TIM1 II

DATA TAPE CODING MANUAL

JANUARY 1993

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#### DATA TAPE CODING MANUAL

#### General Introduction

The Thrombolysis in Myocardial Infarction TIM1 II was designed to compare the following two treatment strategies in patients with acute myocardial infarction: (1) routine coronary arteriography performed 18 to 48 hours after the administration of rt-PA, followed by prophylactic PTCA (or CABG) if arteriography demonstrated that the anatomy was suitable (this was termed the "invasive strategy") and (2) conventional care without coronary arteriography and PTCA during the six weeks after random assignment to treatment, unless there was evidence of recurrent spontaneous or exercise-induced ischemia (the "conservative strategy"). One **substudy** included in this trial examined the effects of early as compared with deferred administration of a relatively cardioselective beta-adrenergic blocking agent in **eligible** patients. Patients were treated with recombinant tissue plasminogen activator (rt-PA). Data are from analysis files as of January 1991. A summary of the design features follows:

TIMI II Start Date: 4/11/86 Stop Date: 6/30/88 No. Treated: 3339 Design Features: rt-PA (G11044) 150 mg over 6 hrs (90 with initial 9 mg bolus, 20, 10, 10, 10, 10); On October 21, 1986 dose changed to rt-PA 100 mg over 6 hrs (60 with initial 6 mg bolus, 20, 5, 5, 5, 5); Onset of pain < 4 hrs; Randomized to PTCA at 18-48 hrs or a conservative strategy in which PTCA was used only if ischemia occurred spontaneously or at the time of pre-discharge exercise testing; Heparin 5000 U bolus and 1000 **U/hr** one hour after bolus; IV heparin for 5 days; Aspirin 80 mg qd; In IIB study patients were also randomized to immediate IV Beta-blocker or deferred oral Beta-blocker.

#### Description of Variables on the Data Tape

The first (short version) analysis file documentation contains a list of items by form (page vi to xiii). The second (long version) analysis file documentation contains the items, variable names and possible codes (Appendix B).

Copies of **TIMI** forms with annotations denoting the variable names are being submitted in a separate binder with this manual.

#### Data Tape Specification

The accompanying tape is g-track, -labeled, and written in EBCDIC with a density of **bpi**. Thus, although written on a Data General Computer, the tape is in IBM format.

Tape specifications: SAS datasets in transport format.

## Same and the second second

The **datasets** on the tape can be read under the **AOS/VS**, PRIMOS, or VMS operating system using the COPY procedure with the IMPORT option. The **datasets** can be read under a CMS, OS, or VSE operating system using the XCOPY procedure with the IMPORT option. The reserved libref IXTAPE must be used in the PROC COPY to refer to the transport library.

The tape contains seventeen SAS files corresponding to TIM1 forms or data files. SAS output documenting each variable with means for continuous variables and frequency distributions for discrete variables is being submitted in a separate binder.

#### Special Considerations

- a) The original identification number containing clinic and patient number has been replaced with a new sequence number, NEWID (1-3339).
- **b) Time** is recorded in military time.
- c) Days to event are calculated with reference to treatment initiation date. Time to events occurring on the same date as treatment initiation is defined as zero days.

#### Further Information on TIM1 II

For further information on the TIM1 II study, the user is directed to the following publications.

- TIM1 Study Group. Comparison of invasive and conservative strategies after treatment with intravenous tissue plasminogen activator in acute myocardial infarction: Results of the Thrombolysis in Myocardial Infarction (TIMI) Phase II Trial. N Engl J Med 1989;320:618-27.
- Bairn DS, Braunwald E, Feit F, Knatterud GL, Passamani ER, Robertson TL, Rogers WJ, Solomon RE, Williams Do. The Thrombolysis in Myocardial Infarction (TIMI) Trial Phase II: Additional information and perspectives. J Am Coll Cardiol 1990;15:1188-92.
- 3. Gore JM, Sloan M, Price TR, Randall AM, Bovill E, Collen D, Forman S, Knatterud G, Sopko G, Terrin ML. Intracerebral hemorrhage, cerebral infarction, and subdural hematoma following acute myocardial infarction and thrombolytic therapy in the Thrombolysis in Myocardial Infarction Study (TIM1 II Pilot and Clinical Trial). Circulation 1991;83:448-459.
- Roberts R, Rogers W, Mueller HS, Lambrew CT, Diver DJ, Smith HC, Willerson JT, Knatterud GL, Forman S, Passamani E, Zaret BL, Wackers FJT, Braunwald E. Immediate versus deferred beta-blockade following myocardial infarction: Results of the Thrombolysis in Myocardial Infarction (TIMI) II-B Study. Circulation 1991;83:422-437.
- 5. Bovill EG, Terrin ML, Stump DC, Berke A, Frederick M, Collen D, Feit F, Gore J, Hillis LD, Lambrew C, Leiboff R, Mann KG, Markis JE, Pratt C, Sharkey S, Sopko G, Tracy R, Chesebro J for the TIM1 Investigators. Hemorrhagic events during treatment with intravenous recombinant tissuetype plasminogen activator, heparin and aspirin for acute myocardial infarction: Results of the Thrombolysis in Myocardial Infarction (TIMI) Phase II Trial. Am Intern Med 1991;115:256-265.

