PROTOCOL = STICH
STUDY BOOK = STICH

ENROLL_DATA POPULATED BY
CTSITEPROC.RANDO_ENROLL

RANDO_ENROLL.DCRI_DATE_TIME=
ENROLL_DATA.ENROLLDT

STICH

Initial Evaluation

NODATA<I:3><ZYES>

Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___   Patient's Initials: ___ ___ ___

Demographics and Vital Signs

ENROLL.ENROLLDT

1. Date of birth: DOBD /DOBM / DOBY ___ DOBDT
   day / month / year

2. Sex: ☐₁ Male   ☐₂ Female   GENDER<ZSEX><I:3>

3. Weight: WEIGHT <F:9:3> ___ ☐₁ lb ☐₂ kg <ZWGTU>   WTUNTS<I:3>

4. Height: HEIGHT<F:9:3> ___ ☐₁ in ☐₂ cm <ZHGTU>   HTUNTS<I:3>

5. Blood pressure: ___ / ___ mm Hg   BPSYS<I:3> BPDIA<I:3>
   systolic / diastolic

6. Pulse: ___ ___ ___ bpm PULSE<I:3>

7. Current status: ☐₁ Outpatient ☐₂ Inpatient   CURSTAT<STSTAT><I:3>

DEMOG (TYPE 1)

8. Ethnicity (check only one): ☐₁ Hispanic or Latino ☐₂ Not Hispanic or Latino
   ETHNIC<STETHC><I:3>

9. Race (check all that apply): <ZYES><I:3>
   ☐ American Indian or Alaska Native AMINRACE
   ☐ Asian ASINRACE
   ☐ Black or African American BLKARACE
   ☐ Native Hawaiian or other Pacific Islander NHPIRACE
   ☐ White WHTRACE
   ☐ Other OTHRACE

COUNTRY_GRP (1=U.S.; 2=Europe; 3=Other)

Medical History

MEDHIST (TYPE 1)

1. Current Canadian Cardiovascular Society (CCS) angina class (check only one): ☐ No angina ☐₁ I ☐₂ II ☐₃ III ☐₄ IV
   CCSANG<STCCSC><I:3>

2. Current NYHA heart failure class (check only one): ☐₁ I ☐₂ II ☐₃ III ☐₄ IV   CURRNYHA<ZCLASS><I:3>

Record patient history by checking "No" or "Yes" for each condition listed.   <YESNO><I:3>

3. Atrial flutter/fibrillation: AFLAFIB ☐₀ No ☐₁ Yes
4. Cancer (excluding skin cancer) within the last 5 years: CANCER ☐₀ No ☐₁ Yes
5. Chronic renal insufficiency (creatinine > 1.5): CRI ☐₀ No ☐₁ Yes
6. Current smoker: CURRSMOK ☐₀ No ☐₁ Yes
7. Depression: DEPRESS ☐₀ No ☐₁ Yes
8. Diabetes: DIABETES ☐₀ No ☐₁ Yes

9. Hyperlipidemia: HYPERLIP ☐₀ No ☐₁ Yes
10. Hypertension: HYPERTEN ☐₀ No ☐₁ Yes
11. Peripheral vascular disease: PVD ☐₀ No ☐₁ Yes
12. Myocardial infarction: MI ☐₀ No ☐₁ Yes
13. Stroke: STROKE ☐₀ No ☐₁ Yes

Procedure History

PROCHIST (TYPE 1)

Check all procedures that occurred prior to initial evaluation: <ZYES><I:3>

☐ PCI ☐ Mitral valve repair or replacement ☐ Pacemaker for heart rate ☐ Pacemaker for resynchronization ☐ ICD
PCI   MVRRE   PACEKHRT   PACESYN   ICD

Current Medications

MEDS (TYPE 4) PS

Check "No" or "Yes" for all medications the patient was taking at the time of initial evaluation.
MEDTYPE<STMEDS><I:3>   MEDTAKEN<ZYESNO><I:3>

1. ACE inhibitor: ☐₀ No ☐₁ Yes
2. Amiodarone: ☐₀ No ☐₁ Yes
3. Angiotensin receptor blocker: ☐₀ No ☐₁ Yes
4. Antiarrhythmic (not amiodarone): ☐₀ No ☐₁ Yes
5. Antidepressant: ☐₀ No ☐₁ Yes
6. Aspirin (daily): ☐₀ No ☐₁ Yes
7. Beta blocker: ☐₀ No ☐₁ Yes
8. Clopidogrel: ☐₀ No ☐₁ Yes
9. Digoxin: ☐₀ No ☐₁ Yes

10. Diuretic (loop/thiazide): ☐₀ No ☐₁ Yes
11. Diuretic (potassium sparing): ☐₀ No ☐₁ Yes
12. Insulin: ☐₀ No ☐₁ Yes
13. Nitrate: ☐₀ No ☐₁ Yes
14. NSAID: ☐₀ No ☐₁ Yes
15. Oral diabetic agent: ☐₀ No ☐₁ Yes
16. Statin: ☐₀ No ☐₁ Yes
17. Thyroid replacement therapy: ☐₀ No ☐₁ Yes
18. Warfarin: ☐₀ No ☐₁ Yes

Laboratory Studies

LABS (TYPE 2) PS

LABVAL<F:9:3>   LABUNTS<STLBUT><I:3>   LABTYPE<STLAB><I:3>

1. Hemoglobin: _____ ☐₆ g/dL ☐₁ g/L ☐₂ mmol/L
2. Creatinine: _____ ☐₃ mg/dL ☐₄ µmol/L

3. Sodium: _____ ☐₅ mEq/L ☐₂ mmol/L
4. BUN: _____ ☐₃ mg/dL ☐₂ mmol/L

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___   Patient's Initials: ___ ___ ___

Qualifying Heart Failure Classification

Highest NYHA heart failure class within prior 3 months *(check only one)*: ☐ II   ☐ III   ☐ IV   ☐ IV   **CARDCATH (TYPE 1)**

HIGHNYHA<ZCLASS><I:3>

Cardiac Catheterization

1. Date performed: CATHD ___ / CATHM ___ / CATHY ___ ___   CATHDT
day / month / year

Maximum % stenosis: **<STMAXS><I:3>**

2. LM: MAXSLM   1 ☐ 0-24%   2 ☐ 25-49%   3 ☐ 50-74%   4 ☐ 75-94%   5 ☐ 95-100%

3. Proximal LAD: MAXSPLAD   ☐ 0-24%   ☐ 25-49%   ☐ 50-74%   ☐ 75-94%   ☐ 95-100%

4. Distal LAD: MAXSDLAD   ☐ 0-24%   ☐ 25-49%   ☐ 50-74%   ☐ 75-94%   ☐ 95-100%

5. LCX: MAXSLCX   ☐ 0-24%   ☐ 25-49%   ☐ 50-74%   ☐ 75-94%   ☐ 95-100%

6. RCA: MAXSRCA   ☐ 0-24%   ☐ 25-49%   ☐ 50-74%   ☐ 75-94%   ☐ 95-100%

7. Prior CABG? PRORCABG<ZYESNO><I:3>   **GRAFTST (TYPE 1)**

0 ☐ No

1 ☐ Yes → If Yes, complete bypass graft status:

Territory	Branch Done <ZYES><I:3> *(check all that apply)*	Conduit Used <ZYES><I:3>			Angiographic Findings <STANGO><I:3>		
LAD	☐ Major LDMAJ	☐ Vein LDMAJV	☐ IMA LDMJIMA	☐ Other artery LDMJOTH 1	☐ Patent LDMJANG	☐ Stenosed 3	☐ Occluded
	☐ Minor LDMIN	☐ Vein LDMINV	☐ IMA LDMNIMA	☐ Other artery LDMNOTH	☐ Patent	☐ Stenosed	☐ Occluded LDMNANG
LCX	☐ Major LXMAJ	☐ Vein LXMAJV	☐ IMA LXMJIMA	☐ Other artery LXMJOTH	☐ Patent LXMJANG	☐ Stenosed	☐ Occluded
	☐ Minor LXMIN	☐ Vein LXMINV	☐ IMA LXMNIMA	☐ Other artery LXMNOTH	☐ Patent	☐ Stenosed	☐ Occluded LXMNANG
RCA	☐ Major RCMAJ	☐ Vein RCMAJV	☐ IMA RCMJIMA	☐ Other artery RCMJOTH	☐ Patent RCMJANG	☐ Stenosed	☐ Occluded
	☐ Minor RCMIN	☐ Vein RCMINV	☐ IMA RCMNIMA	☐ Other artery RCMNOTH	☐ Patent	☐ Stenosed	☐ Occluded RCMNANG

STICH_Annotation (15DEC2004) Version 8.0

MITREG<STMIRG><I:3>
8. Mitral regurgitation? ☐ 0 None or trace   ☐ 1 Mild (≤ 2+)   ☐ 2 Moderate (3+)   ☐ 3 Severe (4+)   ☐ 4 Not assessed

LV Dysfunction Documentation Studies

1. Were any of the following tests performed within 3 months prior to the initial evaluation? *(check "No" or "Yes" for each)*   **LVD (TYPE 1)**

<ZYESNO><I:3>

Dobutamine echocardiogram: ☐ 0 No   ☐ 1 Yes DOBUECHO

Exercise/pharmacologic perfusion study: ☐ 0 No   ☐ 1 Yes EPPSTDY

Radionuclide viability test: ☐ 0 No   ☐ 1 Yes RADIOVT

2. LV study qualifying patient for randomization *(check only one)*: LVSTQUAL<STLVQL><I:3>

☐ 1 Echocardiogram   ☐ 2 CMR ventriculogram   ☐ 3 Contrast ventriculogram   ☐ 4 Gated SPECT ventriculogram

3. Date of qualifying study: QUALD ___ / QUALM ___ / QUALY ___ ___   QUALDT
day / month / year

4. LVEF: LVEF<F:9:3> . ___ ___

5. ESVI: ESVI<I:3> ___ mL/m²

6. Anterior akinesia/dyskinesia: ___ % ANTERIOR<I:3>

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

Initial Evaluation

Site Number: ___ ___ ___ ___ Patient Number: ___ ___ ___ ___ Patient's Initials: ___ ___ ___

Stratum Qualification for All Patients (initial evaluation, registry and randomization patients)

Check only one:
- ☐₁ Stratum A (MED vs CABG) **STRATQUA<STSTRA><I:3>**
- ☐₂ Stratum B (MED vs CABG vs CABG & SVR)
- ☐₃ Stratum C (CABG vs CABG & SVR)

QUALIFY (TYPE 1)

Patient Disposition (check appropriate box and complete details in corresponding column)

1 Initial Evaluation Log	**OR** **PTDISP<STPTDS><I:3>** 2 ☐ Registry	**OR** 3 ☐ **Randomization** **DISPOSIT (TYPE 1)**
Reason physician did not agree to randomization (check all that apply): **<ZYES><I:3>**	Reason patient did not agree to randomization (check all that apply): **<ZYES><I:3>**	Randomization date **RANDDT**
☐ CABG preferred **CABGPREF**	☐ Wants to choose treatment **SELFCHOS**	**RANDD RANDM RANDY** ___/___/___ day month year
☐ SVR preferred **SVRPREF**	☐ Wants physicians to choose treatment **PHYSCHOS**	**TRASSIGN** Treatment assignment (check only one):
☐ PCI preferred **PCIPREF**	☐ Does not feel comfortable with randomization **UNCOMF**	**<STTYP><I:3>** Stratum A → ☐1 Medicine
☐ Medical therapy preferred **MEDTHER**	☐ Study requires too many tests **TOOMANY**	☐2 CABG
☐ Consent process disruptive to best patient care **CONSDISR**	☐ Follow-up imposes time and expense **TIMEEXP**	Stratum B → ☐3 Medicine ☐4 CABG
☐ Other clinical trial preferred **OTHPREF**	☐ Will not provide reason **REGNOREA**	☐5 CABG & SVR
NONADH ☐ Patient likely to be nonadherent		Stratum C → ☐6 CABG
☐ Will not provide reason **INTNOREA**		☐7 CABG & SVR

Investigator's Signature

SIGNATUR (TYPE 4)

I have reviewed and found all data pertaining to this subject to be complete and accurate.

Coordinator's signature: _____ **NOT DATABASED**

Investigator's signature: _____ **SIGNANS<ZYES>**   Date: ___/___/___ day month year **SIGDT** **SIGD SIGM SIGY**

STICH

Baseline Studies for Randomized Patients

Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___   Patient's Initials: ___ ___ ___

Core Laboratory (studies required on all patients)

1. Date blood obtained for NCG core lab: ___CLNCGD___ / ___CLNCGM___ / ___CLNCGY___ **CLNCGDT**   **CORELAB (TYPE 1)**
day / month / year

NOTOBTAN<STCLRS><I:3>
OR **Reason not obtained:** [1] Patient refused blood draw [2] Technical problem [ ] NOT DONE

2. Date echocardiogram sent to ECHO core lab: ___CLECHOD___ / ___CLECHOM___ / ___CLECHOY___ **CLECHODT**
day / month / year

NOTSENT<STCLRS><I:3>
OR **Reason not sent:** [3] Poor acoustical windows [2] Technical problem [ ] NOT DONE

Exercise Studies (required on patients able to exercise)

WLKDT
1. Date of 6-minute walk: ___WLKD___ / ___WLKM___ / ___WLKY___ OR [ ] Patient unable **WLKPTUN<ZYES><I:3>**   **WALKTEST (TYPE 1)**
day / month / year

DISTWLK<I:4>
2. Distance walked: _____ [ ]1 feet [ ]2 meter(s) **DISUNT<STDIST><I:3>**

3. Symptoms (check all that apply): [ ] None [ ] Angina [ ] Lightheadedness [ ] Syncope **<ZYES><I:3>**
WLKNONE   **WLKANG**   **WLKLTHD**   **WLKSYN**

4. Borg dyspnea score: _____ (0-10) **WLKBORG<I:2>**

ECGDT
5. Date of ECG stress test: ___ECGD___ / ___ECGM___ / ___ECGY___ OR [ ] Patient unable **PTUNABLE<ZYES><I:3>**   **ECGTEST (TYPE 3)**
day / month / year

6. ECG rhythm (check only one): [ ]1 Sinus [ ]2 Not sinus [ ]3 Paced **ECGRHYTM<STRHYM><I:3>**

7. Exercised on: [ ]1 Treadmill [ ]2 Bicycle **EXERCISE<STEXER><I:3>**

EXDURMIN<I:2> EXDURSEC<I:2>   **PKWRK<F:9:3>**
8. Exercise duration: ____ : ____ OR Peak work: _____ [ ]1 METS [ ]2 KPM **PKWRKUNT<STPKWK><I:3>**
mins / sec

PEBPSYS<I:3>   **PEBPDIA<I:3>**
9. BP at peak exercise: _____ / _____ mm Hg
systolic / diastolic

10. Modified Bruce stage: [0] 1/2 [1] 1 [2] 2 [3] ≥ 3 **MBSTAGE<STSTAG><I:3>**

ANGEXER<ZYESNO><I:3>
11. Angina during exercise: [ ]0 No [ ]1 Yes

MAXSTDEP<F:9:3>   **STSEGNI<ZYES><I:3>**
12. Maximal net ST depression: _____ mm OR [ ] ST segment not interpreted

Stratum

Check only one stratum **and** complete the related information.   [ ] NOT DONE   **STRATUM (TYPE 1)**

[ ]1 Stratum A **STRATYPE<STSTRA><I:3>**   **<STRTRE><I:3>**

	Sent	Not sent: technical problem	Not sent: patient related
Myocardial perfusion test to RN core lab: **AMYPERF**	[ ]	[ ]	[ ]
Myocardial viability test to RN core lab: **AMYVIAB**	[ ]	[ ]	[ ]
Gated SPECT ventriculogram to core lab: **AGTSPECT**	[ ]	[ ]	[ ]

[ ]2 Stratum B

	Sent	Not sent: technical problem	Not sent: patient related
Myocardial perfusion test to RN core lab: **BMYPERF**	[ ]	[ ]	[ ]
Myocardial viability test to RN core lab: **BMYVIAB**	[ ]	[ ]	[ ]
CMR ventriculogram to core lab: **BCMRSPEC**	[ ]	[ ]	[ ]
Gated SPECT ventriculogram to core lab: **BGATSPEC**	[ ]	[ ]	[ ]

[ ]3 Stratum C **CCMRSPEC**

	Sent	Not sent: technical problem	Not sent: patient related
CMR ventriculogram to core lab: **CGATSPEC**	[ ]	[ ]	[ ]
Gated SPECT ventriculogram to core lab:	[ ]	[ ]	[ ]

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Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___   Patient's Initials: ___ ___ ___

Current Medications

Check "No" or "Yes" for all medications the patient was taking at the time of discharge or day 30.

