NETWORK FOR CT SURGICAL INVESTIGATIONS

EVALUATION OF OUTCOMES FOLLOWING MITRAL VALVE REPAIR/REPLACEMENT IN SEVERE CHRONIC ISCHEMIC MITRAL REGURGITATION

CASE REPORT FORMS

Patient I.D. ☐☐☐-☐☐-☐☐☐

1.	Date of Birth:	☐☐/☐☐☐/☐☐☐☐ d d m m m y y y y
2.	Sex (check one):	☐ Male ☐ Female
3.	Ethnic Category (check one):	☐ Hispanic or Latino ☐ Non-Hispanic or Non-Latino
4.	Racial Category (check one): ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White	

Patient I.D. ☐☐☐-☐☐-☐☐☐

Cardiovascular History		
1. Heart Failure	☐ No	☐ Yes
2. Myocardial Infarction	☐ No	☐ Yes
3. Family history of coronary artery disease	☐ No	☐ Yes
4. Hypertension	☐ No	☐ Yes
5. Dyslipidemia	☐ No	☐ Yes
6. Atrial Fibrillation	☐ No	☐ Yes
7. Ventricular arrhythmia	☐ No	☐ Yes
8. Diabetes	☐ No	☐ Yes
9. Infectious endocarditis	☐ No	☐ Yes
10. Peripheral arterial disease	☐ No	☐ Yes
11. Peripheral vascular disease	☐ No	☐ Yes
Cardiovascular Procedure History		
12. Coronary artery bypass (CABG)	☐ No	☐ Yes
13. PCI (Percutaneous Coronary Intervention)	☐ No	☐ Yes
14. ICD	☐ No	☐ Yes
15. Permanent Pacemaker	☐ No	☐ Yes
16. Cardiac transplant	☐ No	☐ Yes
17. Cardiomyoplasty	☐ No	☐ Yes
18. Left ventricular reduction surgery/ Aneurysmectomy	☐ No	☐ Yes
19. Number of prior sternotomies:	☐☐	
20. Congenital heart surgery	☐ No	☐ Yes
21. Valve Repair	☐ No	☐ Yes
22. Valve Replacement	☐ No	☐ Yes (If yes, indicate below)
Cerebrovascular History		
23. Cerebrovascular disease	☐ No	☐ Yes
24. Stroke	☐ No	☐ Yes
25. TIA (< 24 hours)	☐ No	☐ Yes
26. Carotid stenosis > 75%	☐ No	☐ Yes ☐ ~~Not tested~~
27. Prior carotid surgery	☐ No	☐ Yes
Other History (as defined as STS definition)		
28. Thyroid disease	☐ No	☐ Yes
29. Intrinsic liver disease	☐ No	☐ Yes
30. Renal insufficiency	☐ No	☐ Yes
31. Gastrointestinal bleeding	☐ No	☐ Yes
32. Malignancy	☐ No	☐ Yes
33. Chronic lung disease	☐ None ☐ Mild ☐ Moderate ☐ Severe	
34. Tobacco use	☐ No	☐ Yes
35. Major Depressive disorder or other psychiatric illness	☐ No	☐ Yes
Current Medical Condition		
36. Is the patient on an IABP?	☐ No	☐ Yes

Patient I.D. ☐☐☐-☐☐-☐☐☐☐

1. Date of Randomization ☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)	
2. Randomization Assignment	
☐ Mitral Valve Replacement	☐ Mitral Valve Repair