- 6. Bairn DS, Diver DJ, Feit F, Greenberg MA, Holmes DR, Weiner BH, Williams DO, Schweiger MJ, Brown BG, Frederick MM, Knatterud GL, Braunwald E for the TIM1 II Investigators. Coronary angioplasty performed within the Thrombolysis in Myocardial Infarction (TIM1 II) Study. Circulation 1992;85:93-105.
- 7. Zaret BL, Wackers FJT, Terrin ML, Ross R, Weiss M, Slater J, Morrison J, Bourge RC, Passamani E, Knatterud G, Braunwald E for the TIM1 Investigators. Assessment of global and regional left ventricular performance at rest and during exercise following thrombolytic therapy for acute myocardial infarction: Results of the Thrombolysis in Myocardial Infarction (TIM1 II) Study. Am J Cardiol 1992;69:1-9.
- 8. Williams DO, Braunwald E, Knatterud G, Babb J, Bresnahan J, Greenberg MA, Raizner A, Wasserman A, Robertson T, Ross R and the **TIMI** Investigators. One-Year results of the Thrombolysis in Myocardial Infarction Investigation (**TIMI**) Phase II Trial. Circulation 1992;85:533-542.
- 9. Mueller HS, Cohen LS, Braunwald E, Forman S, Feit F, Ross A, Schweiger M, Cabin H, Davison R, Miller D, Solomon R, Knatterud GL, for the TIM1 Investigators. Analyses of patient subgroups in the Thrombolysis in Myocardial Infarction (TIMI) Trial, Phase II: Predictors of early morbidity and mortality. Circulation 1992;85:1254-1264.
- 10. Kleiman NS, Terrin M, Mueller H, Chaitman B, Roberts R, Knatterud GL, Solomon R, McMahon RP, Braunwald E and the TIM1 Investigators. Mechanisms of early death despite thrombolytic therapy: Experience from the Thrombolysis in Myocardial Infarction Phase II (TIM1 II) Study. JACC 1992;19:1129-35.

## TIMI II ANALYSIS FILES

ARRANGEMENT OF FILES BY FORM

FORM	SAS FILE NAME	NUMBER OF <u>RECORDS</u>	NUMBER OF VARIABLES
03	NIH.II03.SSD	3339	73
04	NIH.II04.SSD	3339	94
05	NIH.1105.SSD	3339	123
06, <b>7C,</b> 7F	NIH.IICATH.SSD	3339	266
<b>08A, 08C, 08D,</b> 39	NIH.II08.SSD	3339	23
10	NIH.II10.SSD	3339	144
11, 12, 13	NIH.IIFU.SSD	3339	55
14, 23	NIH.II14.SSD	3339	108
15, 16, 17, 23, 25, 43	NIH.II17.SSD	3339	67
19	NIH.II19.SSD	3339	100
24, 26, 44	NIH.II44.SSD	3339	65
27, 28	NIH.II2728.SSD	52	90
40, 41	NIH.II40.SSD	3339	39
CORE LAB DATA			
CONTRAST VENTRICULOGRAM	NIH.IILV.SSD	3339	68
QUALIFYING ECG	NIH.IIECG.SSD	3339	42
COAGULATION	NIH.IIGT.SSD	3339	22
OTHER DATA			
RECURRENT PAINFUL ISCHEMIC EVENTS	NIH.IIRPIE.SSD	3339	<b>9</b> ·

TIMI II Analysis File Documentation Item List

Form 03 Rev 1. 2. 3. 4. 5. Screening Form

Item 3 • date and time of qualifying ECG Item 5 • sex Item 7 • age Item 9A • date and time of pain onset (if missing use Form 5D Item 2) Item 10A • leads with ST elevation Item 10B • ST elevation in inferior leads Item 10C • ST elevation in anterior leads Item 10D • ST elevation in I and AVL leads Item 11 • presence of Q-waves Item 11A • leads with Q-waves Item 12 • ST depression  $\geq 0.1 \text{ mv}$ Item 12A • leads with ST depression Items 15A-15G, 16 • beta-blocker exclusion criteria Items 17-22 • risk factors Item 31 • location of qualifying ECG (Rev 5 only)

Form 04 Rev 0. Admission Form

Item 3 - race Item 4 - education Items 5, **5A-5E** - smoking habits Item 6 • activity at pain onset Items 7, 7A, 8, 9, 9B - previous pain episodes Items 10, 10B1-10B5 - history of MI Items 11A-11D - previous events Items 12A-12J - previous diseases or conditions Items 15A-15P - previous medications Item 16 • baseline height Item 17 • baseline weight Item 18 • baseline heart rate Item 19 - baseline respiratory rate Item 20 - baseline blood pressure Item 21 • baseline neck vein distension Items 22A-22D, 22D1A-22D1E - heart sounds Items 23A, 23B - integument Items 25-38 - baseline blood chemistries (if **#31**, 32, or 35 is missing, appropriate item on Form 19 is used)

#### Form 05 Rev 0. Treatment Assignment Form

Item 5 • treatment assignment
Items 6, 7A, 7B • initiation of rt-PA
Items 8, 9A, 9C • initiation of metoprolol
Item 10 • date and time of heparin bolus
Item 11 • date and time of rt-PA initiation
Item 12, 13 • date and time of IV and oral beta blockers
Item 14 • date and time of heparin infusion initiation
Item 16 • transfusions within 24 hours
Item 17, 18A-18M • complications within first 24 hours
Items 21A-21H • timing of events during rt-PA infusion
Items 22, 23A-23H • arrhythmias within 24 hours

Form 06 Rev 0. 1 PTCA Procedures Form (maximum of 2 forms, one protocol and one nonprotocol)

Rev 0	Rev 1
Item	Item
2	2 • date and time of PTCA
3	3 • PTCA type
4	4 • emergency or elective PTCA (only for nonprotocol PTCA)
5	5 • indication for PTCA (only for nonprotocol PTCA)
6,7	6,7 - PTCA attempts
8A-8V	8A-8W - procedure notes for PTCA on lesion 1
9A-9G	<b>9A-9H</b> - PTCA complications
10	10 • total elapsed <b>fluoroscopy</b> time
12	12 • 24 hour complications
14A-14C	14A-14C - angina status prior to PTCA (only for nonprotocol PTCA)