MEDS (TYPE 4) PS

ANNOTATION SAME AS PAGE 1

1. ACE inhibitor:	☐₀ No ☐₁ Yes	**10.** Diuretic (loop/thiazide): ☐₀ No ☐₁ Yes
2. Amiodarone:	☐₀ No ☐₁ Yes	**11.** Diuretic (potassium sparing): ☐₀ No ☐₁ Yes
3. Angiotensin receptor blocker:	☐₀ No ☐₁ Yes	**12.** Insulin: ☐₀ No ☐₁ Yes
4. Antiarrhythmic (not amiodarone):	☐₀ No ☐₁ Yes	**13.** Nitrate: ☐₀ No ☐₁ Yes
5. Antidepressant:	☐₀ No ☐₁ Yes	**14.** NSAID: ☐₀ No ☐₁ Yes
6. Aspirin (daily):	☐₀ No ☐₁ Yes	**15.** Oral diabetic agent: ☐₀ No ☐₁ Yes
7. Beta blocker:	☐₀ No ☐₁ Yes	**16.** Statin: ☐₀ No ☐₁ Yes
8. Clopidogrel:	☐₀ No ☐₁ Yes	**17.** Thyroid replacement therapy: ☐₀ No ☐₁ Yes
9. Digoxin:	☐₀ No ☐₁ Yes	**18.** Warfarin: ☐₀ No ☐₁ Yes

Events After Randomization Until Hospital Discharge or within 30 Days

Check "No" or "Yes" for each event.   <ZYESNO><I:3>

EVENTS (TYPE 4)

1. PA catheter placement: EVPACATH   ☐₀ No ☐₁ Yes   ...cardiac output: EVIABP   ☐₀ No ☐₁ Yes

2. Pacemaker for heart rate: EVPACMKR   ☐₀ No   ...low cardiac output: EVINOTRP   ☐₀ No ☐₁ Yes

3. Pacemaker for resynchronization: EPACRSYN   ☐₀ No   ...ELIR   ☐₀ No ☐₁ Yes

4. New onset atrial flutter/fibrillation: EVNEWAF   ☐₀ No   ...dema requiring intubation: EVPULEDM   ☐₀ No ☐₁ Yes

5. New onset ventricular arrhythmia: ENEWVARR   ☐₀ No   ...st requiring CPR: EVCPR   ☐₀ No ☐₁ Yes

6. Worsening renal insufficiency: EVWRSRI   ☐₀ No ☐₁ Yes   **12.** ...   EVTOTH<V:200>   ☐₀ No ☐₁ Yes

DCRI MEDRA
MEDRTEXA<V:100>
MEDRCODA<V:8>
WORKFLOA<V:5>
CODETA <DATETIME>
CODEA<V:20>
CONFLVA <V:2>
MATCHEA <V:4>

DCRI MEDRA
MEDRTEXB<V:100>
MEDRCODB<V:8>
WORKFLOB<V:5>
CODETB <DATETIME>
CODEB<V:20>
CONFLVB <V:2>
MATCHEB <V:4>

Additional Other (specify)1   OTHEVA<V:60>
Additional Other (specify)2   OTHEVB<V:60>
Additional Other (specify)3   OTHEVC<V:60>
Additional Other (specify)4   OTHEVD<V:60>
Additional Other (specify)5   OTHEVE<V:60>

...ospital Dis... ...ays

ENDPOINT (TYPE 4) PS

...e provide date...
ENDPTD   ...   OPTDT
...ate: ___/___   day

...ate: ___/___   day

3. PCI: ☐₀ No ☐₁ Yes → If Yes, date: ___/___/___   day   month   year

☐₁ Ye...   ___/___   year

DCRI MEDRA
MEDRTEXD<V:100>
MEDRCODD<V:8>
WORKFLOD<V:5>
CODETD <DATETIME>
CODED<V:20>
CONFLVD <V:2>
MATCHED <V:4>

DCRI MEDRA
MEDRTEXE<V:100>
MEDRCOEE<V:8>
WORKFLOE<V:5>
CODETE <DATETIME>
CODEE<V:20>
CONFLVE <V:2>
MATCHEE <V:4>

DCRI MEDRA
MEDRTEXC<V:100>
MEDRCODC<V:8>
WORKFLOC<V:5>
CODETC <DATETIME>
CODEC<V:20>
CONFLVC <V:2>
MATCHEC <V:4>

☐₁ Ye...   ___/___   year

☐₁ Ye...   ___/___   year

☐₁ Ye...   ___/___   year

8. Death: ☐₀ No ☐₁ Yes → If Yes, complete "End of Study" page.

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STICH CRF_V3.0_24 JUL 2006   **2006 DCRI — Confidential**   CRF, page 5
STICH CRF Annotation Version 10.1   21JUL2008

STICH — Medical Treatment

NOTE: EITHER THE 'IN THE HOSPITAL' OR 'OUTPATIENT' PANEL WILL BE COMPLETED - NOT BOTH. MAKE EACH A SEPARATE PAGE WITH A SIGNATURE PANEL WITHIN CLINTRIAL

Site Number: __ __ __ __   Patient Number: __ __ __ __   Patient's Initials: __ __ __

For **Patients Initially Treated in the Hospital**, Complete this Section.

PTDISCG<ZYESNO><I:3>
Was patient discharged prior to 30 days?   INASSESS (TYPE 3)

☐ 0 No → Date of evaluation for data recorded on form: EVALD / EVALM / EVALY __   EVALDT
                                                      day   month   year

☐ 1 Yes → Date of discharge: DISCHD / DISCHM / DISCHY __   DISCHDT
                             day   month   year

DISTYPE<STPTDI><I:3>
☐ 1 Discharged to home

☐ 2 Transferred to another care facility → **Date of transfer:** TRANSD / TRANSM / TRANSDY __   TRANSDT
                                                                 day   month   year

Name of institution: **NOT DATABASED**

Address: **NOT DATABASED**   City: **NOT DATABASED**   State: **NOT DATABASED**

For **Patients Initially Treated as Outpatients**, Complete this Section.

1. Date of evaluation for data recorded on form: OEVALD / OEVALM / OEVALY __   OEVALDT   OUTASSES (TYPE 1)
                                                 day   month   year

2. Number of non-STICH clinic visits **between randomization and completion of the form:** ONUMSTV<I:3>

3. Number of nonadmission ED visits **between randomization and completion of the form:** ONUMEDV<I:3>

4. Number of hospitalizations **between randomization and completion of the form:** ONUMHOS<I:3> → If any, complete information below:

HOSPNUM<STHOS><I:3>

HOSP 1
Admission date: HADMDT HADMD / HADMM / HADMY __   HDISCHDT Discharge date: HDISCHD / HDISCHM / HDISCHY __   HOSP (TYPE 2) PS   OR ☐ Stay continues
                       day   month   year   day   month   year   at this time
Reason code(s): REACODE1, REACODE2, REACODE3, REACODE4, REACODE5, REACODE6 <I:3>   STAYCONT<ZYES>
Name of institution: **NOT DATABASED**   City: **NOT DATABASED**   State: **NOT DATABASED**

HOSP 2
Admission date: ___ / ___ / ___   Discharge date: ___ / ___ / ___   OR ☐ Stay continues
                day   month year   day   month year   at this time
Reason code(s): ___, ___, ___, ___, ___, ___   **ANNOTATION SAME AS HOSP1**
Name of institution: _____   City: _____   State: _____

OUTPROC<ZYESNO><I:3>
5. Any outpatient procedures?

☐ 0 No

☐ 1 Yes → Check all that apply: <ZYES>
   OPCATH<I:3>   OPPACEHR<I:3>   OPPACESY<I:3>
   ☐ 1 Cardiac cath   ☐ 1 Pacemaker for heart rate   ☐ 1 Pacemaker for resynchronization

OPPCI<I:3>   OPCIDT OPCID OPCIM OPCIY   OICDDT OICDD   OICDM OICDY
☐ 1 PCI → ___ / ___ / ___   ☐ 1 ICD implantation → ___ / ___ / ___
             day   month   year   OICDDT   day   month year
                                    OPICD<I:3>

Name of institution: **NOT DATABASED**

Address: _____   City: **NOT DATABASED**   State: **NOT DATABASED**

NURSHM<ZYESNO><I:3>
6. Nursing home/rehabilitation facility admission?

☐ 0 No

☐ 1 Yes → Name of institution: **NOT DATABASED**

Address: **NOT DATABASED**   City: **NOT DATABASED**   State: **NOT DATABASED**

Investigator's Signature

I have reviewed and found all data pertaining to this subject to be complete and accurate.

Coordinator's signature: **NOT DATABASED**

Investigator's signature: **ANNOTATION SAME AS CRF PAGE 3**   Date: **ANNOTATION SAME AS CRF PAGE 3**
                                                                      day   month   year

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STICH

FORM = SURGICAL

Surgical Treatment

Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___   Patient's Initials: ___ ___ ___

Events After Randomization and Before Transport to Operating Room

Check "No" or "Yes" for each event. **ANNOTATION SAME AS CRF PAGE 5**   **EVENTS (TYPE 4)**

1. PA catheter placement:	☐₀ No ☐₁ Yes	**7.**	IABP for low cardiac output:	☐₀ No ☐₁ Yes
2. Pacemaker for heart rate:	☐₀ No ☐₁ Yes	**8.**	Inotropes for low cardiac output:	☐₀ No ☐₁ Yes
3. Pacemaker for resynchronization:	☐₀ No ☐₁ Yes	**9.**	Delirium:	☐₀ No ☐₁ Yes
4. New onset atrial flutter/fibrillation:	☐₀ No ☐₁ Yes	**10.**	Pulmonary edema requiring intubation:	☐₀ No ☐₁ Yes
5. New onset ventricular arrhythmia:	☐₀ No ☐₁ Yes	**11.**	Cardiac arrest requiring CPR:	☐₀ No ☐₁ Yes
6. Worsening renal insufficiency:	☐₀ No ☐₁ Yes	**12.**	Other (specify): _____	☐₀ No ☐₁ Yes

Endpoints After Randomization and Before Transport to Operating Room

Check "No" or "Yes" for each endpoint. If Yes, please provide date.   **ENDPOINT (TYPE 4) PS**

ANNOTATION SAME AS CRF PAGE 5

1. Acute MI: ☐₀ No ☐₁ Yes → ___/___/___ day month year   **5.** Heart transplant: ☐₀ No ☐₁ Yes → ___/___/___ day month year

2. CABG: ☐₀ No ☐₁ Yes → ___/___/___ day month year   **6.** Stroke: ☐₀ No ☐₁ Yes → ___/___/___ day month year

3. PCI: ☐₀ No ☐₁ Yes → ___/___/___ day month year   **7.** ICD implantation: ☐₀ No ☐₁ Yes → ___/___/___ day month year

4. LVAD insert: ☐₀ No ☐₁ Yes → ___/___/___ day month year   **8.** Death: ☐₀ No ☐₁ Yes → Complete "End of Study" page.

Surgical Data

SURGDATA (TYPE1)

1. Number of conduits (check only one): **CONDUNUM** ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐≥6

2. Number of arterial conduits (check only one): **ARTERNUM** ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐≥6   **<STNUM><I:3>**

3. Total number of distal anastomoses (check only one): **DISTANUM** ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐≥6

4. Other procedures performed at this time: **PROCNONE<ZYES>** ☐None

PROCMV<ZYES> ☐On mitral valve → **MITVALVE<STMITV><I:3>** ☐Repair ☐Bioprosthesis ☐Mechanical

PROCOTH<ZYES> ☐Other

PROCSVR<ZYES> ☐SVR → SVR procedure: **SVRPROC<STSVRP><I:3>** ☐Patch ☐No patch

During SVR portion of procedure: **SVRPORT<STPORT><I:3>** ☐Beating heart ☐Cardioplegia

5. Cardioplegia: **CARDPLEG<STCARD><I:3>**

0 ☐None
1 ☐Crystalloid
2 ☐Blood
3 Both

DELIVERY<STDELV><I:3> Method of delivery: ☐Antegrade ☐Retrograde ☐Antegrade and retrograde

INDUCT At induction: ☐Cold ☐Tepid ☐Warm

MAINT For maintenance: ☐None ☐Cold ☐Tepid ☐Warm   **<STTEMP><I:3>**

REPERF Reperfusion: ☐None ☐Cold ☐Tepid ☐Warm

Efficiency Data

ACUTEOP<STACUT><I:3>   **EFFCDATA (TYPE 1)**

1. Acuteness at operation (check only one): ☐₁ Elective ☐₂ Urgent ☐₃ Ongoing ischemia ☐₄ Hemodynamic instability ☐₅ Salvage

NO. 4 & NO. 5 TIMES ARE ASSO. WITH NO. 3 OPERATING ROOM IN DATE

2. ET:

ETINDT Intubation: **ETIND** ___/___/___ day month year **ETINM** **ETINY** **ETINTM** ___:___ 00:00 to 23:59

ETEXDT Extubation: **ETEXD** ___/___/___ day month year **ETEXM** **ETEXY** **ETEXTM** ___:___ 00:00 to 23:59

3. Operating room:

OPINDT In: **OPIND** ___/___/___ day month year **OPINM** **OPINY** **OPINTM** ___:___ 00:00 to 23:59

OPOUTDT Out: **OPOUTD** ___/___/___ day month year **OPOUTM** **OPOUTY** **OPOUTTM** ___:___ 00:00 to 23:59

4. Bypass pump: **BPONTM** On: ___:___ 00:00 to 23:59 **BPOFFTM** Off: ___:___ 00:00 to 23:59

OR Total minutes: **BPMIN<I:4>** _____

5. Aorta cross-clamp: **ACONTM** On: ___:___ 00:00 to 23:59 **ACOFFTM** Off: ___:___ 00:00 to 23:59

OR Total minutes: **ACMIN<I:4>** _____

6. CCU/ICU:

ADMDT Admission: **ADMD** ___/ day **ADMM** ___/ month **ADMY** ___ year **ADMTM** ___:___ 00:00 to 23:59

DISTRDT Discharge/transfer: **DISTRD** ___/ day **DISTRM** ___/ month **DISTRY** ___ year **DISTRTM** ___:___ 00:00 to 23:59

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

STICH

Surgical Treatment

Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___   Patient's Initials: ___ ___ ___

Current Medications

Check "No" or "Yes" for all medications the patient was taking at the time of discharge or at day 30.   **MEDS (TYPE 4) PS**

ANNOTATION SAME AS CRF PAGE 1

1. ACE inhibitor: ☐₀ No ☐₁ Yes
2. Amiodarone: ☐₀ No ☐₁ Yes
3. Angiotensin receptor blocker: ☐₀ No ☐₁ Yes
4. Antiarrhythmic (not amiodarone): ☐₀ No ☐₁ Yes
5. Antidepressant: ☐₀ No ☐₁ Yes
6. Aspirin (daily): ☐₀ No ☐₁ Yes
7. Beta blocker: ☐₀ No ☐₁ Yes
8. Clopidogrel: ☐₀ No ☐₁ Yes
9. Digoxin: ☐₀ No ☐₁ Yes

10. Diuretic (loop/thiazide): ☐₀ No ☐₁ Yes
11. Diuretic (potassium sparing): ☐₀ No ☐₁ Yes
12. Insulin: ☐₀ No ☐₁ Yes
13. Nitrate: ☐₀ No ☐₁ Yes
14. NSAID: ☐₀ No ☐₁ Yes
15. Oral diabetic agent: ☐₀ No ☐₁ Yes
16. Statin: ☐₀ No ☐₁ Yes
17. Thyroid replacement therapy: ☐₀ No ☐₁ Yes
18. Warfarin: ☐₀ No ☐₁ Yes