Patient I.D. ☐☐☐-☐☐-☐☐☐

Surgery Date: ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

Patient I.D. ☐☐☐-☐☐-☐☐☐

1. Was NYHA assessed?

☐ Yes

If yes, Test Date: ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

☐ No

2. Current NYHA Classification

☐Class I ☐ Class II ☐ Class III ☐Class IV

SMR23: TTE

1:1

Patient I.D. ☐☐☐-☐☐-☐☐☐

1.	Assessment timepoint :	☐ Baseline ☐ 6 mos post intervention	☐ 30 Day post intervention ☐ 12 mos post intervention ☐ 24 mos post intervention
2.	Was Echo performed? ☐No ☐Yes		
	If yes, test Date: ☐☐/☐☐☐/☐☐☐☐ (d d / m m m / y y y y)		
3.	**Mitral Valve Section**		
	Mitral regurgitation		
	a. EROA (PISA Method)	☐.☐☐ cm^2	
	b. Vena Contracta	☐☐.☐ mm	
	c. Integrative assessment of MR	☐ none ☐ mild ☐ severe	☐ trace ☐ moderate
4.	**Left Ventricle Section**		
	a. ESV_{Index}	☐☐☐.☐ml/ m^2	
	b. Left ventricular ejection fraction	☐ ☐ %	
	c. LV Sphericity (ED)	☐ .☐ ☐	

Patient I.D. ☐☐☐-☐☐-☐☐☐

Date completed: ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.
Remember to think about ONLY THE LAST MONTH.

Did your heart failure prevent you from living as you wanted **during the past month (4 weeks)** by. . .

	No	**Very Little**				**Very Much**
MLHF1. causing swelling in your ankles, legs?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF2. making you sit or lie down to rest during the day?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF3. making your walking about or climbing stairs difficult?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF4. making your working around the house or yard difficult?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF5. making your going places away from home difficult?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF6. making your sleeping well at night difficult?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF7. making your relating to or doing things with your friends or family difficult?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF8. making your working to earn a living difficult?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF9. making your recreational pastimes, sports, or hobbies difficult?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF10. making your sexual activities difficult?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF11. making you eat less of the foods you like?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF12. making you short of breath?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF13. making you tired, fatigued, or low energy?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF14. making you stay in a hospital?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF15. costing you money for medical care?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF16. giving you side effects from treatments?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF17. making you feel you are a burden to your family or friends?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF18. making you feel a loss of self-control in your life?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF19. making you worry?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF20. making it difficult for you to concentrate or remember things?	0 ☐	1☐	2☐	3☐	4☐	5☐
MLHF21. making you feel depressed?	0 ☐	1☐	2☐	3☐	4☐	5☐

Patient I.D. ☐☐☐-☐☐☐-☐☐ **Test Date:** ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

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

2. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐1	☐2	☐3
b. Climbing <u>several</u> flights of stairs	☐1	☐2	☐3

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

	Yes	No
a. <u>Accomplished less</u> than you would like	☐1	☐2
b. Were limited in the kind of work or other activities	☐1	☐2

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

	Yes	No
a. Accomplished less than you would like	☐1	☐2
b. Did work or other activities less carefully than usual	☐1	☐2

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

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

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

How much of the time during the past 4 weeks…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful?	☐1	☐2	☐3	☐4	☐5	☐6
b. Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5	☐6
c. Have you felt downhearted and blue?	☐1	☐2	☐3	☐4	☐5	☐6

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

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

Patient I.D. ☐☐☐-☐☐☐-☐☐ **Test Date:** ☐☐/☐☐☐/☐☐
d d m m m y y

Check <u>one</u> box for each of the following six health dimensions.

Mobility
I have no problems in walking about ❑
I have some problems in walking about ❑
I am confined to bed ❑

Self-Care
I have no problems with self-care ❑
I have some problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