Form 7C Rev 0. Cardiac Catheterization Procedures Form (maximum of 3 forms: protocol, nonprotocol and hospital discharge)

Item 2 • date and time of catheterization
Item 4 • protocol/nonprotocol catheterization
Item 5 • reason for nonprotocol catheterization
Items 6A-6D • left ventricular pressure
Items 8A, 8B • perfusion grade and stenosis
Item 9 • infarct artery
Item 12, 13A-13E, 14, 14A-14C • complications
Item 15 • arrhythmias
Item 16A-16D • clinical complications

Form 7F Rev 0. **1**. 2. 3. 4 Coronarv Arterioeranhv Visual Asessment (maximum of 3 forms: protocol, nonprotocol and hospital discharge)

7	Rev <b>2,3</b> Item 6	Rev 4 Item 6	- film type (P, NP, HD) - dominance
		7 7.1-7.27 7.1-7.27	
<b>6A</b> 8B <b>calc</b>	8D1 8D2 8F	<b>8D1</b> 8D2 8F	only) • pre stenosis, pre grade • post stenosis, post grade • success of procedure (recalculated based on grade and stenosis)

Form 8A Rev 0. Rest/Exercise RVG Shipping Form (hospital discharge and 6 weeks)

Item 2 • date of study
Item 4A • rest study done
Item 4B • exercise study done
Item 32 • peak exercise stage (if missing use Form 8D #17)
Item 33 • exercise ECG results (Clinic interpretation)
Item 34 • chest pain (used if Form 39 Item 11 is missing)

Form 8C Rev 0.1. Resting RVG Analysis Report (hospital discharge and 6 weeks)

Item 8A - resting global LVEF (left ventricular ejection fraction)

Form 8D Rev 0. 1. Exercise RVG Analysis Report (hospital discharge and 6 weeks)

Items 5A - baseline LVEF
Items 14A - recovery RVG results
Item 16 - LVEF change (recalculated using peak exercise and baseline EF)
Item 17 - peak exercise stage (only used if Form 8A Item 32 is missing)
Item 18 - peak exercise LVEF

Form 10 Rev 0. Hospital Discharge Form

Item 2 - Date of hospital discharge
Item 3 - patient dead or alive at hospital discharge
Items 5, **5A, 5B** - confirmation of myocardial infarction
Item 7 - clinical complications occurred
Item 10 - date of congestive heart failure
Item 11 - date of cardiogenic shock
Item 12 - date of ventricular septal rupture
Item 13 - date of mitral regurgitation

Form 10 Rev 0. Hospital Discharge Form (Continued) Item 14 - date of cardiac arrest Item 15 • date of recurrent ischemic pain Items 16, 16A-16L - hemorrhagic complications with dates Items 17, 17A-17B - occurrence of infection with dates Items 18, 18A-18F - vascular complications with dates Items 19, **19A-19F** - thoracic complications with dates Items 20, **20A-20D** - other complications with dates Items 21-30  $\hdots$  special procedures with dates Items  ${\bf 40A1}{\textbf{-}40P2}$  - drugs prescribed during hospitalization and at hospital discharge Items 41, 41A - heparin infusion Items 42, 42B • oral beta blocker therapy Form 11 Rev 0. Follow-up Visit Form (6 weeks and 1 year) Item 2 • date of follow-up Item 6 • activity level Item 7 - current Canadian heart class Item 9B - cardiac arrest Item 9C - congestive heart failure Item **9D** • angina pectoris Items 13A, B, Cl, C5, D-K, L-P - current medication Form 12 Rev 0. Missed Visit Form (6 weeks and 1 year) Item 2 - date of contact Item 4 • able to locate patient Item 4B • need Coordinating Center help Item 5 • alive at contact Item 7 • reason visit was missed Item 8B • cardiac arrest Item 8C - congestive heart failure Item 8D • angina pectoris Item 12A - source of information for this form

Form 13 Rev 0. Telephone Contact Form (3 months, 6 months, 18 months, 2 years, 3 years, 4 years)

Item 2 • date of contact
Item 4 • able to locate patient
Item 4B • need Coordinating Center help

Form 14 Rev 0. Subseauent Hospitalization Form (up to 5 forms)

Item 2 • date of hospitalization Item 7 • cause of hospitalization is cardiovascular Items 8A-8G - description of **cardiovascular** reasons

Form 15 Rev 0. Death Notification Form

Item 3 - date of death (use only if missing on Form 17)
Item 5 - preliminary cause of death

Form 16 Rev 0. Cause of Death Form

Item 16 - autopsy

#### Form 17 Rev 2. 3. MMCC Death Classification Form

Item 2 • date and time of death (if missing use Form 15)
Items 6A-6E - complications
Items 7, 8A, 8B, 8B1 - death from cardiovascular disease (For Rev 2)
Items 7, 8A, SB, 8B1, 8B2 - death from cardiovascular disease (For Rev 3)
Items ac - fatal cardiac disease

Form 19 Rev 0. Laboratory Data Form

Form 23 Rev 0. 1. 2. Myocardial Infarction Event Form (multiple events possible, current maximum = 3)

Item 2 • date and time of event (used only if Form 43 is missing)
Item 3B • reappearance of pain

Form 24 Rev 0. 1. Hemorrhagic Event Form (multiple events possible)

Form 25 Rev 0. 1. Cardiac Surgery Form (multiple events possible)

Item 2 • date and time of surgery
Item 4 • emergency or elective
Item 4A • reason for surgery
Item 5A, B, C • angina status
Item 6, 6A, 6B1 • exercise test
Item 7 • angiography performed
Items 8A-8F • arteries grafted
Items 9A-D • conduits used
Items 10A, 10B • complications
Item 11 • transfusion (Rev 1 only)