Events After Operation Until Hospital Discharge or 30 Days

Check "No" or "Yes" for each event.   **EVENTS (TYPE 4)**

ANNOTATION SAME AS CRF PAGE 5 - NOTING NEW VARIABLES

1. Return to OR for bleeding: ☐₀ No ☐₁ Yes   *EVRETBL*
2. Return to OR for other reason: ☐₀ No ☐₁ Yes   *EVRETOTH*
3. Mediastinitis: ☐₀ No ☐₁ Yes   *EVMEDIAS*
4. Other infection: ☐₀ No ☐₁ Yes   *EVOTHINF*
5. PA catheter placement: ☐₀ No ☐₁ Yes
6. Pacemaker for heart rate: ☐₀ No ☐₁ Yes
7. Pacemaker for resynchronization: ☐₀ No ☐₁ Yes
8. New onset atrial flutter/fibrillation: ☐₀ No ☐₁ Yes

9. New onset ventricular arrhythmia: ☐₀ No ☐₁ Yes
10. Worsening renal insufficiency: ☐₀ No ☐₁ Yes
11. IABP for low cardiac output: ☐₀ No ☐₁ Yes
12. Inotropes for low cardiac output: ☐₀ No ☐₁ Yes
13. Delirium: ☐₀ No ☐₁ Yes
14. Pulmonary edema requiring intubation: ☐₀ No ☐₁ Yes
15. Cardiac arrest requiring CPR: ☐₀ No ☐₁ Yes
16. Other (specify): _____ ☐₀ No ☐₁ Yes

Endpoints After Operation Until Hospital Discharge or 30 Days

Check "No" or "Yes" for each endpoint. If Yes, please provide date.   **ENDPOINT (TYPE 4) PS**

ANNOTATION SAME AS CRF PAGE 5

1. Acute MI: ☐₀ No ☐₁ Yes → ___/___/___ day month year
2. CABG: ☐₀ No ☐₁ Yes → ___/___/___ day month year
3. PCI: ☐₀ No ☐₁ Yes → ___/___/___ day month year
4. LVAD insert: ☐₀ No ☐₁ Yes → ___/___/___ day month year

5. Heart transplant: ☐₀ No ☐₁ Yes → ___/___/___ day month year
6. Stroke: ☐₀ No ☐₁ Yes → ___/___/___ day month year
7. ICD implantation: ☐₀ No ☐₁ Yes → ___/___/___ day month year
8. Death: ☐₀ No ☐₁ Yes → **Complete "End of Study" page.**

Patient Assessment at Hospital Discharge or 30 Days

Was patient discharged?   **INASSESS (TYPE 3)**

☐₀ No → Date of evaluation for data recorded on form: ___/___/___ day month year

☐₁ Yes → Date of discharge: ___/___/___ day month year

ANNOTATION SAME AS CRF PAGE 6

☐ Discharged to home

☐ Transferred to another care facility → Date of transfer: ___/___/___ day month year

Name of institution: _____

Address: _____   City: _____   State: _____

Investigator's Signature

I have reviewed and found all data pertaining to this subject to be complete and accurate.   **SIGNATUR (TYPE 4)**

Coordinator's signature: _____   ~~NOT DATABASED~~

Investigator's signature: _____ **ANNOTATION SAME AS CRF PAGE 3**   **ANNOTATION SAME AS CRF PAGE 3** Date: ___/___/___ day month year

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

FORM = ENDOFSTUDY

Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___   Patient's Initials: ___ ___ ___

End of Study

1. End of study date: ___ ___ / ___ ___ / ___ ___ ___ ___   **ENDSTUDY (TYPE 1)**
ENDSTYD ENDSTYM ENDSTYY
day   month   year   **ENDSTYDT**

2. Did the patient complete the study? ☐₀ No   ☐₁ Yes   **STDYCOMP<ZYESNO><I:3>**

PRIMREAS<STPRES><I:3>
→ If No, choose primary reason (check only one):

   ☐1 Withdrew consent

   ☐2 Other → Specify   **OTHREAS<V:200>**   _____

   ☐3 Death → Date of death: DTHD / DTHM / DTHY ___   **DTHDT**
                              day   month   year

         Cause of death (check only one):   **DTHCAUSE<STDTHC><I:3>**

         ☐1 Cardiac reason(s) →   If cardiac reason(s), check all that apply: **<ZYES><I:3>**
                                   ☐1 MI   **CMI**
                                   ☐1 Arrhythmia/sudden death   **CASUDTH**
                                   ☐1 Heart failure   **CHEARTFL**
        OR   ☐1 Other cardiac   **COTHCAR**
                                   ☐1 Stroke   **CSTROKE**

         ☐2 Noncardiac reason(s) → If noncardiac reason(s), check all that apply:
                                   ☐1 Infection   **NCINFEC**
                                   ☐1 Neurologic   **NCNEURO**
                                   ☐1 Pulmonary   **NCPULM**
                                   ☐1 Renal   **NCRENAL**
                                   ☐1 Malignancy   **NCMALIG**
                                   ☐1 Other → Spec   **NCOTHTXT<V:200>**   _____
                                        NCOTH
         Report the event as an SAE, if appropriate. Submit an autopsy report, if available.

From the date of last contact to the date of death or withdrawal of consent: **ENDASSES (TYPE 4)**

3. Number of hospitalizations (> 24 hours): ENUMHOSP<I:3> ___ → Complete "Hospitalization Form" for each admission.

4. Number of non-STICH clinic visits: ENUMSTV<I:3> ___

5. Number of nonadmission ED visits: ENUMEDV<I:3> ___

6. Number of admissions to a nursing home/rehabilitation facility: ENUADMIS<I:3> ___ → If any, complete information below.

   Name of institution: **NOT DATABASED** _____

   Address: **NOT DATABASED** _____ City: **NOT DATABASED** _____ State: **NOT DATABASED** ___

EOPROC<ZYESNO><I:3>
7. Any outpatient procedures?   **<ZYES>**

   ☐₀ No
   ☐₁ Yes → Check all that apply: EOPCATH<I:3> ☐ Cardiac cath   EOPACEHR<I:3> ☐ Pacemaker for heart rate   EOPACESY<I:3> ☐ Pacemaker for resynchronization

   EOPPCI<I:3> ☐ PCI → EPCIDT ___ / ___ ___ / ___ ___ ___   ☐ ICD implantation → EICDDT ___ / ___ ___ / ___ ___ ___
                        day   month   year   EOPICDI<I:3>   day   month   year

   Name of institution: _____

   Address: **NOT DATABASED** _____ City: **NOT DATABASED** _____ State: **NOT DATABASED** ___
            NOT DATABASED

Investigator's Signature

I have reviewed and found all data pertaining to this subject to be complete and accurate.   **SIGNATUR (TYPE 4)**

ANNOTATION SAME AS CRF PAGE 3

Coordinator's signature: **NOT DATABASED** _____

Investigator's signature: **ANNOTATION SAME AS CRF PAGE 3** _____ Date: ___ ___ / ___ ___ / ___ ___ ___
                                                                            day   month   year

Revised Visit Schedule

FORM = SEE FORM NAMES NEXT PAGE

Clinical Follow-up

Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___   Patient's Initials: ___ ___ ___

Date of visit: **CONTEXT**
VISITDT
VISITD / **VISITM** / **VISITY** ___
day   month   year

Follow-up visit *(check only one)*:
☐ 4 month ☐ 8 month ☐ 12 month ☐ 18 month ☐ 24 month
☐ 30 month ☐ 36 month ☐ 42 month ☐ 48 month ☐ 54 month ☐ 60 month ☐ 66 month
☐ 72 month ☐ 78 month ☐ 84 month ☐ 90 month ☐ 96 month ☐ > 96 month

Type of Visit/Contact

☐ Clinic **CLINIC**   ☐ Phone **PHONE** *(Skip to Current Medications section.)* <I:3><ZYES>   ☐ Missed visit *(Skip to Investigator's Signature section.)* **MISSVIST**<ZYES><I:3>   **VISCOTAC (TYPE 4)**

History & Vital Signs

1. Current Canadian Cardiovascular Society (CCS) angina class *(check only one)*: ☐ No angina ☐ I ☐ II ☐ III ☐ IV **ANGCLASS (TYPE 4)**

2. Current NYHA heart failure class *(check only one)*: ☐ I ☐ II ☐ III ☐ IV **HISTNYHA**<ZCLASS><I:3>   **HISTANG**<STCCSC><I:3>

3. Blood pressure: _____ / _____ mm Hg **HBPSYS**<I:3> **HBPDIA**<I:3>
   systolic   diastolic

4. Pulse: ___ ___ ___ bpm **HPULSE**<I:3>

Current Medications

MEDS (TYPE 4) PS

Check "No" or "Yes" for all medications the patient was taking at the time of contact.

1. ACE inhibitor: ☐ No ☐ Yes	10. Diuretic *(loop/thiazide)*: ☐ No ☐ Yes	
2. Amiodarone: ☐ No ☐ Yes	11. Diuretic *(potassium sparing)*: ☐ No ☐ Yes	
3. Angiotensin receptor blocker: ☐ No ☐ Yes	12. Insulin: ☐ No ☐ Yes	
4. Antiarrhythmic *(not amiodarone)*: ☐ No ☐ Yes	13. Nitrate: ☐ No ☐ Yes	
5. Antidepressant: ☐ No ☐ Yes	14. NSAID: ☐ No ☐ Yes	
6. Aspirin *(daily)*: ☐ No ☐ Yes	15. Oral diabetic agent: ☐ No ☐ Yes	
7. Beta blocker: ☐ No ☐ Yes	16. Statin: ☐ No ☐ Yes	
8. Clopidogrel: ☐ No ☐ Yes	17. Thyroid replacement therapy: ☐ No ☐ Yes	
9. Digoxin: ☐ No ☐ Yes	18. Warfarin: ☐ No ☐ Yes	

ANNOTATION SAME AS CRF PAGE 1
STICH_Annotation (15DEC2004) Version 8.0

Medical Utilization *(since last contact for STICH trial)*

1. Number of hospitalizations *(> 24 hours)*: _____ → Complete "Hospitalization Form" for each admission **ENDASSES (TYPE 4)**

2. Number of non-STICH clinic visits: _____

3. Number of nonadmission ED visits: _____

4. Number of admissions to a nursing home/rehabilitation facility: _____ → If any, complete information below.

   Name of institution: _____
   ANNOTATION SAME AS END OF STUDY PAGE
   Address: _____ City: _____ State: _____

5. Any outpatient procedures?
   ☐ No
   ☐ Yes → Check all that apply: ☐ Cardiac cath ☐ Pacemaker for heart rate ☐ Pacemaker for resynchronization
   ☐ PCI → ___/___/___   ☐ ICD implantation → ___/___/___
        day month year   day month year

   Name of institution: _____ City: _____ State: _____

Investigator's Signature

I have reviewed and found all data pertaining to this subject to be complete and accurate. **SIGNATUR (TYPE 4)**

Coordinator's signature: _____

Investigator's signature: **ANNOTATION SAME AS CRF PAGE 3**   Date: ___/___/___
                                                                       day month year

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

STICH CRF_V3.0 24 JUL 2006   **2006 DCRI — Confidential**   Clinical Follow-Up
STICH CRF Annotation Version 10.1   21JUL2008

FORMS:
4MONTH
8MONTH
12MONTH
16MONTH
18MONTH

20MONTH
24MONTH
28MONTH

30MONTH

32MONTH
36MONTH
40MONTH

42MONTH

44MONTH
48MONTH
52MONTH

54MONTH

56MONTH

60MONTH
66MONTH
72MONTH
78MONTH
84MONTH
90MONTH
96MONTH
>96MONTH
64MONTH
68MONTH
76MONTH
80MONTH
88MONTH
92MONTH

Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___   Patient's Initials: ___ ___ ___

4-Month Follow-Up Studies Required For All Randomized Patients

FUNCG<ZYESNO><I:3>   **FOLLOWUP (TYPE 4)**

1. Blood sample obtained for NCG core lab?

NCGREAS<STREAS><I:3>

☐₀ No → **Reason:** ⓪ Not obtained at baseline   ① Patient refused   ③ Technical problem   ④ Patient not seen at clinic

☐₁ Yes → **Date obtained:** FUNCGD / FUNCGM / FUNCGY   FUNCGDT
day   month   year

FUECHO<ZYESNO><I:3>

2. Echocardiogram sent to ECHO core lab?

ECHOREAS<STREAS><I:3>

☐₀ No → **Reason:** ⓪ Not obtained at baseline   ① Patient refused   ③ Technical problem   ④ Patient not seen at clinic

☐₁ Yes → **Date sent:** FUECHOD FUECHOM FUECHOY FUECHODT
day   month   year

FUEQOL<ZYESNO><I:3>

3. EuroQol completed?

EUROREAS<STREAS><I:3>

☐₀ No → **Reason:** ① Patient refused   ② Patient unable   ④ Patient not seen at clinic   6   Patient not Contacted

☐₁ Yes → Submit with CRF.

FUWALK<ZYESNO><I:3>

4. Did patient perform 6-minute walk?

FUREASON<STREAS><I:3>

☐₀ No → **Reason:** ① Patient refused   ② Patient unable   ④ Patient not seen at clinic

☐₁ Yes → Date of 6-minute walk: FUWLKD / FUWLKM / FUWLKY FUWLKDT
day   month   year

FUDISWLK<I:4>
Distance walked: _____   ☐₁ feet   ☐₂ meter(s) FUDISTY<STDIST><I:3>

<ZYES><I:3>
Symptoms (check all that apply): ☐ None   ☐ Angina   ☐ Lightheadedness   ☐ Syncope
FUNONE   FUANGA   FULIGHT   FUSYNCOP

Borg dyspnea score: _____ (0 - 10) BORGDYS><I:2>

Study Required for Stratum B and Stratum C Patients

STRATREQ<ZYESNO><I:3>   **STRATBC (TYPE 3)**

CMR ventriculogram sent to core lab? STRATREA<STREAS><I:3>

☐₀ No → **Reason:** ⓪ Not obtained at baseline   ⑤ Patient related   ③ Technical problem   ④ Patient not seen at clinic

☐₁ Yes → **Date sent:** STRATD / STRATM / STRATY   STRATDT
day   month   year

SPECTREQ<ZYESNO><I:3>

Gated SPECT ventriculogram sent to core lab? SPECTREA<STREAS><I:3>

☐₀ No → **Reason:** ⓪ Not obtained at baseline   ⑤ Patient related   ③ Technical problem   ④ Patient not seen at clinic

☐₁ Yes → **Date sent:** SPECTD / SPECTM / SPECTY   SPECTDT
day   month   year

Submit WHITE and YELLOW pages to Duke Clinical Research Institute.   •   Retain PINK page at site.

STICH CRF_V3.0_24 JUL 2006   **2006 DCRI — Confidential**   4-Month Studies
STICH CRF Annotation Version 10.1   21JUL2008

STICH

Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___   Patient's Initials: ___ ___ ___

Follow-up visit (check only one): ☐ 12 month   ☐ 36 month   ☐ 48 month

12, 36, or 48-Month Follow-up For All Randomized Patients

1. EuroQol completed?   **FOLLOWUP (TYPE 4)**

☐$_0$ No → **Reason:** ☐ Patient refused   ☐ Patient unable   ☐ Patient not seen at clinic

☐$_1$ Yes → Submit with CRF.

ANNOTATION SAME AS CRF PAGE 4-MONTH STUDIES

2. Did patient perform 6-minute walk?

☐$_0$ No → **Reason:** ☐ Patient refused   ☐ Patient unable   ☐ Patient not seen at clinic

☐$_1$ Yes → **Date of 6-minute walk:** __ __ / __ __ / __ __ __ __
                                                            day   month   year

Distance walked: _____ ☐$_1$ feet   ☐$_2$ meter(s)

Symptoms (check all that apply): ☐ None   ☐ Angina   ☐ Lightheadedness   ☐ Syncope

Borg dyspnea score: _____ (0 - 10)

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • **Retain PINK page at site.**

STICH CRF_V3.0_24 JUL 2006   **2006 DCRI — Confidential**   12, 36, or 48-Month Studies
STICH CRF Annotation Version 10.1   21JUL2008

STICH

Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___   Patient's Initials: ___ ___ ___

24-Month Follow-up Studies Required for All Randomized Patients

1. Echocardiogram sent to ECHO core lab?   **FOLLOWUP (TYPE 4)**

☐₀ No → **Reason:** ☐ Not obtained at baseline   ☐ Patient refused   ☐ Technical problem   ☐ Patient not seen at clinic

☐₁ Yes → **Date sent:** ___/___/___ day month year

2. EuroQol completed?   **ANNOTATION SAME AS CRF PAGE 4-MONTH STUDIES**

☐₀ No → **Reason:** ☐ Patient refused   ☐ Patient unable   ☐ Patient not seen at clinic

☐₁ Yes → **Submit with CRF.**

3. Did patient perform 6-minute walk?

☐₀ No → **Reason:** ☐ Patient refused   ☐ Patient unable   ☐ Patient not seen at clinic

☐₁ Yes → **Date of 6-minute walk:** ___/___/___ day month year

Distance walked: _____ ☐₁ feet   ☐₂ meter(s)

Symptoms (check all that apply): ☐ None   ☐ Angina   ☐ Lightheadedness   ☐ Syncope

Borg dyspnea score: _____ (0 - 10)

Study Required for All Patients With Baseline Study

ECGSTRST<ZYESNO><I:3>

Did patient perform baseline ECG stress test?   **ECGTEST (TYPE 3)**

☐₀ No → No study required.

