date study medication scheduled to start: BDRUGDT _____/_____/_____
mo day yr

(Start study drug within 3 working days from randomization)

1 ☐ **ICD Therapy**

Date implant scheduled: _____/_____/ BIMPLDT
mo day yr

(Implant ICD within 3 working days from randomization)

- Please FAX all pages of this form to the Data Coordinating Center at Duke.
- Complete the **Baseline Case Report Form**, the **ICD Implant Form** for patients receiving an ICD, and the **EQOL Baseline Questionnaire & Summary Forms.**

Coordinator signature: _____ Date: _____/_____/_____
mo day yr

BCRREV TYPE=3 (see CRF pg 11)

SHSIG

Sudden Cardiac Death

SCD HeFT

Heart Failure Trial

Supplemental Medication Form Regarding Beta Blocker Therapy

Complete this form at the baseline visit and every 12 months thereafter.

Patient Study Number: ____ ____ ____ — ____ ____ ____ STUDYNO<V:10>

Patient Initials: ____ ____ ____ PATINIT<V:3>

Date of visit: ____/____/____ BBVISDT
mo day yr

Patient visit: *(check one box only)* BBVIS<SCVISI>

31 ☐ Baseline 6 ☐ 12 month 10 ☐ 24 month 14 ☐ 36 month 18 ☐ 48 month 22 ☐ 60 month 26 ☐ 72 month

35 ☐ Other: BBOVIS<V:60> _____ (*specify*)

Is this patient currently taking a beta blocker? TBETABL<ZYESNO> 0 ☐ No 1 ☐ Yes

➔ If **No,** indicate reason patient is not taking a beta blocker: *(check all that apply)*

BBBRADY 1 ☐ Bradycardia <ZYES>
BBLUNGDZ 1 ☐ Lung disease
BBPVD 1 ☐ Peripheral vascular disease
BBDIAB 1 ☐ Diabetes
BBEXHF 1 ☐ Concern about exacerbating heart failure
BBINTOL 1 ☐ Previously intolerant to beta blocker
1 ☐ Do not use routinely in CHF BBNOUSE
BBOREAS 1 ☐ Other: BBOREAST<V:200> _____

SBETABL TYPE=3

Please forward this form with the Baseline Case Report Form or Follow-up Form to the Data Coordinating Center at Duke.

Coordinator signature: _____ Date: ____/____/____
mo day yr

SHSIG

Annotation Date = 9/27/02