Form 26 Rev 0. Transfusion Report Form

Form 27 Rev 0. Severe Neuroloeic Event Form

Item 6 • alcohol consumption
Item 11 • date and time of onset
Item 12 • signs and symptoms
Item 13 • onset
Item 14 • maximum stable deficit \_Item 15 • improvement within 24 hours
Item 16, 16A • blood pressure change
Item 17 • medication
Item 18 • cardiovascular stability
Item 19-21 • examination
Item 46 • CT scan
Item 53 • recovery

Form 28 Rev 0. Severe Neurologic Event Classification Form

Item 2 - date of event Item 3A-E - classification Item 4A-F, 5A-F - location Item 6 - hours from onset to entry Item 7 - class of infarct Item 8 - class of hemorrhage Item 9, 10 - extension of hemorrhage Item 11A-N - casual factors

Form 39 Rev 0. Bicycle\_Ergonometry Test Form (hospital discharge and 6 weeks)

Item 11 - chest pain

Form 40 Rev 0. 1. One-Year Treadmill Exercise Test Form

Form 41 Rev 0. 1. Treadmill Exercise Test Non-Performance Form

Item 3 - reason for not performing test

Form 43 Rev 1. 2. Nonfatal Mvocardial Infarction Event Classification Form (multiple events)

Rev 1	Rev 2
Item	Item
2	2 - date and time of nonfatal MI
	4 - timing of MI
4	SD, <b>6A -</b> classification of event

Form 44 Rev 1. 2. Hemorrhagic Event Classification Form (multiple events)

Item 2 - date and time of hemorrhagic event Item 4A - severity of event Item 4B - surgical event Item 5A - primary location Item 5B - contributing location Item 8A - event occurred within 24 hours of rt-PA initiation

#### File Qualifying ECG

- ECG number
- sequence number
- mean RR interval in msec
- PR interval in msec
- Q amplitude in leads I, II, III, AVR, AVL, AVF,  $V_1$ - $V_6$  R amplitude in leads I, II, III, AVR, AVL, AVF,  $V_1$ - $V_6$
- ST deviation in leads I, II, III, AVR, AVL, AVF,  $\bar{V}_1$ - $\bar{V}_6$
- (positive value indicates ST elevation, a negative value indicates ST depression)

#### File GT. Coagulation Core Lab Data

- fibrinogen (Claus) at pre-treatment, 50 minutes, 5 hours and 8 hours
- FDP at pre-treatment, 50 minutes, 5 hours, and 8 hours

- TPA at pre-treatment, 50 minutes, 5 hours, and 8 hours
  Plasminogen at pre-treatment, 50 minutes, 5 hours, and 8 hours
  Alpha-2 antiplasmin at pre-treatment, 50 minutes, 5 hours, and 8 hours

File LV. Contrast Left Ventriculograms\_(protocol, hospital discharge and nonprotocol)

- systolic and diastolic volume
- stroke volume
- cardiac output
- ejection fraction
- hypokinesis
- hyperkinesis
- length of hypokinetic segment
- length of akinetic or dyskinetic segment

### APPENDIX B

## TIM1 II ANALYSIS FILES

## ARRANGEMENT OF FILES AS OF 9/90

FORM	SAS FILE	PAGE NUMBER
03	FORM03.SSD	B-1
04	FORM04.SSD	B-4
05	FORM05.SSD	B-8
06	FORMCATH.SSD	B-12
7C, 7F	FORMCATH.SSD	B-18
8A, 8C, 8D	FORMO8.SSD	B-23
10	FORM10.SSD	B-27
11, 12, 13	FORMFU.SSD	B-32
14	FORM14.SSD	B-34
15	FORM17.SSD	B-37
16	FORM17.SSD	B-38
17	FORM17.SSD	B-39
19	FORM19.SSD	B-40
23	FORM17.SSD, FORM14.SSD	B-42
RECURRENT PAINFUL		- 10
ISCHEMIC EVENTS	RPIE.SSD	B-43
24, 44	FORM44.SSD	B-44
25	FORM17.SSD	B-47
26	FORM44.SSD	B-49
27	FORM2728.SSD	B-50
28	FORM2728.SSD	B-52
31	FORMCATH.SSD	в-54
39	FORMO8.SSD	B-55
40	FORM40.SSD	B-57
41	FORM40.SSD	B-59
43	FORM17.SSD	B-60
<u>CORE LAB DATA</u>		
QUALIFYING ECG	FILEECG.SSD	B-62
COAGULATION	FILEGT.SSD	B-63
CONTRAST VENTRICULOGRAM	FILELV.SSD	B-64

FORM 03 (REV 0, 1, 2, 3, 4, 5) Screening Form

ITEM	LENGTH	NAME	CODES
	11	FORM03	1 = Form received
3	F10.5	ERTIME	Emergency-room time (days) to treatment initiation (negative)
5	11	SEX	1 = Male, 2 = Female
7	13	AGE	Years
9A	12	ONMO ONDA ONYR ONHR ONMN	Month of pain onset Day of pain onset Year of pain onset Hour of pain onset (military) Minute of pain onset
9A	F10.5	ONTIME	Onset of symptoms time (days) to treatment initiation (negative)
10A	12	NSTE	Total number of leads with ST elevation: 0-12
10A	11	STEII STEAVF STEV1 STEV2 STEV3 STEV4 STEV5 STEV6 STEI STEAVL_1 STEAVR	<pre>1 = item checked 0 = item not checked</pre>
10B 10C 10D	11 11 11	STEINF STEANT STEAVL	$\left.\right\} 1 = \text{Yes}, 2 = \text{No}$
11	11	QWAVES	1 = Yes, 2 = No
11A	12	NQ	Number of leads with Q waves: 0-12
11A	11	QII QIII QAVF QV1 QV2 QV3 QV4 QV5 QV6 QI QAVL QAVL QAVR	<pre>1 = item checked 0 = item not checked</pre>