☐₁ Yes → If Yes, did patient perform ECG stress test at this visit?

ECGVIS<ZYESNO><I:3>   **ECGREAS <STREAS><I:3>**

☐₀ No → **Reason:** 1 ☐ Patient refused   2 ☐ Patient unable   4 ☐ Patient not seen at clinic

☐₁ Yes → **Date of ECG stress test:** ___/___/___ day month year

ECG rhythm (check only one): ☐₁ Sinus   ☐₂ Not sinus   ☐₃ Paced

ANNOTATION SAME AS CRF PAGE 4 - NOTING NEW VARIABLES

Exercised on: ☐₁ Treadmill   ☐₂ Bicycle

Exercise duration: ___:___ mins sec   OR   **Peak work:** _____ ☐₁ METS   ☐₂ KPM

BP at peak exercise: ___/___ mm Hg systolic diastolic

Modified Bruce stage: ☐ 1/2   ☐ 1   ☐ 2   ☐ ≥ 3

Angina during exercise: ☐₀ No   ☐₁ Yes

Maximal net ST depression: _____ mm   OR   ☐ ST segment not interpreted

Study Required for Stratum B and Stratum C Patients

STRATBC (TYPE 3)

CMR ventriculogram sent to core lab?

☐₀ No → **Reason:** ☐ Not obtained at baseline   ☐ Patient related   ☐ Technical problem   ☐ Patient not seen at clinic

☐₁ Yes → **Date sent:** ___/___/___ day month year

ANNOTATION SAME AS CRF PAGE 4-MONTH

Gated SPECT ventriculogram sent to core lab?

☐₀ No → **Reason:** ☐ Not obtained at baseline   ☐ Patient related   ☐ Technical problem   ☐ Patient not seen at clinic

☐₁ Yes → **Date sent:** ___/___/___ day month year

STUDY BOOK = STICH *

STICH

Revised Visit Schedule

STUDY BOOK = STICH_FOLLOWUP
ALL REMAINING VISITS TO MATCH UP
WITH CLINICAL FOLLOW-UP FORM

Hospitalization

Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___   Patient's Initials: ___ ___ ___

Follow-up visit (check only one)

☐ 30 month	☐ 36 month	☐ 4 month	☐ 8 month	☐ 12 month	☐ 18 month
☐ 72 month	☐ 78 month	☐ 42 month	☐ 48 month	☐ 54 month	☐ 60 month
		☐ 84 month	☐ 90 month	☐ 96 month	☐ > 96 month

☐ 24 month   ☐ 66 month   ☐ End of study

HOSDT
Admission date: **HOSD** / **HOSM** / **HOSY** ___ ___
  day   month   year

Name of institution: **NOT DATABASED** _____   **HOSPDATA (TYPE 4)**

HADMCON<ZYES>
OR ☐ Stay continues from prior contact

Address: **NOT DATABASED** _____

City: **NOT DATABASED** _____   **NOT DATABASED** State: _____

HOSDCDT   HOSDCD   HOSDCM   HOSDCY
Discharge date: ___ ___ / ___ ___ / ___ ___ ___
  day   month   year

HDCCON<ZYES>
OR ☐ Stay continues at time of form completion

Please submit a copy of the hospital discharge summary.

Indicate the reason(s) for admission including any events or procedures that occurred during the hospitalization.   **HOSPEVNT (TYPE 4)**

1. Events (check all that apply):

NEWMR
☐ [1] New/worsening mitral regurgitation

HRTF
☐ [1] Heart failure (HF) → Date of HF increasing:

HFDT
HFD ___ ___ / **HFM** ___ ___ / **HFY** ___ ___ ___
  day   month   year

Evidence for increasing
heart failure (check all that apply):

<ZYES><I:3>
☐ [1] Increasing dyspnea **INCRDYS**
☐ [1] GI distress **GIDIST**
☐ [1] Elevated JVP **ELEJVP**
☐ [1] Edema or ascites **EDEMA**
☐ [1] Rales **RALES**
☐ [1] SBP < 90 mm Hg **SBP**
☐ [1] Worsening renal function **WORRF**

ARRHY
☐ [1] Arrhythmia →

Check all that apply:
SUDDEATH
☐ [1] Sudden death without resuscitation
☐ [1] Sustained VT **SUSVT**
☐ [1] Syncope **SYNC**
☐ [1] Supraventricular arrhythmia **SUPRAV**

UNSTAANG
☐ [1] Unstable angina

AMI
[1] ☐ Acute MI →   **AMIDT** **AMID** **AMIM** **AMIY**
Date: ___ ___ / ___ ___ / ___ ___ ___
  day   month   year

Evidence (check all that apply):
<ZYES><I:3>
☐ [1] + Cardiac markers **CARDMRK**
☐ [1] ECG changes **ECGCH**
☐ [1] Ischemic symptoms **ISHSYM**

MONPICD
☐ [1] Monitoring/adjustment of previously implanted ICD

☐ [1] Other cardiac **OTHCAR**

STRK
☐ [1] Stroke → Date: **STRKD** ___ ___ / **STRKM** ___ ___ / **STRKY** ___ ___ ___   **STRKDT**
  day   month   year

☐ [1] Gastrointestinal **GASTRO**
☐ [1] Infection **INFECT**
☐ [1] Malignancy **MALIG**
☐ [1] Pulmonary **PULM**
☐ [1] Renal **RENAL**
☐ [1] Other noncardiac **OTHNCAR**

2. Procedures (check all that apply):   **HOSPROC (TYPE 4)**

<ZYES>
☐ [1] Cardiac cath **CARCATH**
☐ [1] Pacemaker for heart rate **PACEKHR**
PACEKSYN
☐ [1] Pacemaker for resynchronization
HPPCI
☐ [1] PCI → Date: **PCID** ___ / **PCIM** ___ / **PCIY** ___   **PCIDT**
  day   month   year

☐ [1] ICD implanted → Date: **ICDD** ___ / **ICDM** ___ / **ICDY** ___   **ICDDT**
  day   month   year
☐ [1] CABG → Date: **CABGD** ___ / **CABGM** ___ / **CABGY** ___   **CABGDT**
  day   month   year
☐ [1] LVAD inserted → Date: **LVADD** ___ / **LVADM** ___ / **LVADY** ___   **LVADDT**
  day   month   year
☐ [1] Heart transplant → Date: **HTD** ___ / **HTM** ___ / **HTY** ___   **HTDT**
  day   month   year

* WHERE FORM = ENDOFSTUDY MATCH WITH End of Study Hospitalization page

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

STICH CRF_V3.0_24 JUL 2006   **2006 DCRI — Confidential**   Hospitalization
STICH CRF Annotation Version 10.1   21JUL2008

STICH

Death & Unexpected/Protocol Related SAE

SAE (TYPE 4)

1 Report type: RPTTYPE<STRTYP> 1 ☐ Initial 2 ☐ Follow-up → If Follow-up: #: _____ FUPNUM<I:3>

2 Site and patient number: ___ ___ ___ ___ - ___ ___ ___ ___ SUBJNO=INVSITE||PATID   Patient initials: ___ ___ ___ INITIALS<V:3> first middle last   Date and time received at DCRI:

3 Stratum assessment for randomized patients (check only one) STRATUM<STSTRA><I:3>
1 ☐ Stratum A (MED vs CABG)   2 ☐ Stratum B (MED vs CABG vs CABG & SVR)   3 ☐ Stratum C (CABG vs CABG & SVR)

4 Did the patient have randomized surgery: RANDSURG<ZYESNO> 0 ☐ No 1 ☐ Yes → Date of randomized surgery: SURGDT<DATE> ___/___/___ day month year

5 Serious reporting criteria (check all that apply):
☐ Death → If Death: Complete and fax the End of Study form along with this DEATH<ZYES>
Death & Unexpected/Protocol Related SAE form to DCRI Safety Surveillance at (919) 668-7138.
Was the death related to unexpected/protocol related SAE?
0 ☐ No → Complete #10 and 11. DEATHREL<ZYESNO>
1 ☐ Yes → Complete all sections below.
☐ Life-threatening LFTHREAT<ZYES>
☐ Prolonged or required hospitalization PROLONG<ZYES>
☐ Resulted in a persistent or significant disability/incapacity PERSDIS<ZYES>
☐ Other significant event requiring medical and/or surgical intervention OTHEVENT<ZYES>

6 SAE term: SAETERM<STTERM><I:3>
1 ☐ Major disabling stroke
2 ☐ Ventricular rupture
3 ☐ New ventricular septal defect
4 ☐ New acute renal failure requiring dialysis
5 ☐ Peripheral arterial embolization requiring surgery or PCI
98 ☐ Other (specify): ___ SAEOTH<V:200> _____

DCRI MEDRA
MEDRTEXT<V:100>
MEDRCODE<V:8>
WORKFLOW<V:5>
CODETM <DATETIME>
CODER<V:20>
CONFLVL <V:2>
MATCHES <V:4>

7 SAE onset date: SAEDT<DATE> ___/___/___ day month year

8 Outcome (check only one): OUTCOM<STRESL><I:3>
1 ☐ Resolved – no sequelae 2 ☐ Resolved with sequelae 3 ☐ Unresolved 4 ☐ Death

9 Date of outcome: OUTCOMDT<DATE> ___/___/___ day month year

10 Narrative (include relationship to study, relevant lab tests and patient history). Please use an additional page for narrative, if needed.
NOT ENTERED
_____
_____
_____
_____
_____
_____

SIGNATUR (Type 4)

11 Information Source:
Person completing: NOT ENTERED _____
Telephone #: (NOT ENTERED ___ ___ ___) ___ ___ ___ - ___ ___ ___ ___   Fax #: (NOT ENTERED ___ ___ ___) ___ ___ ___ - ___ ___ ___ ___
PI name: NOT ENTERED _____
PI signature: SIGNANS<ZYES> _____   Date of signature: SIGDT<DATE> ___/___/___ day month year

Fax this Report to DCRI Safety Surveillance (919) 668-7138

STICH

Death & Unexpected/Protocol Related SAE

12 Report type: ☐ Initial ☐ Follow-up → If Follow-up: # _____

13 Site and patient number: ___ ___ ___ ___ - ___ ___ ___ ___   Patient initials: ___ ___ ___
<u>first middle last</u>

Date and time received at DCRI:

14 Additional narrative *(please provide any additional information)*:

_____
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STICH

Clinical Events Classifications—Death Form

SUBJNO=INVSITE||PATID

INITIALS
<V:3>

Site Number: __ __ __   Patient Number: __ __ __ __   Patient's Initials: __ __ __

TYPEDT<STTYPE>

Enter this page: ☐

Review Type: ☐₁ Phase 1   ☐₂ Phase 2   ☐₃ Full Committee   ☐₄ QA   ☐₅ Re-review

NOT TO BE ENTERED

Reviewer codes: __I:2__ / __I:2__

Death

1 Date of death: __DETHDT<DATE>__
day / month / year.

REVONE   REVTWO

DEATH(TYPE 1)

CECFORM I:2
<STVIST>

2 Cause of death (check only one):

DTHCAU<STCAU>

☐₁ Cardiovascular death → Check only one:

DNUMDETH<I:6>

  ☐₁ Sudden death → Check only one:
    ☐₁ VT/Vf
    ☐₂ Bradyarrhythmia
    ☐₉₉ Unknown

CARD<STCADT>   SUDDTH<STSUD>

  ☐₂ Fatal pump failure
  ☐₃ Fatal myocardial infarction
  ☐₄ Fatal CVA
  ☐₅ Cardiovascular procedure → Check all that apply:
    ☐ PCI
    ☐ CABG
    ☐ Surgical ventricular restoration and CABG
    ☐ ICD/Bi-ventricular pacemaker
    ☐ Other (specify)

PCIDTH<ZYES>
CABGDTH<ZYES>
SVR<ZYES>
ICDDTH<ZYES>
OTH<ZYES>

SPECIFY<V:200>

  ☐₉₈ Other cardiac (specify):

OTHSP<V:200>

☐₃ Vascular death → Check only one:

VASDTH<STVASC>

  ☐₁ Peripheral vascular disease
  ☐₂ Peripheral emboli
  ☐₃ Vascular complication
  ☐₄ Venous thrombosis
  ☐₉₈ Other vascular (specify).

VASCSP<V:200>

☐₂ Non-cardiovascular death → Check all that apply:
  ☐ Infection
  ☐ Neurologic
  ☐ Pulmonary
  ☐ Renal
  ☐ Malignancy
  ☐ Other (specify):

INF<ZYES>
NEURO<ZYES>
PULMO<ZYES>
RENALDTH<ZYES>
MALIGDTH<ZYES>
OTHER<ZYES>

SPEC<V:200>

☐₉₉ Unknown

[THIS SECTION WILL NOT

BE DATA ENTERED]
SIGNATUR (TYPE 4)

(ANNOTATION SAME AS
PAGE 3 OF CRF)

day / month / year

Confidential

CRF, page 1

CEC ANNOTATION VERSION 2.3 (021JUL2008)

STICH

Clinical Events Classifications—Hospitalization Form

SUBJNO=INVSITE||PATID

Site Number: __ __ __ __ __   Patient Number: __ __ __ __ __   Patient's Initials: <V:3> __

INITIALS

TYPEHS<STTYPE>

Review Type: ☐1 Phase 1   ☐2 Phase 2   ☐3 Full Committee   ☐4 QA   ☐5 Re-review

Enter this page: ☐

NOT TO BE ENTERED

Reviewer codes: __:2 __ / __ I:2 __

Hospitalization

1 Date of hospitalization: __ __ / __ __ / __ __   **HOSPDT**

CECHOSP(TYPE 4)

REVONE   REVTWO

2 Primary reason for admission (check only one):

☐1 Cardiovascular hospitalization → Check only one:

CECFORM I:2 <STVIST>

CHOSP<STHOSP>

☐1 New/worsening mitral regurgitation
☐2 Heart failure
☐3 Acute MI
☐4 Unstable angina
☐5 Stroke
☐6 TIA
☐ Arrhythmia → If arrhythmia: Check all that apply:

DNUMHOSP<I:6>

REASON<STREA>

☐ Sudden death without resuscitation   SUDDEN<ZYES>
☐ Sustained VT   SUSVTHS<ZYES>
☐ Syncope   SYNCHS<ZYES>
☐ Supraventricular arrhythmia   SVA<ZYES>

OR

STVIST
1=4MONTH, 2=8MONTH, 3=12MONTH,
4=16MONTH, 5=20MONTH, 6=24MONTH,
7=28MONTH, 8=32MONTH, 9=36MONTH,
10=40MONTH, 11=44MONTH, 12=48MONTH,
13=52MONTH, 14=56MONTH,15=ENDOFSTUDY,
16=MEDICAL, 17=18MONTH, 18=30MONTH,
19=42MONTH, 20=54MONTH, 21=60MONTH,
22=66MONTH, 23=72MONTH, 24=78MONTH,
25=84MONTH, 26=90MONTH, 27=96MONTH,
28=>96MONTH, 29=64MONTH, 30=68MONTH,
31=76MONTH, 32=80MONTH, 33=88MONTH,
34=92MONTH

...cedure: Check all that apply:

☐ Cardiac catheterization   CATH<ZYES>
☐ Pacemaker for heart rate   PACEHR<ZYES>
☐ Pacemaker for resynchronization   PACE<ZYES>
☐ PCI   PCIHS<ZYES>
☐ ICD implanted   ICDHS<ZYES>
☐ CABG   CABGHS<ZYES>
☐ LVAD inserted   LVADHS<ZYES>
☐ Heart transplant   TRANS<ZYES>
☐ Monitoring/adjustment of previously implanted ICD   MONADJ<ZYES
☐ Complications of cardiovascular procedure (check only one):   COMP<ZYES>
  ☐1 Cardiac
  ☐2 Noncardiac

CARDCMP<STCMPL>

☐3 Vascular → If vascular: Check only one:

OR

☐1 Peripheral vascular disease   ☐3 Vascular complication   ☐98 Other vascular
☐2 Peripheral emboli   ☐4 Venous thrombosis

VASCLR<STVASC>

☐ Non-cardiovascular hospitalization → If non-cardiovascular procedure: Check only one:

☐1 Gastrointestinal   ☐4 Pulmonary
OR ☐2 Infection   ☐5 Renal
☐3 Malignancy   ☐98 Other non-cardiovascular
☐99 Unknown

NONCD<STNCD>

Additional data needed: **[THIS SECTION WILL NOT BE DATA ENTERED]** _____   SIGNATUR(TYPE 4)

Reviewer's Signature

Reviewer's signature: _____   **ANNOTATION SAME AS PAGE 3 OF CRF**   Date: __ __ / __ __ / __ __

CEC ANNOTATION VERSION 2.3 (21JUL2008)

Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___   Patient's Initials: ___ ___ ___

Enter this page: ☐

Review Type: ☐₁ Phase 1   ☐₂ Phase 2   ☐₃ Full Committee   ☐₄ QA   ☐₅ Re-review

Reviewer codes: ___ ___ / ___ ___

Death

1 Date of death: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
day   month   year

2 Cause of death *(check only one)*:

☐₁ <u>Cardiovascular death</u> → **Check only one:**

    ☐₁ Sudden death → **Check only one:**

        ☐₁ VT/VF

        ☐₂ Bradyarrhythmia

        ☐₉₉ Unknown

    ☐₂ Fatal pump failure

    ☐₃ Fatal myocardial infarction

    ☐₄ Fatal CVA

    ☐₅ Cardiovascular procedure → **Check all that apply:**

        ☐ PCI

        ☐ CABG

        ☐ Surgical ventricular restoration and CABG

        ☐ ICD/Bi-ventricular pacemaker

        ☐ Other *(specify)*: _____

    ☐₉₈ Other cardiac *(specify)*: _____

☐₃ <u>Vascular death</u> → **Check only one:**

    ☐₁ Peripheral vascular disease

    ☐₂ Peripheral emboli

    ☐₃ Vascular complication

    ☐₄ Venous thrombosis

    ☐₉₈ Other vascular *(specify)*: _____

☐₂ <u>Non-cardiovascular death</u> → **Check all that apply:**

    ☐ Infection

    ☐ Neurologic

    ☐ Pulmonary

    ☐ Renal

    ☐ Malignancy

    ☐ Other *(specify)*: _____

☐₉₉ <u>Unknown</u>

Additional data needed: _____
_____
_____

Reviewer's Signature

Reviewer's signature: _____   Date: ___ ___ / ___ ___ / ___ ___ ___ ___
day   month   year

Clinical Events Classifications—Hospitalization Form

Site Number: __ __ __ __   Patient Number: __ __ __ __   Patient's Initials: __ __ __

Enter this page: ☐

Review Type: ☐₁ Phase 1   ☐₂ Phase 2   ☐₃ Full Committee   ☐₄ QA   ☐₅ Re-review

Reviewer codes: __ __ / __ __

Hospitalization

1 Date of hospitalization: __ __ / __ __ __ / __ __ __ __
    day   month   year

2 Primary reason for admission (check only one):

☐₁ <u>Cardiovascular</u> <u>hospitalization</u> → **Check only one:**

  ☐₁ New/worsening mitral regurgitation
  ☐₂ Heart failure
  ☐₃ Acute MI
  ☐₄ Unstable angina
  ☐₅ Stroke
  ☐₆ TIA
  ☐₆ Arrhythmia → **If arrhythmia: Check all that apply:**
        ☐ Sudden death without resuscitation
        ☐ Sustained VT
        ☐ Syncope
        ☐ Supraventricular arrhythmia

  OR

  ☐₉₈ Other cardiac
  ☐₇ Cardiovascular procedure → **If cardiovascular procedure: Check all that apply:**
        ☐ Cardiac catheterization
        ☐ Pacemaker for heart rate
        ☐ Pacemaker for resynchronization
        ☐ PCI
        ☐ ICD implanted
        ☐ CABG
        ☐ LVAD inserted
        ☐ Heart transplant
        ☐ Monitoring/adjustment of previously implanted ICD
        ☐ Complications of cardiovascular procedure (check only one):
            ☐₁ Cardiac
            ☐₂ Non-cardiac

☐₃ <u>Vascular</u> → **If vascular: Check only one:**
  ☐₁ Peripheral vascular disease   ☐₃ Vascular complication   ☐₉₈ Other vascular
  ☐₂ Peripheral emboli   ☐₄ Venous thrombosis

☐₂ <u>Non-cardiovascular</u> <u>hospitalization</u> → **If non-cardiovascular procedure: Check only one:**
  ☐₁ Gastrointestinal   ☐₄ Pulmonary
  ☐₂ Infection   ☐₅ Renal
  ☐₃ Malignancy   ☐₉₈ Other non-cardiovascular
☐₉₉ <u>Unknown</u>

Additional data needed: _____

Reviewer's Signature

Reviewer's signature: _____   Date: __ __ / __ __ __ / __ __ __ __
                                                                   day   month   year

TRACK(TYPE 1)

STICH

24-HOUR TRACKING FAX

SUBJNO=INVSITE||PATID

Site Number: __ __ __ __   Patient Number: __ __ __ __   Patient's Initials: __ __ __
                                                                            first middle last

BASELINE STUDIES INTENDED

1 Echo completion date:
(Required all strata)

ECHODT<DATE>
day   month   year

☐ Not done
ECHOND <ZYES>

2 Nuclear viability completion date:

NUCLDT<DATE>
day   month   year

☐ Not done
NUCLND <ZYES>

  • Stress/rest perfusion (optional):

STRESDT<DATE>
day   month   year

☐ Not done
STREND <ZYES>

3 What is your test for LVF?   ☐ CMR (preferred):

LVCMR<ZYES>

LVFCMRDT<DATE>
day   month   year

☐ Not done
CMRND <ZYES>

                                    ☐ Gated Spect:

LVSPECT<ZYES>

LVFGATDT<DATE>
day   month   year

☐ Not done
SPECND <ZYES>

                                    ☐ Echo:

LVECHO<ZYES>

LVFECHDT<DATE>
day   month   year

☐ Not done
LVFECHND <ZYES>

4 NCG Blood

  • Neurohormonal cytokines:

NEURODT<DATE>
day / month / year

☐ Not done
NEUROND <ZYES>

  • Genetics:

GENEDT<DATE>
day   month   year

☐ Not done
GENEND<ZYES>

ANCILL(TYPE 1)

ANCILLARY STUDY ENROLLMENT

Patient enrolled in the following Ancillary study: A. TEE: ☐ No   ☐ Yes   TEE<ZYESNO><I:3>

                                                      B. DECIPHER: ☐ No   ☐ Yes   DEC<ZYESNO><I:3>

                                                      C. NUCMR: ☐ No   ☐ Yes   NUC<ZYESNO><I:3>

Fax this tracking form within 24 hours following randomization to

Duke Clinical Research Institute

919-668-7100

STICH

SVR Report Form

Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___ - ___ ___ ___ ___   Patient's Initials: ___ ___ ___
first middle last

Required Information for Free Replacement of Commercial Devices

DEVICE (TYPE 1)

1 LV sizing device (check only one): ☐₁ None ☐₂ Balloon ☐₃ Somanetics
LVSIZE<STLVSZ><ZYES><I:3> ☐₄ Chase Medical → **Size:** ☐₁ 90 ☐₂ 100 ☐₃ 110 ☐₄ 120 ☐₅ 130 ☐₆ 140
CHMED<STSIZE><I:3>

2 LV volume (mL) (check only one): ☐₁ < 90 ☐₂ 90 ☐₃ 100 ☐₄ 110 ☐₅ 120 ☐₆ 130 ☐₇ 140 ☐₈ > 140
LVVOL<STVOL>

3 LV Patch for closure (check only one): ☐₁ None ☐₂ Fabric ☐₃ Autologous pericardium
LVPTCH<STPTCH><I:3> ☐₄ Preserved pericardium ☐₅ Somanetics

LONGAX<STLONG><I:3>
4 LV Patch long axis (cm) (check only one): ☐₁ < 2 ☐₂ 2 ☐₃ 3 ☐₄ 4 ☐₅ > 4

5 LV Patch short axis (cm) (check only one): ☐₁ < 1.5 ☐₂ 1.5 ☐₃ 2 ☐₄ 3 ☐₅ 4 ☐₆ > 4
SHRTAX<STSHRT><I:3>

Information to be Used to Refine Conduct of Operation

Operative Findings

LVWALL<STWALL><I:3>   REFINE (TYPE 1)

1 LV wall thickness at thinnest region (cm) (check only one): ☐₁ < 0.5 ☐₂ 0.5-1 ☐₃ 1.1-2 ☐₄ 2.1-3 ☐₅ > 3
CNTONE<STANT><I:3>

2 Percentage of anterior wall akinetic or dyskinetic (check only one): ☐₁ < 25 ☐₂ 25-50 ☐₃ >50
THROMB<ZYESNO><I:3>   PRESNT<STPRS><I:3>

3 Was thrombus present in LV? ☐₀ No ☐₁ Yes → If Yes: Check only one: ☐₁ Old/organized ☐₂ Recent/soft
                                                    Was thrombus removed? ☐₀ No ☐₁ Yes
SCAR<ZYESNO><I:3>   REMOVE<ZYESNO><I:3>

4 Was endocardial scar excised or cryoablated? ☐₀ No ☐₁ Yes

Intraoperative Echocardiogram Findings

INTRA (TYPE 1)

1 Was TEE performed before SVR?
☐₀ No   TEEPRE<ZYESNO><I:3>   CNTTWO<STANT><I:3>
☐₁ Yes → If Yes: **Percentage of anterior wall akinetic or dyskinetic** (check only one): ☐₁ < 25 ☐₂ 25-50 ☐₃ >50
                  Mitral regurgitation (check only one): ☐₁ None ☐₂ Trace ☐₃ 1+ ☐₄ 2+ ☐₅ 3+ ☐₆ 4+
MTRONE<STRGRG><I:3>
2 Was TEE performed after SVR?   POSTEE<ZYESNO><I:3>
☐₀ No   CNTHRE<STANT><I:3>
☐₁ Yes → If Yes: **Percentage of anterior wall akinetic or dyskinetic** (check only one): ☐₁ < 25 ☐₂ 25-50 ☐₃ >50
                  Mitral regurgitation (check only one): ☐₁ None ☐₂ Trace ☐₃ 1+ ☐₄ 2+ ☐₅ 3+ ☐₆ 4+
MTRTWO<STRGRG><I:3>

If pre and postoperative ECHO performed, complete questions 3 and 4.

3 Estimated EF change (post-EF .XX – pre-EF .XX) (check only one): ☐₀ < .00 ☐₁ .00 ☐₂ .05 ☐₃ .10 ☐₄ .15 ☐₅ .20 ☐₆ > .20
EFCHG<STCHNG><I:3>

4 Estimated % EDV change $\left(\frac{\text{post-EDV} - \text{pre-EDV}}{\text{pre-EDV}} \times 100\right)$ (check only one): ☐₀ < 0 ☐₁ 0 ☐₂ 10 ☐₃ 20 ☐₄ 30 ☐₅ 40 ☐₆ > 40
EDVCHG<STEDV><I:3>

Plan for Postoperative Anticoagulation Treatment

POSTOP(TYPE 1)
ASPIRIN <ZYES><I:3> PLTINHIB <ZYES><I:3> WARF <ZYES><I:3> HEP <ZYES><I:3> NONE <ZYES><I:3>
1 Check all that apply: ☐ Aspirin ☐ Other platelet inhibitors ☐ Warfarin ☐ Heparin ☐ None

2 Planned months of postoperative anticoagulation treatment (check only one): ☐₁ 0 ☐₂ < 3 ☐₃ 3-12 ☐₄ > 12
TRMNT<STTRT><I:3>

Investigator Signature

SIGNATUR(TYPE 4)

I have reviewed all of the data recorded here and certify that they are accurate and complete to the best of my knowledge.

SIGNANS<ZYES><I:3>
Investigator Signature: _____   Date: ___ ___ / ___ ___ / ___ ___
SIGDT   day   month   year
SIGD/SIGM/SIGY

Fax this form to Duke Clinical Research Institute at 919-668-7100

STICH CRF Annotation Version 10.1   21JUL2008

PROTOCOL=STICH **NODATA<I:3><ZYES>**
STUDY BOOK=STICH **CONTEXT**
FORM=REGISTRY

SUBJNO=INVSITE||PATID

Site Number: __ __ __ Patient Number: __ __ __ __ - __ __ __ __ Patient's Initials: ___ ___ ___
first middle last

Patient Status

THIS IS A REPEATING PAGE (Visits as noted)

VSIT<STVIS>I:3

☐₁ 4 month
☐₂ 1 year
☐₉₈ Other

PTSTAT(TYPE4)

1 Interview date: __ __ /INVIEWDT/__ __ __ __
day   month   year

2 Person interviewed: ☐₁ Patient   PERSON<STPRNT><I:3>
☐₂ Spouse
☐₉₈ Other *(specify)*: ____SPE<V:60>_____

3 Patient status: ☐₁ Alive   PTSTAT<STPTST><I:3>

STATDT

☐₂ Dead → Date of death: __ __ /__ __ __ /__ __ __ __
day   month   year

☐₃ Lost to follow-up → Date last known alive: __ __ /__ __ /__ __ __ __
day   month   year

☐₄ Withdrawn from study → Date last known alive: __ __ /__ __ /__ __ __ __
day   month   year

Activity Status

ACTSTAT(TYPE4)

☐₉₉ Unknown   ACT<ZYES><I:3>

1 Over the past month, how are you feeling compared to when you signed up to participate in STICH?
☐₁ Much better   ☐₂ A little better   ☐₃ The same   ☐₄ A little worse   ☐₅ A lot worse
FEEL<STCMPR><I:3>

2 Do you have chest or arm discomfort that you think is caused by your heart?
☐₀ No   DISCOMFT<ZYESNO ><I:3>   YDISC<STDISC><I:3>
☐₁ Yes → If Yes: How often: ☐₁ Once a month or less   ☐₂ Once a week   ☐₃ Once a day or more

3 Do you have any limits to your activity?
☐₀ No
☐₁ Yes   LIMITS<ZYNUNK><I:3>
☐₉₉ Unknown

4 What is the main limit to your activity?
☐₁ Chest/arm discomfort
☐₂ Fatigue
☐₃ Shortness of breath   MAINLIM<STACT><I:3>
☐₄ Pain in the calves or thighs
☐₅ Joint or back pain
☐₉₈ Other *(specify)*: _____SPEC<V:60>_____

5 Are you able to get dressed without stopping to rest?
☐₀ No
☐₁ Yes   DRESS<ZYESNO><I:3>

6 How many blocks can you walk without stopping? __ __ __ blocks   BLOCKS<I:3>

STICH Registry Annotation version 2.0   9MAY2005

Registry

Current Medications/Enrollment Information

Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___ - ___ ___ ___ ___   Patient's Initials: ___ ___ ___
first middle last

Current Medications

CRMEDS(TYPE4)

List all current medications taken since enrollment into the Registry.