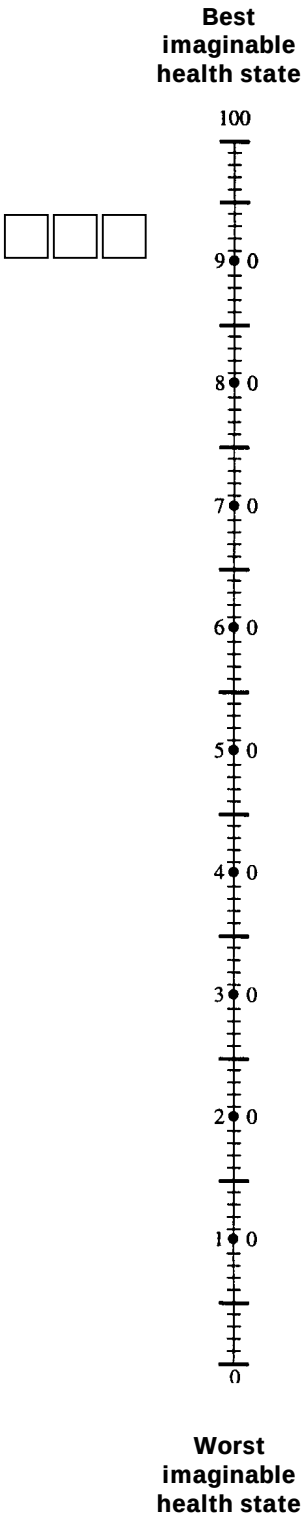
Usual Activities (*e.g. work, study, housework, family or leisure activities*)
I have no problems with performing my usual activities ❑
I have some problems with performing my usual activities ❑
I am unable to perform my usual activities ❑

Pain/Discomfort
I have no pain or discomfort ❑
I have moderate pain or discomfort ❑
I have extreme pain or discomfort ❑

Anxiety/Depression
I am not anxious or depressed ❑
I am moderately anxious or depressed ❑
I am extremely anxious or depressed ❑

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 is your own health today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your current health state is.



Your own health state today

Patient I.D. ☐☐☐-☐☐-☐☐☐☐

Date Completed: ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

Could you…	**Yes with no <u>difficulty</u>**	**Yes, but with some <u>difficulty</u>**	**No I couldn't <u>do this</u>**	**Don't do it for other <u>reasons</u>**
1. take care of yourself, that is, eating, dressing, bathing,and using the toilet?	☐	☐	☐	☐
2. walk indoors, such as around your house?	☐	☐	☐	☐
3. walk a block or two on level ground?	☐	☐	☐	☐
4. climb a flight of stairs or walk up a hill?	☐	☐	☐	☐
5. run a short distance?	☐	☐	☐	☐
6. do light work around the house like dusting or washing dishes?	☐	☐	☐	☐
7. do moderate work around the house like vacuuming, sweeping floors, or carrying in groceries?	☐	☐	☐	☐
8. do heavy work around the house like scrubbing floors or lifting or moving heavy furniture?	☐	☐	☐	☐
9. do yard work like raking leaves, weeding, or pushing a power mower?	☐	☐	☐	☐
10. have sexual relations?	☐	☐	☐	☐
11. participate in moderate recreational activities like golf, bowling, dancing, doubles tennis, or throwing a baseball or football?	☐	☐	☐	☐
12. participate in strenuous sports like swimming, singles tennis, football, basketball, or skiing?	☐	☐	☐	☐

Patient I.D. ☐☐☐-☐☐-☐☐☐☐ Adverse Event I.D.:☐☐☐

1. Type of adverse event you are reporting (check one event per form submission):

- ☐ A. Bleeding
- ☐ B. Cardiac Arrhythmias (specify):
  - ☐ 1. Sustained ventricular arrhythmia requiring defibrillation or cardioversion
  - ☐ 2. Sustained supraventricular arrhythmia requiring drug treatment or cardioversion
- ☐ C. Pericardial Fluid Collection
- ☐ D. Pleural Effusion
- ☐ E. Pneumothorax
- ☐ F. Hepatic Dysfunction
- ☐ G. Major Infection (specify)
  - ☐ 1. Localized Infection
  - ☐ 2. Endocarditis
  - ☐ 3 Sepsis
- ☐ H. Myocardial Infarction (specify)
  - ☐ 1. Myocardial Infarction
  - ☐ 2. Peri-CABG Myocardial Infarction
  - ☐ 3. Peri-Percutaneous Intervention (PCI) Myocardial Infarction
- ☐ I. Neurological Dysfunction
  - ☐ 1. Transient Ischemic Attack -TIA
  - ☐ 2. Cerebrovascular Accident/CVA (specify):
    - ☐ a. Ischemic
    - ☐ b. Hemorrhagic
  - ☐ 3. Toxic Metabolic Encephalopathy
  - ☐ 4. Other Neurological Dysfunction
- ☐ J. Renal Events (specify)
  - ☐ 1. Renal Dysfunction
  - ☐ 2. Renal Failure
- ☐ K. Respiratory Failure
- ☐ L. Heart Failure
- ☐ M. Arterial Non-CNS Thromboembolism
- ☐ N. Venous Thromboembolism Event
- ☐ O. Wound Dehiscence
- ☐ Z. Other