## FORM 03 (REV 0, 1, 2, 3, 4, 5) Screening Form (Continued)

ITEM	LENGTH	NAME	CODES
12	11	STD	1 -Yes, <b>2 - No</b>
12A	12 11 11 11 11 11 11 11 11 11	NSTD STDII STDIII STDAVF <b>STDV1</b> STDV2 STDV3 STDV4 <b>STDV5</b> STDV6 STDI STDAVL STDAVL	Number of leads with ST depression: 0-12 1 = ST depression present in lead 0 = not present
<b>15A</b> 15B 15c 15D 15E <b>15F</b> 15G	11 11 11 11 11 11 11	BBINELA BBINELC BBINELD BBINELE BBINELF BBINELG	$ \  \  \  \  \  \  \  \  \  \  \  \  \ $
16	11	BBINEL	1 = Yes, 2 = No
17	11	BLMI	1 = Yes, 2 = No
18	11	BLRALES	1 = Yes, 2 = No
18A	11	BLEXTENT	0 = None $1 = \leq 1/3$ lung fields 2 = > 1/3 lung fields but not all 3 = both entire lung fields
19	11	BLHYPO	1 <b>= Yes,</b> 2 -No
20	11	BLAF	1 = Yes, 2 = No
21	11	BLPE	1 = Yes, 2 = No
22	11	BLSHOCK	1 -Yes, 2 -No
31	11	WHEREECG	<pre>1 = TIM1 Clinical Center 2 = Emergency room extension (only</pre>

## FORM 03 (REV 0, 1, 2, 3, 4, 5) Screening Form (Continued)

ITEM	LENGTH	NAME	CODES
CALCULATED	11	HIGHRISK	<pre>1 = Yes 0 = No (Defined as any of the following being present: Age ≥ 70, prior MI, anterior MI, rales &gt; 1/3 lung fields, hypotension, atrial fibrillation or flutter, pulmonary edema or cardiogenic shock)</pre>
CALCULATED	11	TWOHRS	<pre>1 = Treatment was initiated within 2 hours (&lt; 2)     of pain onset 0 = Treatment initiated later than 2 hours after     pain onset</pre>

FORM 04 (REV **0)** Admission Form

ITEM	<u>LENGTH</u>	<u>NAME</u>	CODES
	11	FORM04	1 - Form received
3	11	RACE	<b>1 -</b> White, 2 <b>-</b> Black, 3 <b>-</b> Hispanic, 4 <b>-</b> Other
4	11	EDUCATE	<pre>1 = No formal education 2 = ≤ Grade 11 3 = High school graduate 4 = Some college 5 - 4 yr degree 6== Some graduate school 7 = Graduate degree</pre>
5	11	SMOKE	<b>1 =</b> Yes, 2 <b>=</b> No
5A	11	MAXPACKS	$\begin{array}{l} 0 = \text{None} \\ 1 = \leq 1/2 \text{ pack} \\ 2 = 1/2 < \text{packs} \leq 1 \\ 3 - 1 < \text{packs} \leq 2 \\ 4 - > 2 \text{ packs} \end{array}$
5B	12	YRSMOKE	number of years smoked (0 - None)
5c	11	CURSMOKE	1 -Yes, <b>2 - No</b>
5D	11	PACKSDAY	0 = None 1 = $\leq 1/2$ pack 2 = $1/2 < $ packs $\leq 1$ 3 = 1 < packs $\leq 2$ 4 = > 2 packs
5E	11	STOPSMOK	<pre>o = Never stopped <math>1 = \leq 3</math> months <math>2 = 3 &lt; months \leq 12</math> <math>3 = 1 &lt; years \leq 5</math> 4 = &gt; 5 years 5 = Never smoked</pre>
6	11	ACTONSET	<pre>1 = sleeping 2 = rest 3 - mild physical activity 4 - moderate physical activity 5 = marked physical activity</pre>
7	11	INDXPAIN	1 -Yes, <b>2 = No</b>
7A	11	OTHEPISD	<pre>minimum of 7A1-7A6: 0 = None 1 = &lt; 1 hour 2 = 1-2 hours 3 = 3-5 hours 4 = 6-11 hours 5 = 12-23 hours 6 = 24-48 hours</pre>

			(concinued)
<u>ITEM</u>	LENGTH	NAME	CODES
8A	I1	BLPATTA	
8B	11	BLPATTB	
8C	11	BLPATTC	
8D	11	BLPATTD	0 - No, 1 <b>- Yes</b>
8E	11	BLPATTE	
8F	11	BLPATTF	
8G	11	BLPATTG	
CALCULATEI	) Il	PATT3WK	<pre>0 = None 1 = No pattern 2 = New onset (D) 3 = Increasing frequency (E and no D) 4 - Variant (F only) or (F and G only)</pre>
CALCULATEI	D I1	ANG3WK	<pre>0 - None (A) 1 - Unstable (B) or (G only) 2 - Stable (C, D, E and not B) 3 = Variant (F and G only) or (F only)</pre>
9	11	CHSTPAIN	1 -Yes, 2 -No
9A	11	BLANGINA	0 = Probably not angina or not angina 1 - Definite angina or probable angina
9B	11	ANGONSET	<pre>0 - None 1 = ≤ 7 days 2 - 8-14 days 3 = 15-21 days 4 = 22-30 days 5 - 31-180 days 6 - 6 months-1 year 7 = &gt; 1 year</pre>
10	11	F04BLMI	1 = Definite, 2 - No, 3 - Suspect, 4 = Unknown
10B1	11	BLMILOC1	
10B1 10B2	II	BLMILOC2	
			0  No. $1 - Xor$
10B3	11	BLMILOC3	0 -No, <b>1 - Yes</b>
10B4	11	BLMILOC4	
10B5	11	BLMILOC5	
	- 1		
11A	11	BLCHF	
11B	11	BLICIA	1 - Definite, 2 - No, 3 - Suspect, 4 - Unknown
11C	11	BLSTK	
11D	11	BLIC	
12A	11	BLDIAB	
12B	11	BLHYP	
12c	11	BLPVD	
12D	11	BLVHD	
12E	11	BLOCD	1 = Yes, 2 = No, 3 - Unknown
12F	I1	BLGI	
12G	11	BLHMD	
12H	11	BLRENAL	
121	11	BLNEURO	
12J	11 11	BLOTHDIS	