☐ 0 None taken   NONE<ZYES> <I:3>

☐ 99 Unknown/not provided   UNK<ZYES><I:3>

1 Aspirin: ☐ 0 No ☐ 1 Yes ASPIRN<ZYESNO><I:3>	**16**	
2 NSAIDS: ☐ 0 No ☐ 1 Yes NSAIDS<ZYESNO><I:3>	**17**	
3 CMED<V:20>	**18**	CURMED(TYPE4)R
4	**19**	
5	**20**	
6	**21**	
7	**22**	
8	**23**	
9	**24**	
10	**25**	
11	**26**	
12	**27**	
13	**28**	
14	**29**	
15	**30**	

SEQNO <I:2>

Medical Utilization

MEDUTIL(TYPE4)

☐ 99 Unknown   UNKONE<ZYES><I:3>

1 Registry enrollment date: ___ ___ / ___ ___ / ___ ___ ___ ___   REGENRDT
day   month   year
OR ☐ 99 Unknown   UNK<ZYES><I:3>

2 Were you in the hospital at the time of enrollment into the Registry (first contact only)?

☐ 0 No   HOSENR<ZYESNO><I:3>

☐ 1 Yes → If Yes: Complete the Hospitalization Form and check the box for Baseline.

3 Since enrollment or last contact, have you been hospitalized for > 24 hours since enrollment into Registry?

(includes ED visits > 24 hrs)

☐ 0 No   HOSGRT<ZYESNO><I:3>

☐ 1 Yes → If Yes: Number of hospitalizations? _____   HOSNUM<1:2>   (complete Hospitalization Form for each and check the box for Subsequent)

4 Since enrollment or last contact, have you been admitted to a nursing home/rehabilitation facility?

☐ 0 No   HOSADM<ZYESNO><I:3>

☐ 1 Yes → If Yes: Number of admissions? _____   ADMNUM<1:2>   (complete Hospitalization Form for each and check the box for Subsequent)

STICH Registry Annotation version 2.0 9MAY2004

STICH

Site Number: ___ ___ ___ ___   Patient Number: ___ ___ ___ ___ - ___ ___ ___ ___   Patient's Initials: ___ ___ ___
first middle last

Follow-up Hospitalization

1 Date of admission: ___ ___ / ___ ___ / ___ ___ ___ ___ → □₁ Hospital OR □₂ Rehab/nursing home
day   month   year

ADMTDT

TYPADM<STADM><I:3>

□₁ Baseline
OR ADMTYP<STTY><I:3>
□₂ Subsequent

ADMISS(TYPE4)

2 Was this admission for heart-related problems (check only one)?

□₀ No → If No: Reason for admission (check all that apply) (caller to classify involved system from the patient's answers):

□ Stroke STROKE<ZYES>

□ Blood clot → □ Leg □ Lung □ Other (specify): _____ SPECI<V:30>
BLDCLT<ZYES>   BCLOT<STCLOT> 1=LEG   2=LUNG   3=OTHER
□ Gastrointestinal (stomach, gall bladder, liver, pancreas, colon)   GASTRO<ZYES>
□ Infection □ Cancer □ Pulmonary (lung) □ Renal (kidney)
INFECT<ZYES> CANC<ZYES> PULM<ZYES> RENAL<ZYES>
□ Other (specify) _____   SPECIF<V:200>
OTHER<ZYES>

□₁ Yes → If Yes: Reason for admission (check all that apply):

□ Heart failure, kidney failure, or fluid retention   □ Chest pain CHEST<ZYES>
HFAIL<ZYES>
□ Shortness of breath   □ Losing consciousness LOSING <ZYES>
SOB<ZYES>
□ **Heart-related** (but do not know more   ADMPRB>ZYNUNK><I:3>
RELATE<ZYES>
□ Heart rhythm problem, including related to pacemaker or defibrillator
RHYTHM<ZYES>
□ Planned procedure only (proceed to question 4 below)
PROCED<ZYES>

□₉₉ Unknown

3 Did you have any heart problems diagnosed during the admission? DIAG<ZYNUNK><I:3>

□₀ No
□₁ Yes → If Yes: Check all that apply: MI<ZYES>
□ Heart attack (myocardial infarction, MI)   □ Heart failure HRTFL<ZYES>
□ Stroke STR<ZYES>   □ Fast heart rhythm requiring shock
□ **Heart problem** (do not know what kind)   FASTRH<ZYES>
HPROB<ZYES
□ Cardiac procedure (proceed to question 4 below)
CARDPR<ZYES>

□₉₉ Unknown

HRTPROCS(TYPE4)

4 Did you have any heart procedures during this admission?

□₀ No HPROC<ZYESNO><I:3>
□₁ Yes → If Yes: Check all appropriate responses below for each procedure listed:

	No	Yes	Unknown
CATH<ZYNUNK><I:3> Cardiac catheterization (heart catheterization):	□₀ No	□₁ Yes	□₉₉ Unknown
ANGIO<ZYNUNK><I:3> Balloon angioplasty (PTCA, PCI, or stent):	□₀ No	□₁ Yes	□₉₉ Unknown
CABG<ZYNUNK><I:3> Heart bypass surgery (CABG):	□₀ No	□₁ Yes	□₉₉ Unknown
→ If Yes: Did procedure include ventricular restoration? YESCBG<ZYNUNK><I:3>	□₀ No	□₁ Yes	□₉₉ Unknown
VENRES<ZYNUNK><I:3> Heart valve surgery:	□₀ No	□₁ Yes	□₉₉ Unknown
LVAD<ZYNUNK><I:3> LVAD:	□₀ No	□₁ Yes	□₉₉ Unknown
TRNSPLT<ZYNUNK><I:3> Heart transplant:	□₀ No	□₁ Yes	□₉₉ Unknown
ICD<ZYNUNK><I:3> Defibrillator/ICD Implantation:	□₀ No	□₁ Yes	□₉₉ Unknown
→ If Yes: Bi-V, resynchronization, or extra lead for left: YESICD<ZYNUNK><I:3>	□₀ No	□₁ Yes	□₉₉ Unknown
PACEMK<ZYNUNK><I:3> Pacemaker for heart rate:	□₀ No	□₁ Yes	□₉₉ Unknown
→ If Yes: Bi-V, resynchronization, or extra lead for left: YESPAC<ZYNUNK><I:3>	□₀ No	□₁ Yes	□₉₉ Unknown

Other heart surgery (specify): _____ SPECIFY<V:60>

STICH

EQOL Summary

Randomization Date: __ __ / __ __ __ / __ __ __ __
d d   m m m   y y y y

---

qstatus **FINAL QUESTIONNAIRE STATUS:**

- ☐₁ Complete
- ☐₂ Incomplete → → → → → → → → → →
- ☐₃ Not Done → → → → → → → → → →

infosrc **SOURCE OF INFORMATION:**

- ☐₁ Patient
- ☐₂ Proxy
- ☐₃ Translator Interview
- ☐₄ Medical record

admntype **TYPE OF ADMINISTRATION:**

- ☐₁ In person
- ☐₂ Phone
- ☐₃ Mail

residenc **RESIDENCE** (of pt at time Summary Completed)**:**

- ☐₁ Community / Outpatient Clinic
- ☐₂ Acute Care (in-pt hosp) → **Admission Date:** __ __ / __ __ __ / __ __ __ __ **admissdt**
  d d   m m m   y y y y

INTERVIEWER: **intrvwr** ____ ____ ____

missreas **REASON FOR <u>INCOMPLETE OR NOT DONE</u>:**

- ☐₁ Patient Died; Date of Death __ __ / __ __ __ / __ __ __ __ **dieddt**
  d d   m m m   y y y y
- ☐₂ Patient too ill or deaf
- ☐₃ Patient unreliable
- ☐₄ Language barrier
- ☐₅ Situation not conducive for phone call
- ☐₆ Patient refused
- ☐₇ Other: Specify: _____ **missoth**

8 *Unable to locate / contact* _____

COMMENTS: **comment** _____

_____

_____

_____

_____

Do Not Complete Below This Line: Duke EQOL Use Only

JOB CLASS: **jobclass**

- ☐₁ Exec/Managerial
- ☐₂ Tech/Sales/Clerical
- ☐₃ Service
- ☐₄ Farm/Forestry
- ☐₅ Prod/Prec/Repair
- ☐₆ Operator/Laborer
- ☐ DK

Summary Form Entered: Date:___/___/_____ Initials: _____

Questionnaire Entered: Date:___/___/_____ Initials: _____

**Submit original in the Confidential Patient Envelope
to the Duke Clinical Research Institute (retain copy at site).**

PDF created with FinePrint pdfFactory trial version http://www.fineprint.com

STICH

EQOL Questionnaire

The following questions are about your overall health and recent activities. Please check (✓) your choice for each question. The numbers beside each answer are there simply to help us record the information. Do not worry about them. Answer each question as best you can. This information is <u>confidential and will not be released to anyone without your permission</u>.

TODAY'S DATE: qxdt __ __ / __ __ __ / __ __ __ __   *[Example: 01/Nov/2002]*
d d   m m m   y y y y

sfgenhl12 **1. In general, would you say your health is:** (SF-12 GH) SF 36 number 1
- ☐₁ Excellent
- ☐₂ Very Good
- ☐₃ Good
- ☐₄ Fair
- ☐₅ Poor

2. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? SF-36 number 3

		Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
sfactmod12 a.	**Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf . B (SF-12 PF)	1	2	3
sfactsts12 b.	Climbing **several** flights of stairs D (SF-12 PF)	1	2	3

The next questions are about your work and daily activities.

wrkstat **3. Which <u>one</u> of the following best describes your current working status?** *(BARI)*
- ☐₁ Working full-time
- ☐₂ Working part-time
- ☐₃ On short-term sick leave
- ☐₄ On long-term sick leave (at least three months)
- ☐₅ Temporarily laid off
- ☐₆ Homemaker → → → → → → → → → → →
- ☐₇ Disabled → → → → → → → → → → → →
- ☐₈ Unemployed or looking for work→ → → → →
- ☐₉ Retired → → → → → → → → → → → →
- ☐₁₀ Other *Please specify:* wrkothr _____

┌───┐
│ **Did you ever work for pay?** wrkever   │
│   │
│ ☐₁Yes ➔ **When did you stop?** wrkstpdt   │
│   __ __ / __ __ __ / __ __ __ __   │
│   d d   m m m   y y y y   │
│ ☐₂ No ➔ **SKIP to Question 9**   │
│   │
│ **Is this date <u>within the past 6 months</u>?** wrk6mos │
│   │
│ ☐₁Yes   │
│ ☐₂ No ➔ **SKIP to Question 9**   │
│   BASE ONLY ALL ITEMS   │
└───┘

wrkretrn **4. Are you planning to return to work?** *(BARI)*
BASE ONLY
- ☐₁ Yes
- ☐₂ No
- ☐₃ DK

5. **What kind of work did you do for pay in the past six months?**

Main Job: <u>wrkmnjob</u>   **BASE ONLY** *(BARI)* _____

6. **What were the most important activities or duties of your main job?**

Examples: Drive truck, Operate tool and dye machine, Supervise road crew.

<u>wrkduty</u>   **BASE ONLY** *(BARI)* _____

wrkhowpd 7. **Which best describes how you are (or were) paid?** *(BARI)*

BASE ONLY
- ❏₁ Hourly wages
- ❏₂ Annual/Monthly salary
- ❏₃ Work on commission or tips
- ❏₄ Self-employed on own business, professional practice or farm
- ❏₅ Work in family business or farm

8. **During the time you worked, how many hours per week did you usually work at your job?**

(BARI)   **BASE ONLY**   # <u>wrknhrs</u>

SF-36 number 4

9. **During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?**   (circle one number on each line)

		Yes	No
sfphcutw	a. Cut down on the **amount of time** you spent on work or other activities (SF-36 RP)	1	2
sfphaccl12	b. **Accomplished less** than you would like (SF-12 RP)	1	2
sf___nt12	c. Were limited in the **kind** of work or other activities (SF-12 RP)	1	2
sfphdiff	d. Had **difficulty** performing the work or other activities (for example, it took extra effort) (SF-36 RP)	1	2

The next questions refer to your heart failure and how it may affect your life. **KCCQ number 1**

10. **Heart failure affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by heart failure (shortness of breath or fatigue) in your ability to do the following activities over the past 2 weeks.**

(Kansas City Cardiomyopathy Questionnaire; KCCQ)		Extremely Limited	Quite a bit Limited	Moderately Limited	Slightly Limited	Not at all Limited	Limited for other reasons or did not do the activity
kcdress	a. Dressing yourself	1	2	3	4	5	6
kcshowr	b. Showering/Bathing	1	2	3	4	5	6
kcwalk	c. Walking 1 block on level ground	1	2	3	4	5	6
kchouswk	d. Doing yardwork, housework or carrying groceries	1	2	3	4	5	6
kcstrs	e. Climbing a flight of stairs without stopping	1	2	3	4	5	6
kchuryng	f. Hurrying or jogging (as if to catch a bus)	1	2	3	4	5	6

fsymp **11. Compared with 2 weeks ago, have your symptoms of *heart failure* (shortness of breath, fatigue, or ankle swelling) changed?** (KCCQ) number 2

My symptoms of *heart failure* have become…
- ❑₁ Much worse
- ❑₂ Slightly worse
- ❑₃ Not changed
- ❑₄ Slightly better
- ❑₅ Much better
- ❑₆ I've had no symptoms over the past 2 weeks

kcswln **12. Over the past 2 weeks, how many times did you have *swelling* in your feet, ankles or legs when you woke up in the morning?** (KCCQ) number 3
- ❑₁ Every morning
- ❑₂ 3 or more times a week, but not every day
- ❑₃ 1-2 times a week
- ❑₄ Less than once a week
- ❑₅ Never over the past 2 weeks

kcswlamt **13. Over the past 2 weeks, how much has *swelling* in your feet, ankles or legs bothered you?**
- ❑₁ **Extremely** bothersome   (KCCQ) number 4
- ❑₂ **Quite a bit** bothersome
- ❑₃ **Moderately** bothersome
- ❑₄ **Slightly** bothersome
- ❑₅ **Not at all** bothersome
- ❑₆ I've had **no swelling**

kcftgn **14. Over the past 2 weeks, on average, how many times has *fatigue* limited your ability to do what you want?** (KCCQ) number 5
- ❑₁ All of the time
- ❑₂ Several times per day
- ❑₃ At least once a day
- ❑₄ 3 or more times a week, but not every day
- ❑₅ 1-2 times per week
- ❑₆ Less than once a week
- ❑₇ Never over the past 2 weeks

kcftgamt **15. Over the past 2 weeks, how much has your *fatigue* bothered you?** (KCCQ) number 6
- ❑₁ **Extremely** bothersome
- ❑₂ **Quite a bit** bothersome
- ❑₃ **Moderately** bothersome
- ❑₄ **Slightly** bothersome
- ❑₅ **Not at all** bothersome
- ❑₆ I've had no **fatigue**

kcsbn   16. Over the <u>past 2 weeks</u>, on average, how many times has *shortness of breath* limited your
ability to do what you wanted? **(KCCQ) number 7**
- ❑₁ All of the time
- ❑₂ Several times per day
- ❑₃ At least once a day
- ❑₄ 3 or more times a week, but not every day
- ❑₅ 1-2 times per week
- ❑₆ Less than once a week
- ❑₇ Never over the past 2 weeks

kcsbamt 17. Over the <u>past 2 weeks</u>, how much has your *shortness of breath* bothered you? **(KCCQ) number 8**
- ❑₁ **Extremely** bothersome
- ❑₂ **Quite a bit** bothersome
- ❑₃ **Moderately** bothersome
- ❑₄ **Slightly** bothersome
- ❑₅ **Not at all** bothersome
- ❑₆ **I've had** no shortness of breath

kcsleep 18. Over the <u>past 2 weeks</u>, on average, how many times have you been forced to sleep sitting
up in a chair or with at least 3 pillows to prop you up because of *shortness of breath*?
- ❑₁ Every night **(KCCQ) number 9**
- ❑₂ 3 or more times a week, but not every day
- ❑₃ 1-2 times a week
- ❑₄ Less than once a week
- ❑₅ Never over the past 2 weeks

kcenjoy 19. Over the <u>past 2 weeks</u>, how much has your heart failure limited your enjoyment of life?
- ❑₁ It has **extremely** limited my enjoyment of life. **(KCCQ) number 12**
- ❑₂ It has limited my enjoyment of life **quite a bit**.
- ❑₃ It has **moderately** limited my enjoyment of life.
- ❑₄ It has **slightly** limited my enjoyment of life.
- ❑₅ It has **not limited** my enjoyment of life at all.