2. Date of onset:

☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

3. Seriousness of Adverse Event:

Fatal; Life threatening; Resulted in permanent disability; Required hospitalization or prolongation of hospital stay.

- ☐ Serious. Notify DCC immediately
- ☐ Not Serious

Patient I.D. ☐☐☐-☐☐-☐☐☐☐

1. Date of Hospital Admission: ☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)

2. Date of Hospital Discharge: ☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)

3. Reason for admission:
   - ☐ Index hospitalization
   - ☐ Re-hospitalization (specify primary reason):
     - ☐ Cardiovascular
       - ☐ Heart failure
       - ☐ Valve Dysfunction (specify): ☐ AV ☐ MV ☐ TV
       - ☐ Other cardiovascular
     - ☐ Non cardiovascular

4. Disposition at hospital discharge:
   - ☐ Home
   - ☐ Skilled nursing care facility
   - ☐ Inpatient rehabilitation facility
   - ☐ Hospice
   - ☐ Death
   - ☐ Other

Patient I.D. ☐☐☐-☐☐-☐☐☐

Surgery Date: ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

1. Specify primary procedure performed
☐ Valve repair ☐ MV
☐ Valve replacement ☐ MV

Patient I.D. ☐☐☐-☐☐-☐☐☐

Date of Death: ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

Patient I.D. ☐☐☐-☐☐-☐☐☐

Date of Study completion/Early termination: ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

Patient ID ☐☐☐-☐☐-☐☐☐☐

Adverse Event I.D.: ☐☐☐

Date of Adjudication ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

OVERALL ADVERSE EVENT ASSESSMENT	
Overall Event Assessment	☐ Agree with Adverse Event Classification ☐ Disagree with Adverse Event Classification

SERIOUSNESS OF ADVERSE EVENT:

☐ Agree with Seriousness of Adverse Event Classification
☐ Disagree with Seriousness of Adverse Event Classification
If Disagree, Reclassify:
☐ Serious ☐ Not Serious

AE Reclassification (if disagree with adverse event classification):	
1.	☐ Bleeding
2.	☐ Cardiac Arrhythmias- Sustained ventricular arrhythmia requiring defibrillation or cardioversion
3.	☐ Cardiac Arrhythmias- Sustained supraventricular arrhythmia requiring drug treatment or cardioversion
4.	☐ Pericardial Fluid Collection
5.	☐ Pleural Effusion
6.	☐ Pneumothorax
7.	☐ Hepatic Dysfunction
8.	☐ Major Infection-Localized
9.	☐ Major Infection-Endocarditis
10.	☐ Major Infection-Sepsis
11.	☐ Myocardial infarction
12.	☐ Myocardial infarction- Peri-CABG Myocardial Infarction
13.	☐ Myocardial infarction- Peri-Percutaneous Intervention (PCI) Myocardial Infarction
14.	☐ Neurological Dysfunction-TIA
15.	☐ Neurological Dysfunction-CVA-Ischemic
16.	☐ Neurological Dysfunction-CVA-Hemorrhagic
17.	☐ Neurological Dysfunction-Toxic Metabolic Encephalopathy
18.	☐ Neurological Dysfunction-Other
19.	☐ Renal Events-Renal dysfunction
20.	☐ Renal Events-Renal failure
21.	☐ Respiratory Failure
22.	☐ Heart Failure
23.	☐ Arterial Non-CNS Thromboembolism
24.	☐ Venous Thromboembolism Event
25.	☐ Wound Dehiscence
26.	☐ Other Adverse Event