			(concinaed)
ITEM	<u>LENGTH</u>	<u>NAME</u>	CODES
15A 15B 15C1 15C2 15D 15E 15F 15G 15H 15J 15J 15K 15L 15K 15L 15M 15N 150 15P	11 11 11 11 11 11 11 11 11 11	BLRXA BLRXB BLRXC1 BLRXC2 BLRXD BLRXF BLRXF BLRXG BLRXH BLRXI BLRXJ BLRXK BLRXK BLRXN BLRXN BLRXN BLRXN BLRXN	<b>0 = No</b> 1 <b>-</b> < 6 hrs. 2 <b>-</b> 6-24 hrs. 3 <b>-</b> > 24 hrs.
16	13	BLHT	Height in cm
17	F5.1	BLWT	Weight in kg
18	13	BLHR	Heart rate in beats/minute
19	12	BLRESP	Respiratory rate in respirations/minute
20A 20B	13 13	BLSBP BLDBP	Systolic blood pressure (mm Hg) Diastolic blood pressure (mm Hg)
21	11	BLNKVEIN	1 = Present, 2 = Absent, 3 = Unknown
22A 22B 22c 22D	11 11 11 11	BLS3 BLS4 BLPFR BLMURMUR	1 = Present, 2 = Absent, 3 = Unknown
22D1 22D1B 22D1C 22D1D 22D1E	11 11 11 11 11	BLBSE BLMR BLAR BLVSR BLOTHMUR	0 = No, <b>1 = Yes</b>
23A 23B	11 11	BLECCHY BLHEMAT	1 = Present, 2 = Absent 1 = Present, 2 = Absent
25	F4.1	BLCREAT	mg/dl
26	13	BLBUN	mg/dl
27	F4.1	BLBILI	mg/dl
28	14	BLSGOT	IU/L

ITEM	LENGTH	NAME	CODES
29	14	BLLDH	IU/L
30 31	13 F4.1	BLALKPHS BLHCT	IU/L % (if missing, Form 19 Item 5B was used)
32	F4.1	BLHGB	gm/dl (if missing, Form 19 Item 5A was used)
33	F4.1	BLWBC	thousands/mm <sup>3</sup>
34	F3.1	BLK	mEq/L
35	14	BLPLAT	thousands/mm $^{3}$ (if missing, Form 19 Item 5C was used)
36	11	BLUPROT	1 = Present, 2 = Absent, 3 = Unknown
37	11	BLOCCBLD	1 = Present, 2 = Absent, 3 = Unknown
38	11	BLGUIAIC	1 = Present, 2 = Absent, 3 = Unknown

## FORM 05 (REV 0) Treatment Assignment Form

ITEM	<u>LENGTH</u>	<u>NAME</u>	CODES
	11	FORM05	1 - Form received
HEADER	11	PHASE	<b>1 -</b> Open Label E <b>2 -</b> Phase II
5	11	ASSIGN	<pre>1 = 2 hr PTCA 2 = 18-24 hr PTCA 3 = No PTCA 4 = IV BB/18-48 hr PTCA 5 = IV BB/No PTCA 6 = DEF BB/18-48 hr PTCA 7 = DEF BB/No PTCA 8 = BB Inel./18-48 hr PTCA 9 = BB Inel./No PTCA</pre>
CALCULATED	11	DOSEASGN	<b>1 -</b> 150 mg rt-PA <b>2 -</b> 100 mg rt-PA
CALCULATED	11	PTCAGRP	<pre>1 = Immediate invasive 2 = Delayed invasive 3 = Conservative</pre>
CALCULATED	11	BBGRP	<b>1 =</b> Immediate Beta-Blocker <b>2 =</b> Deferred Beta-Blocker
6	11	TRTINIT	<b>1 =</b> Yes, 2 <b>=</b> No
7A 7B	13 12	RTPADOSE RTPALESS	<pre>mg 1 = Urticaria 2 = Fever or chills 3 = Nausea or vomiting 4 = Bleeding at arterial access 5 = Bleeding at central vein access 6 = Bleeding at other puncture sites 7 = Other bleeding 8 = Convulsions 9 = Anaphylaxis 10 = Hypotension 11 = Bronchospasm 12 = Death 13 = Other</pre>
8	11	IVMET	1 <b>- Yes,</b> 2 -No
9A 9C	12 13	IVDOSE ORALDOSE	mg mg
10	11 F10.5	HEPBOL HEPBTIME	<b>0 = No, 1 = Yes</b> Time from treatment initiation (days)
11	512	TIMO, TIDA, TIYR, TIHR, TIMN	Date and time of rt-PA initiation (ALL TIME VARIABLES ARE CALCULATED FROM THIS ONE)