kcsatisf 20. If you had to spend the rest of your life with your heart failure the way it is <u>right now</u>, how
would you feel about this? **(KCCQ) number 13**
- ❑₁ Not at all satisfied
- ❑₂ Mostly dissatisfied
- ❑₃ Somewhat satisfied
- ❑₄ Mostly satisfied
- ❑₅ Completely satisfied

kcdumps 21. Over the <u>past 2 weeks</u>, how often have you felt discouraged or down in the dumps because
of your heart failure? **(KCCQ) number 14**
- ❑₁ I felt that way **all of the time**.
- ❑₂ I felt that way **most of the time**.
- ❑₃ I **occasionally** felt that way.
- ❑₄ I **rarely** felt that way.
- ❑₅ I **never** felt that way

22. **How much does your heart failure affect your lifestyle? Please indicate how your heart failure may have limited your participation in the following activities <u>over the past 2 weeks</u>.**
    (KCCQ) number 15

			Extremely Limited	Quite a bit Limited	Moderately Limited	Slightly Limited	Not at all Limited	Limited for other reasons or did not do the activity
kchobby	a.	Hobbies, recreational activities	1	2	3	4	5	6
kcchores	b.	Working or doing household chores	1	2	3	4	5	6
kcvisits	c.	Visiting family or friends out of your home	1	2	3	4	5	6
kcrelat	d.	Intimate relationships with loved ones	1	2	3	4	5	6

The following questions refer to your angina, chest pain or chest tightness:

sacpstrn 23. <u>Compared with 4 weeks ago</u>, how often do you have chest pain, chest tightness or angina when doing your *most strenuous* level of activity? **(Seattle Angina Questionnaire; SAQ) number 2**
I have had *chest pain, chest tightness*, or *angina*…
- ☐₁ **Much more** often
- ☐₂ **Slightly more** often
- ☐₃ About **the same**
- ☐₄ **Slightly less** often
- ☐₅ **Much less** often

sacpavg 24. **Over the <u>past 4 weeks</u>, on average, how many times have you had *chest pain, chest tightness*, or *angina*?**   (SAQ) number 3
I get *chest pain, chest tightness*, or *angina*…
- ☐₁ 4 or more times per day
- ☐₂ 1-3 times per day
- ☐₃ 3 or more times per week, but not every day
- ☐₄ 1-2 times per week
- ☐₅ Less than once a week
- ☐₆ None over the past 4 weeks

sanitros 25. **Over the <u>past 4 weeks</u>, how many times have you had to take nitros (nitroglycerin tablets) for your *chest pain, chest tightness*, or *angina*?**
I take nitros…. (SAQ) number 4
- ☐₁ 4 or more times per day
- ☐₂ 1-3 times per day
- ☐₃ 3 or more times per week, but not every day
- ☐₄ 1-2 times per week
- ☐₅ Less than once a week
- ☐₆ None over the past 4 weeks

saenjoy

26. Over the <u>past 4 weeks</u>, how much has your *chest pain, chest tightness, or angina* interfered with your enjoyment of life? (SAQ) number 9

- ☐₁ It has **severely** limited my enjoyment of life
- ☐₂ It has **moderately** limited my enjoyment of life
- ☐₃ It has **slightly** limited my enjoyment of life
- ☐₄ It has **barely** limited my enjoyment of life
- ☐₅ It has **not** limited my enjoyment of life

sasatisf

27. If you had to spend the rest of your life with your *chest pain, chest tightness, or angina* the way it is right now, how would you feel about that? (SAQ) number 10

- ☐₁ Not satisfied at all
- ☐₂ Mostly dissatisfied
- ☐₃ Somewhat satisfied
- ☐₄ Mostly satisfied
- ☐₅ Highly satisfied

saworry

28. How often do you worry that you may have a heart attack or die suddenly? (SAQ) number 11

- ☐₁ I **can't stop** worrying about it
- ☐₂ I **often** think or worry about it
- ☐₃ I **occasionally** worry about it
- ☐₄ I **rarely** think or worry about it
- ☐₅ I **never** think or worry about it

29. How confident are you that you know how or can: (circle one number on each line)
(Cardiac Self Efficacy: CSE)

		Not At All Confident	Somewhat Confident	Moderately Confident	Very Confident	Completely Confident
csecpact	a. Control your chest pain by changing your activity levels.	1	2	3	4	5
csesbact	b. Control your breathlessness by changing your activity levels	1	2	3	4	5
csecpmed	c. Control your chest pain by taking your medications.	1	2	3	4	5
csesbmed	d. Control your breathlessness by taking your medications.	1	2	3	4	5
csecallmd	e. When you should call or visit your doctor about your heart disease.	1	2	3	4	5
csemdkno	f. How to make your doctor understand your concerns about your heart.	1	2	3	4	5
csetkmed	g. How to take your cardiac medications.	1	2	3	4	5
csephys	h. How much physical activity is good for you. . .	1	2	3	4	5
csesocl	i. Maintain your usual social activities.	1	2	3	4	5
csefamly	j. Maintain your usual activities at home with your family	1	2	3	4	5
csewrk	k. Maintain your usual activities at work.	1	2	3	4	5
csesex	l. Maintain your sexual relationship with your spouse	1	2	3	4	5
csexer	m. Get regular aerobic exercise (work up a sweat and increase your heart rate).	1	2	3	4	5

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created 01/Mar/2001; revised 01/Nov/2002

sfpainin12 **30. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?** (SF-12 BP) SF 36 number 8
- ❑₁ Not at all
- ❑₂ A little bit
- ❑₃ Moderately
- ❑₄ Quite a bit
- ❑₅ Extremely

31. During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities as a result of any <u>emotional problems</u> (such as feeling depressed or anxious)? (circle one number on each line) SF-36 number 5

			<u>Yes</u>	<u>No</u>
sfemcutw	a.	Cut down the amount of time you spent on work or other activities (SF-36 RE)	1	2
sfemaccl12	b.	Accomplished less than you would like (SF-12 RE)	1	2
sfemslop12	c.	Didn't do work or other activities as carefully as usual (SF-12 RE)	1	2

sfextent **32. During the <u>past 4 weeks</u>, to what extent has your <u>physical health or emotional problems</u> interfered with your normal social activities with family, friends, neighbors, or groups?**
- ❑₁ Not at all **(SF-36 SF)** SF-36 number 6
- ❑₂ Slightly
- ❑₃ Moderately
- ❑₄ Quite a bit
- ❑₅ Extremely

33. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. SF-36 number 9

How much of the time . . .

		All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
sfflpep	a. did you feel full of pep? (SF-36 VT)	1	2	3	4	5	6
sfflnerv	b. have you been a very nervous person? (SF-36 MH)	1	2	3	4	5	6
sffldown	c. have you felt so down in the dumps nothing could cheer you up? (SF-36 MH)	1	2	3	4	5	6
sfflcalm12	d. have you felt calm and peaceful? (SF-12 MH)	1	2	3	4	5	6
sfflnrgy12	e. did you have a lot of energy? (SF-12 VT)	1	2	3	4	5	6
sfflblue12	f. have you felt downhearted and blue? (SF-12 MH)	1	2	3	4	5	6
sfflworn	g. did you feel worn out? (SF-36 VT)	1	2	3	4	5	6
sfflhapy	h. have you been a happy person? (SF-36 MH)	1	2	3	4	5	6
sffltird	i. did you feel tired? (SF-36 VT)	1	2	3	4	5	6

sfsocint12 **34. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, close relatives, etc.)?** (SF-12 SF) SF -36 number 10

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

35. Please choose an answer based on how you felt <u>in the week before</u> you were enrolled in STICH. (CES-D)

		Rarely or none of the time (< 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of the time (3-4 days)	Most or all of the time (5-7 days)
csdbothr	a. I was bothered by things that don't usually bother me.	1	2	3	4
csdappet	b. I did not feel like eating; my appetite was poor	1	2	3	4
csdblues	c. I felt that I could not shake off the blues even with help from my family or friends	1	2	3	4
csdgood	d. I felt that I was just as good as other people	1	2	3	4
csdmind	e. I had trouble keeping my mind on what I was doing . .	1	2	3	4
csddepre	f. I felt depressed	1	2	3	4
deffor	g. I felt that everything I did was an effort	1	2	3	4
csdfutur	h. I felt hopeful about the future	1	2	3	4
csdfail	i. I thought my life had been a failure	1	2	3	4
csdfear	j. I felt fearful.	1	2	3	4
csdrestl	k. My sleep was restless	1	2	3	4
csdhappy	l. I was happy	1	2	3	4
csdtalk	m. I talked less than usual	1	2	3	4
csdlonel	n. I felt lonely	1	2	3	4
csdunfri	o. People were unfriendly	1	2	3	4
csdenjoy	p. I enjoyed life	1	2	3	4
csdcrysp	q. I had crying spells	1	2	3	4
csdsad	r. I felt sad	1	2	3	4
csddislk	s. I felt people disliked me	1	2	3	4
csdgoing	t. I could not get "going"	1	2	3	4

36. On a scale of 0 to 100, with 0 being equal to death and 100 being equal to excellent health, what number best describes your state of health <u>in the past month?</u>

(Health Utility)   # rate100 _____

The next set of questions are about you and your household.

educatn_grp **37. What is the <u>highest grade (# of years)</u> you completed in school?** *(Circle one.)* (Demo)
BASE ONLY

    0

    1   2   3   4   5   6   7   8

    9   10   11   12   Equivalency Certificate

   13 14 15 16

   17 18 19 20   21+   EDUCATN_GRP [1= 0-8 (yrs); 2= 9-12 (yrs); 3= 13-16 (yrs); 4= 17+ (yrs)]

marstat **38. Are you presently:** (Demo)
BASE ONLY

❑₁ Married or living as married

❑₂ Divorced

❑₃ Separated

❑₄ Widowed

❑₅ Never Married

Finally, we would like to ask your total household income level. It will not affect your medical care in any way; it's strictly for demographic purposes for this study.

come **39. Roughly how much income from all sources (including earnings, pensions, investments, etc.) did your household have last year (before taxes)?** (Demo)
BASE ONLY

❑₁ $10,000 or less

❑₂ $10,001 to $20,000

❑₃ $20,001 to $30, 000

❑₄ $30,001 to $45,000

❑₅ $45,001 to $60,000

❑₆ $60,001 or greater

STICH

EQOL Follow-Up Questionnaire Summary

intervl
Follow-Up Interval: ☐ 4 months   ☐ 12 months   ☐ 24 months   ☐ 36 months

---

qstatus **FINAL QUESTIONNAIRE STATUS:**

☐₁ Complete
☐₂ Incomplete → → → → → → → → →
☐₃ Not Done → → → → → → → → →

infosrc **SOURCE OF INFORMATION:**

☐₁ Patient
☐₂ Proxy
☐₃ Translator Interview
☐₄ Medical record

admntype **TYPE OF ADMINISTRATION:**

☐₁ In person
☐₂ Phone
☐₃ Mail

denc **RESIDENCE** (of pt at time Summary Completed):

☐₁ Community / Outpatient Clinic
☐₂ Acute Care (in-pt hosp)
☐₃ Nursing Home
☐₄ Rehab Institution

INTERVIEWER: *intrvwr* ____ ____ ____

REASON FOR <u>INCOMPLETE OR NOT DONE</u>: *missreas*

☐₁ Patient Died; Date of Death __ __ / __ __ __ / __ __ __ __ *dieddt*
   d d   m m m   y y y y
☐₂ Patient too ill or deaf
☐₃ Patient unreliable
☐₄ Language barrier
☐₅ Situation not conducive for phone call
☐₆ Patient refused
☐₇ Other: Specify: ____ *missoth* ____
☐₈ Unable to locate/contact patient (UTL/UTC)

fustat **FOLLOW-UP STATUS IF UTL/UTC:** *fustatdt*   **FU ONLY**

FU ONLY ☐₁ Alive   Date Last Contact Alive: __ __ / __ __ __ / __ __ __ __
   d d   m m m   y y y y

☐₂ Unknown Date Last Contact Alive: __ __ / __ __ __ / __ __ __ __
   d d   m m m   y y y y

COMMENTS: *comment* _____
_____
_____
_____
_____

Do Not Complete Below This Line: Duke EQOL Use Only

Summary Form Entered: Date: ____ / ____ / ____   Initials: _____

Questionnaire Entered: Date: ____ / ____ / ____   Initials: _____

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EQOL Follow-Up Questionnaire

ON SUMMARY
Follow-Up Interval: ☐ 4 months   ☐ 12 months   ☐ 24 months   ☐ 36 months

---

The following questions are about your overall health and recent activities. Please check (✓) your choice for each question. The numbers beside each answer are there simply to help us record the information. Do not worry about them.   Answer each question as best you can. This information is __confidential and will not be released to anyone without your permission__.

TODAY'S DATE: __ __ / qxdt __ __ / __ __ __ __ [Example: 01/Nov /2002]
                     d d   m m m   y y y y

sfgenhl12 **1. In general, would you say your health is:** SF 36 number 1
    ☐₁ Excellent
    ☐₂ Very Good
    ☐₃ Good
    ☐₄ Fair
    ☐₅ Poor

2. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? SF-36 number 3

	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
sfactmod12 a. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf B	1	2	3
sfactsts12 b. Climbing **several** flights of stairs D	1	2	3

The next questions are about your work and daily activities. BARI

wrkstat **3. Which __one__ of the following best describes your current working status?**
    ☐₁ Working full-time
    ☐₂ Working part-time
    ☐₃ On short-term sick leave
    ☐₄ On long-term sick leave (at least three months)
    ☐₅ Temporarily laid off
    ☐₆ Homemaker
    ☐₇ Disabled
    ☐₈ Unemployed or looking for work
    ☐₉ Retired
    ☐₁₀ Other *Please specify:* wrkothr _____

4. <u>Since the time of last contact</u>, have you resumed working, stopped working or changed jobs or the type of work you do *(for example, work more or fewer hours, take a desk job, quit a second job, retire)*? *BARI*

wrkch

☐₁ Yes → → → → → →
☐₂ No

wrkchres

FU ONLY
For ALL
Question 4 Items

wrkchmor
wrkchfew
wrkchmstren
wrkchlstren
wrkchsck
wrkchoff
wrkchoth

What changed *(check as many as apply)*?

☐₁ Stopped working because of my health....Date: __ / ____ / ____ wrkchstphdt
  wrkchstph   d d   m m m   y y y y

☐₂ Stopped working for some other reason...Date: __ / ____ / ____ wrkchstpodt
  wrkchstpo   d d   m m m   y y y y

☐₃ Resumed working...............................Date: __ / ____ / ____ wrkchresdt
                                                    d d   m m m   y y y y

☐₄ Working more hours

☐₅ Working fewer hours

☐₆ Doing more strenuous work

☐₇ Doing less strenuous work

☐₈ Went on long or short term sick leave

☐₉ Temporarily laid off

☐₁₀ Other: _____ wrkchotx

---

5. **During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?** (circle one number on each line)
   SF-36, number 4

		Yes	No
hcutw	a. Cut down on the **amount of time** you spent on work or other activities	1	2
sfpnaccl12	b. **Accomplished less** than you would like	1	2
sfphlimt12	c. Were limited in the **kind** of work or other activities	1	2
sfphdiff	d. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

The next questions refer to your heart failure and how it may affect your life.