## FORM 05 (REV 0) Treatment Assignment Form (Continued)

ITEM	LENGTH	NAME.	CODES
12	11 F10.5	IVBB IVBBTIME	<b>0 - No, 1 - Yes</b> Time from treatment initiation (days)
13	11 F10.5	ORALBBO5 ORBBTIME	<b>0 =</b> No, 1 <b>=</b> Yes Time from treatment initiation (days)
14	11 <b>F10.5</b>	HEPINF HEPITIME	<b>0 -</b> No, 1 <b>-</b> Yes Time from treatment initiation (days)
16	11	TF24	<b>1 =</b> Yes, 2 <b>=</b> No
17	11	COMP	<b>1 =</b> Yes, 2 <b>=</b> No
<pre>18A 18B 18C 18D 18C 18D 18E 18F 18G 18H 181 18J 18K 18L 18M</pre>	11 11 11 11 11 11 11 11 11 11 11 11 11	COMPA COMPB COMPC COMPD COMPE COMPF COMPG COMPH COMPI COMPJ COMPL COMPL COMPM	<pre>1 = Did not occur 2 = Occurred, but did not interrupt rt-PA treatment 3 = Interrupted rt-PA treatment</pre>
20	13 13 13 13 13 13 13 13	HRO HR30 HR60 HR90 HR120 HR150 HR180	Beats per minute
	13 13 <b>13</b> 13 13 13 13 13	SBPO SBP30 SBP60 SBP90 SBP120 SBP150 SBP180	mm Hg
	13 13 13 13 13 IT 13 13	DBPO DBP30 DBP60 <b>DBP90</b> DBP120 DBP150 <b>DBP180</b>	mm Hg

## FORM 05 (REV 0) Treatment Assignment Form (Continued)

<u>ITEM</u>	LENGTH	NAME	CODES
21A 21B 21c 21D 21E 21F 21G 21H	11, 13 11, 13 11, 13 11, 13 11, 13 11, 13 11, 13 11, 13 11, 13	RPEVA, RPEVAMIN RPEVB, RPEVBMIN RPEVC, RPEVCMIN RPEVD, RPEVDMIN RPEVE, RPEVEMIN RPEVF, RPEVFMIN RPEVG, RPEVGMIN RPEVH, RPEVHMIN	l -Yes, 2 -No If Yes, minutes from treatment initiation
22	11	ARR24	1 = Yes, 2 = No
23A1 23B1 23C1 23D1 23E1 23F1 23G1 23H1	I1 I1 I1 I1 I1 I1 I1 I1	ARRA1 ARRB1 ARRC1 ARRD1 ARRE1 ARRF1 ARRG1 ARRH1	1 = None 0 = Arrhythmias appeared
23A2 23B2 23C2 23D2 2332 23F2 23G2 23H2	11 11 11 11 11 11 11 11	ARRA2 ARRB2 ARRc2 ARRC2 ARRE2 ARRF2 ARRF2 ARRG2 ARRH2	<pre>1 = Prior to thrombolytic therapy 0 = None prior</pre>
23A3 23B3 23C3 23D3 2333 23F3 23G3 23H3	I1 I1 I1 I1 I1 I1 I1 I1	ARRA3 ARRB3 ARRC3 <b>ARRD3</b> ARRE3 ARRF3 ARRG3 ARRH3	1 = During thrombolytic therapy 0 <b>=</b> None during
23A4 23B4 2364 23D4 2334 23F4 23G4 23H4	13 13 13 13 13 13 13 13 13	ARRA4 ARRB4 ARRC4 ARRD4 ARRE4 ARRF4 ARRF4 ARRG4 ARRH4	Minutes after onset of thrombolytic therapy (missing if none during therapy)
23A5 23B5 23C5 23D5 2335 23F5 23F5 23H5	11 11 11 11 11 11 11 11	ARRA5 ARRB5 ARRc5 ARRD5 ARRD5 ARRF5 ARRF5 ARRG5 ARRH5	<pre>1 = After completion of thrombolytic therapy 0 = None after</pre>

# FORM 05 (REV 0) Treatment Assignment Form (Continued)

<u>ITEM</u>	LENGTH	<u>NAME</u>	CODES
24A	11	PAINPRE	<b>1 -</b> Yes, 2 <b>-</b> No
24C	11	PAININIT	1 = Yes, 2 = No
24D	11	PAINCONC	1 <b>= Yes,</b> 2 -No
24E	11	PAINCOMP	<b>1</b> = Increased
			2 <b>=</b> Decreased but still present

- 3 = Same 4 = None

## FORM 6 (REV **0)** PTCA Procedures Form

# Data from the Protocol and first Nonprotocol PTCA (Protocol variables suffixed by "P," Nonprotocol by "NP.")

ITEM	LENGTH	NAME	CODES
	11	F06P/F06NP	1 = Form received, 0 = not received
2	F10.5	F6TIMEP/F6TIMENP	Time to PTCA (days)
2	13	PTCADAYS	Integer days to first PTCA
2	F10.5 F10.5 F10.5 F10.5	PPROTDAY PNP1DAY PNP2DAY PNP3DAY	Days to Protocol PTCA Days to first NP PTCA Days to second NP PTCA Days to third NP PTCA
4	11	PTCAEENP	<pre>1 = Emergency 2 = Elective</pre>
5	11	REASONNP	<pre>1 = Ischemia post infarction 2 = Re-infarction post infarction 3 = Other</pre>
6	11	SITE1P/SITE1NP	<b>1 =</b> Yes, 2 <b>=</b> No
7	11	SITE2P/SITE2NP	1 = Yes, 2 = No
8A1 8B1	11 12	L18AP/L18ANP L18BP/L18BNP	1 = Yes, 2 = No 1 = Prox RCA 2 = Mid RCA 3 = Dist RCA 4 - RPDA 5 - RPLS 6 = 1st RPL 7 = 2nd RPL 8 = 3rd RPL 9 = Inf. septal 10 - AC marg 11 - IMCA 12 = Prox LAD 13 - Mid LAD 14 - Dist LAD 15 = 1st diag 16 - 2nd diag 17 - 1st septal 18 = Prox CX 19 = Dist CX 20 = 1st Ob marg 21 - 2nd Ob marg 22 - 3rd Ob marg 23 - LAV 24 - 1st LPL 25 - 2nd LPL 26 = 3rd LPL 27 = LPDA