6. **Heart failure affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by heart failure (shortness of breath or fatigue) in your ability to do the following activities <u>over the past 2 weeks</u>.**
   KCCQ number 1

		Extremely Limited	Quite a bit Limited	Moderately Limited	Slightly Limited	Not at all Limited	Limited for other reasons or did not do the activity
kcdress	a. Dressing yourself	1	2	3	4	5	6
kcshowr	b. Showering/Bathing.	1	2	3	4	5	6
kcwalk	c. Walking 1 block on level ground. . .	1	2	3	4	5	6
kchouswk	d. Doing yardwork, housework or carrying groceries.	1	2	3	4	5	6
kcstrs	e. Climbing a flight of stairs without stopping	1	2	3	4	5	6
uryng	f. Hurrying or jogging (as if to catch a bus)	1	2	3	4	5	6

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ᐧfsymp **7.** **Compared with <u>2 weeks ago</u>, have your symptoms of *heart failure* (shortness of breath, fatigue, or ankle swelling) changed? KCCQ number 2**

    My symptoms of *heart failure* have become…

    ❏₁ Much worse
    ❏₂ Slightly worse
    ❏₃ Not changed
    ❏₄ Slightly better
    ❏₅ Much better
    ❏₆ I've had no symptoms over the past 2 weeks

kcswln **8.** **Over the <u>past 2 weeks</u>, how many times did you have *swelling* in your feet, ankles or legs when you woke up in the morning? KCCQ number 3**

    ❏₁ Every morning
    ❏₂ 3 or more times a week, but not every day
    ❏₃ 1-2 times a week
    ❏₄ Less than once a week
    ❏₅ Never over the past 2 weeks

kcswlamt **9.** **Over the <u>past 2 weeks</u>, how much has *swelling* in your feet, ankles or legs bothered you?**

    ❏₁ **Extremely** bothersome   **KCCQ number 4**
    ❏₂ **Quite a bit** bothersome
    ❏₃ **Moderately** bothersome
    ❏₄ **Slightly** bothersome
    ❏₅ **Not at all** bothersome
    ❏₆ I've had **no swelling**

kcftgn **10.** **Over the <u>past 2 weeks</u>, on average, how many times has *fatigue* limited your ability to do what you want? KCCQ number 5**

    ❏₁ All of the time
    ❏₂ Several times per day
    ❏₃ At least once a day
    ❏₄ 3 or more times a week, but not every day
    ❏₅ 1-2 times per week
    ❏₆ Less than once a week
    ❏₇ Never over the past 2 weeks

kcftgamt **11.** **Over the <u>past 2 weeks</u>, how much has your *fatigue* bothered you? KCCQ number 6**

    ❏₁ **Extremely** bothersome
    ❏₂ **Quite a bit** bothersome
    ❏₃ **Moderately** bothersome
    ❏₄ **Slightly** bothersome
    ❏₅ **Not at all** bothersome
    ❏₆ I've had **no fatigue**

kcsbn **12. Over the <u>past 2 weeks</u>, on average, how many times has *shortness of breath* limited your ability to do what you wanted?** KCCQ number 7
- ☐₁ All of the time
- ☐₂ Several times per day
- ☐₃ At least once a day
- ☐₄ 3 or more times a week, but not every day
- ☐₅ 1-2 times per week
- ☐₆ Less than once a week
- ☐₇ Never over the past 2 weeks

kcsbamt **13. Over the <u>past 2 weeks</u>, how much has your *shortness of breath* bothered you?** KCCQ number 8
- ☐₁ **Extremely** bothersome
- ☐₂ **Quite a bit** bothersome
- ☐₃ **Moderately** bothersome
- ☐₄ **Slightly** bothersome
- ☐₅ **Not at all** bothersome
- ☐₆ **I've had** no shortness of breath

kcsleep **14. Over the <u>past 2 weeks</u>, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of *shortness of breath*?** KCCQ number 9
- ☐₁ Every night
- ☐₂ 3 or more times a week, but not every day
- ☐₃ 1-2 times a week
- ☐₄ Less than once a week
- ☐₅ Never over the past 2 weeks

kcenjoy **15. Over the <u>past 2 weeks</u>, how much has your heart failure limited your enjoyment of life?**
- ☐₁ It has **extremely** limited my enjoyment of life. KCCQ number 12
- ☐₂ It has limited my enjoyment of life **quite a bit**.
- ☐₃ It has **moderately** limited my enjoyment of life.
- ☐₄ It has **slightly** limited my enjoyment of life.
- ☐₅ It has **not limited** my enjoyment of life at all.

kcsatisf **16. If you had to spend the rest of your life with your heart failure the way it is <u>right now</u>, how would you feel about this?** KCCQ number 13
- ☐₁ Not at all satisfied
- ☐₂ Mostly dissatisfied
- ☐₃ Somewhat satisfied
- ☐₄ Mostly satisfied
- ☐₅ Completely satisfied

kcdumps **17. Over the <u>past 2 weeks</u>, how often have you felt discouraged or down in the dumps because of your heart failure?** KCCQ number 14
- ☐₁ I felt that way **all of the time**.
- ☐₂ I felt that way **most of the time**.
- ☐₃ I **occasionally** felt that way.
- ☐₄ I **rarely** felt that way.
- ☐₅ I **never** felt that way

18. How much does your heart failure affect your lifestyle? Please indicate how your heart failure may have limited your participation in the following activities <u>over the past 2 weeks</u>.
KCCQ number 15

		Extremely Limited	Quite a bit Limited	Moderately Limited	Slightly Limited	Not at all Limited	Limited for other reasons or did not do the activity
kchobby	a. Hobbies, recreational activities	1	2	3	4	5	6
kcchores	b. Working or doing household chores	1	2	3	4	5	6
kcvisits	c. Visiting family or friends out of your home	1	2	3	4	5	6
kcrelat	d. Intimate relationships with loved ones	1	2	3	4	5	6

The following questions refer to your angina, chest pain or chest tightness:

sacpstrn 19. <u>Compared with 4 weeks ago</u>, how often do you have chest pain, chest tightness or angina when doing your *most strenuous* level of activity? SAQ question number 2
I have had *chest pain, chest tightness,* or *angina…*
- ☐₁ **Much more** often
- ☐₂ **Slightly more** often
- ☐₃ About **the same**
- ☐₄ **Slightly less** often
- ☐₅ **Much less** often
- ☐₆ I've had **no chest pain** over the last 4 weeks.

sacpavg 20. Over the <u>past 4 weeks</u>, on average, how many times have you had *chest pain, chest tightness,* or *angina*? SAQ question number 3
I get *chest pain, chest tightness,* or *angina…*
- ☐₁ 4 or more times per day
- ☐₂ 1-3 times per day
- ☐₃ 3 or more times per week, but not every day
- ☐₄ 1-2 times per week
- ☐₅ Less than once a week
- ☐₆ None over the past 4 weeks

sanitros 21. Over the <u>past 4 weeks</u>, how many times have you had to take nitros (nitroglycerin tablets) for your *chest pain, chest tightness,* or *angina*? SAQ question number 4
I take nitros….
- ☐₁ 4 or more times per day
- ☐₂ 1-3 times per day
- ☐₃ 3 or more times per week, but not every day
- ☐₄ 1-2 times per week
- ☐₅ Less than once a week
- ☐₆ None over the past 4 weeks

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saenjoy **22. Over the** <u>**past 4 weeks**</u>**, how much has your** *chest pain, chest tightness, or angina interfered* **with your enjoyment of life?** SAQ question number 9
- ☐₁ It has **severely** limited my enjoyment of life
- ☐₂ It has **moderately** limited my enjoyment of life
- ☐₃ It has **slightly** limited my enjoyment of life
- ☐₄ It has **barely** limited my enjoyment of life
- ☐₅ It has **not** limited my enjoyment of life

sasatisf **23. If you had to spend the rest of your life with your** *chest pain, chest tightness, or angina* **the way it is right now, how would you feel about that?** SAQ question number 10
- ☐₁ Not satisfied at all
- ☐₂ Mostly dissatisfied
- ☐₃ Somewhat satisfied
- ☐₄ Mostly satisfied
- ☐₅ Highly satisfied

saworry **24. How often do you worry that you may have a heart attack or die suddenly?** SAQ question number 11
- ☐₁ I **can't stop** worrying about it
- ☐₂ I **often** think or worry about it
- ☐₃ I **occasionally** worry about it
- ☐₄ I **rarely** think or worry about it
- ☐₅ I **never** think or worry about it

25. How confident are you that you know how or can: (circle one number on each line)
CSE

		Not At All Confident	Somewhat Confident	Moderately Confident	Very Confident	Completely Confident
cpact	a. Control your chest pain by changing your activity levels.	1	2	3	4	5
csesbact	b. Control your breathlessness by changing your activity levels	1	2	3	4	5
csecpmed	c. Control your chest pain by taking your medications.	1	2	3	4	5
csesbmed	d. Control your breathlessness by taking your medications.	1	2	3	4	5
csecallmd	e. When you should call or visit your doctor about your heart disease.	1	2	3	4	5
csemdkno	f. How to make your doctor understand your concerns about your heart.	1	2	3	4	5
csetkmed	g. How to take your cardiac medications.	1	2	3	4	5
csephys	h. How much physical activity is good for you.	1	2	3	4	5
csesocl	i. Maintain your usual social activities.	1	2	3	4	5
csefamly	j. Maintain your usual activities at home with your family	1	2	3	4	5
csewrk	k. Maintain your usual activities at work.	1	2	3	4	5
csesex	l. Maintain your sexual relationship with your spouse	1	2	3	4	5
exer	m. Get regular aerobic exercise (work up a sweat and increase your heart rate).	1	2	3	4	5

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sfpainin12   **26. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?** SF-36, number 8

- ❑₁   Not at all
- ❑₂   A little bit
- ❑₃   Moderately
- ❑₄   Quite a bit
- ❑₅   Extremely

27. During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities as a result of any <u>emotional problems</u> (such as feeling depressed or anxious)? (circle one number on each line) SF-36, number 5

		Yes	No
sfemcutw	a. Cut down the amount of time you spent on work or other activities	1	2
sfemaccl12	b. Accomplished less than you would like	1	2
sfemslop12	c. Didn't do work or other activities as carefully as usual	1	2

sfextent   **28. During the <u>past 4 weeks</u>, to what extent has your <u>physical health or emotional problems</u> interfered with your normal social activities with family, friends, neighbors, or groups?**

- ❑₁   Not at all   SF-36, number 6
- ❑₂   Slightly
- ❑₃   Moderately
- ❑₄   Quite a bit
- ❑₅   Extremely

29. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. SF-36, number 9

How much of the time . . .

		All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
sfflpep	a. did you feel full of pep?	1	2	3	4	5	6
sfflnerv	b. have you been a very nervous person? . . .	1	2	3	4	5	6
sffldown	c. have you felt so down in the dumps nothing could cheer you up?	1	2	3	4	5	6
sfflcalm12	d. have you felt calm and peaceful?	1	2	3	4	5	6
sfflnrgy12	e. did you have a lot of energy?	1	2	3	4	5	6
sfflblue12	f. have you felt downhearted and blue?.	1	2	3	4	5	6
sfflworn	g. did you feel worn out?	1	2	3	4	5	6
sfflhapy	h. have you been a happy person?	1	2	3	4	5	6
sffltird	i. did you feel tired?	1	2	3	4	5	6

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sfsocint12 **30. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, close relatives, etc.)?** *SF-36, number 10*

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

31. Please choose an answer based on how you felt <u>in the past week</u>. *CES*

		Rarely or none of the time (< 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of the time (3-4 days)	Most or all of the time (5-7 days)
csdbothr	a. I was bothered by things that don't usually bother me.	1	2	3	4
csdappet	b. I did not feel like eating; my appetite was poor	1	2	3	4
csdblues	c. I felt that I could not shake off the blues even with help from my family or friends	1	2	3	4
csdgood	d. I felt that I was just as good as other people	1	2	3	4
csdmind	e. I had trouble keeping my mind on what I was doing . .	1	2	3	4
csddepre	f. I felt depressed	1	2	3	4
deffor	g. I felt that everything I did was an effort	1	2	3	4
csdfutur	h. I felt hopeful about the future	1	2	3	4
csdfail	i. I thought my life had been a failure	1	2	3	4
csdfear	j. I felt fearful.	1	2	3	4
csdrestl	k. My sleep was restless	1	2	3	4
csdhappy	l. I was happy	1	2	3	4
csdtalk	m. I talked less than usual	1	2	3	4
csdlonel	n. I felt lonely	1	2	3	4
csdunfri	o. People were unfriendly	1	2	3	4
csdenjoy	p. I enjoyed life	1	2	3	4
csdcrysp	q. I had crying spells	1	2	3	4
csdsad	r. I felt sad	1	2	3	4
csddislk	s. I felt people disliked me	1	2	3	4
csdgoing	t. I could not get "going"	1	2	3	4

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32. On a scale of 0 to 100, with 0 being equal to death and 100 being equal to excellent health, what number best describes your state of health <u>in the past month</u>?

Health Utility

           # <u>rate100</u>

The next set of questions are about you and your household. DEMO

33. How many people, <u>including yourself</u>, live in your household? # <u>housenum</u> people

           FU ONLY

hsincml **34.** Is your current monthly household income more, less or about the same as a year ago?

FU ONLY   DEMO

- ❑₁ More
- ❑₂ Less
- ❑₃ About the same
- ❑₈ DK
- ❑₉ RF

hsincadq **35.** How well does your household's income meet your household's basic needs (i.e., food, clothing, shelter, and medical expenses, including medicines)? DEMO

FU ONLY

- ❑₁ Not at all
- ❑₂ Somewhat
- ❑₃ Adequately
- ❑₄ More than adequately
- ❑₈ DK
- ❑₉ RF

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EuroQoL Thermometer *(Have the patient complete this form at the beginning of the study visit.)*

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

We would like you to indicate on this scale how good or bad your own health is <u>today</u>, in your opinion. Please do this by <u>drawing a line from the box below to whichever point on the scale indicates how good or bad your current health state is.</u>

| Best imaginable health state |

| Your own health state <u>today</u> |

| Worst imaginable health state |
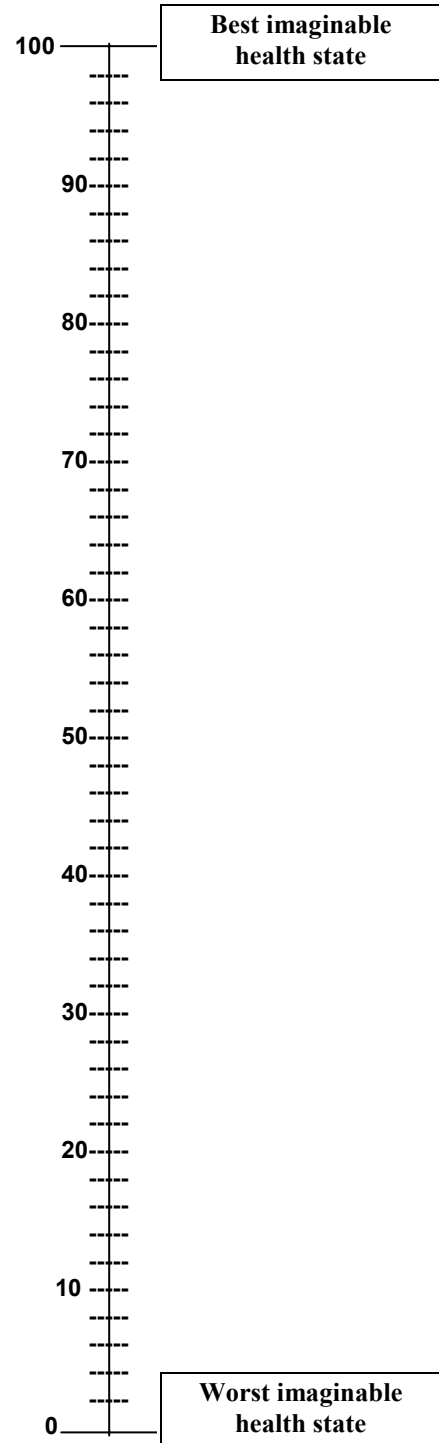
Response on the EuroQoL Thermometer: Eurothrm ___ ___ ___

Study coordinator initials: Euroinit ___ ___ ___

Complete the back side of this form.

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By placing a tick (☑) in one box in each group below, please indicate which statement best describes your own health state <u>today</u>.

Mobility: euromobl

1 ☐ I have no problems in walking about

2 ☐ I have some problems in walking about

3 ☐ I am confined to bed

Self-care: eurocare

1 ☐ I have no problems with self-care

2 ☐ I have some problems washing or dressing myself

3 ☐ I am unable to wash or dress myself

Usual activities *(i.e. work, study, housework, family or leisure activities):* euroactv

1 ☐ I have no problems with performing my usual activities

2 ☐ I have some problems with performing my usual activities

3 ☐ I am unable to perform my usual activities

Pain/Discomfort: europain

1 ☐ I have no pain or discomfort

2 ☐ I have moderate pain or discomfort

3 ☐ I have extreme pain or discomfort

Anxiety/Depression: eurodepn

1 ☐ I am not anxious or depressed

2 ☐ I am moderately anxious or depressed

3 ☐ I am extremely anxious or depressed

Complete the front side of this form.

**Submit this page with the Case Report Form to the
Duke Clinical Research Institute (retain copy at site).**