#### FORM 6 (REV 0) PTCA Procedures Form (Continued)

ITEM	LENGTH	NAME	CODES
8C1 8D1 8E1	11 11 11	L18CP/L18CNP L18DP/L18DNP L18EP/L18ENP	1 -Yes, 2 -No
8F1 8G1	11 11	L18FP/L18FNP L18GP/L18GNP	Perfusion grade pre PTCA = 0, 1, 2, 3
8H1 8J1 8K1 8L1 8M1 8N1 801 8P1 8Q1	I1 I1 I1 I1 I3 I3 I3 I3 I2	L18HP/L18HNP L18IP/L18INP L18JP/L18JNP L18KP/L18KNP L18MP/L18MNP L18MP/L18NNP L180P/L180NP L180P/L180NP L180P/L18PP L18QP/L18QNP	<pre>1 -Yes, 2 -No Perfusion grade post-PTCA = 0, 1, 2, 3 % stenosis pre-PTCA (0 - 100) % stenosis post-PTCA (0 - 100) Gradient pre-PTCA (mm Hg) Gradient post-PTCA (mm Hg) Outcome code 1 = ≥ 20% absolute reduction in stenosis -     sustained 2 = ≥ 20% absolute reduction in stenosis -     with transient reocclusion 3 = ≥ 20% absolute reduction in stenosis -     followed by sustained reocclusion 4 = Failure to enter vessel 5 = Failure to reach lesion 6 = Failure to cross lesion 7 = Vessel resists dilation 8 = Equipment failure 9 = Other</pre>
8R1	11	L18RP/L18RNP	Measure code 1 = Visual estimate 2 = Electronic calipers 3 = Manual caliper
CALCULATED	11	L18SP/L18SNP	1 = full 2 = partial 3 = none
851 5T1 8U1 8V 8VA 8VB 9A 9B 9C 9D 9E 9F 9G	13 11 F3.1 12 13 13 11 11 11 11 11 11 11 11	L18TP/L18TNP L18UP/L18UNP L1MMP/L1MMNP L1INP/L1INNP L1SCP/L1SCNP L1ATP/L1ATNP COMPAP/COMPANP COMPBP/COMPBNP COMPCP/COMPCNP COMPCP/COMPCNP COMPFP/COMPFNP COMPGP/COMPGNP COMPHP/COMPHNP	Seconds Number of catheters mm Number of inflations Seconds Atmospheres 1 = Yes, 2 = No
10	12	FTIMEP/FTIMENP	Minutes

## FORM 6 (REV 0) PTCA Procedures Form (Continued)

ITEM	LENGTH	<u>NAME</u>	CODES
12A 12B	I1 I1	DEATHP/DEATHNP MIP/MINP	1 = Yes, 2 = No 1 -Yes, 2 = No
12c	11	SURGP/SURGNP	1 -Yes, <b>2 = No</b>
14A	11	ANGINANP	<pre>1 - definite angina 2 = probable angina 3 = probably not angina 4 = no angina</pre>
14B	11	CHCNP	<b>0 - 0</b> 1 - I 2 = II 3 = III 4 = IV
14c	11	EPISODNP	1 = Yes, 2 = No
CALCULATED	11	PTCASTAT	<pre>1 = ≤ 15 hours 2 = Protocol PTCA (declared protocol) 3 = Excluding Protocol, PTCA within</pre>
CALCULATEI	D I1	NPREASON	<pre>Reason for Non-Protocol PTCA (defined by Drs. Diver and Bairn) 0 = Emergency PTCA in first 15 hours 1 = Angina 2 = Re-infarction 3 = Positive ETT 4 = Physician request 5 = Clinical determination 6 = Delay due to unavailability of OR backup or clinical instability 7 = To facilitate non-cardiac surgery 8 = Error in treatment assignment</pre>

#### FORM 6 (REV 1) PTCA Procedures Form

Data from the Protocol and first Nonprotocol PTCA (Protocol variables suffixed by "P," Nonprotocol by "NP.")

ITEM	LENGTH	NAME	<u>CODES</u>
	11	F06P/F06NP	1 - Form received, 0 - not received
2	F10.5	F6TIMEP/F6TIMENP	Time to PTCA (days)
2	13	PTCADAYS	Integer days to first PTCA
2	F10.5 F10.5 F10.5 F10.5	PPROTDAY PNP1DAY PNP2DAY PNP3DAY	Days to Protocol PTCA Days to first NP PTCA Days to second NP PTCA Days to third NP PTCA
4	11	PTCAEENP	<pre>1 = Emergency 2 = Elective</pre>
5	11	REASONNP	<pre>1 = Ischemia post infarction 2 = Re-infarction post infarction 3 = Other</pre>
6	11	SITE1P/SITE1NP	1 -Yes, <b>2 = No</b>
7	11	SITE2P/SITE2NP	1 -Yes, <b>2 = No</b>
8A1 8B1	<b>11</b> 12	L18AP/L18ANP L18BP/L18BNP	1 -Yes, 2 -No 1 = Prox RCA 2 = Mid RCA 3 = Dist RCA 4 = RPDA 5 = RPLS 6 = 1st RPL 7 - 2nd RPL 8 - 3rd RPL 9 = Inf. septal 10 = AC marg 11 = LMCA 12 = Prox LAD 13 = Mid LAD 14 = Dist LAD 15 = 1st diag 16 = 2nd diag 17 = 1st septal 18 = Prox CX 19 = Dist CX 20 = 1st Ob marg 21 = 2nd Ob marg 22 = 3rd Ob marg 23 = LAV 24 = 1st LPL 25 = 2nd LPL 26 = 3rd LPL 27 = LPDA

### FORM 6 (REV 1) PTCA Procedures Form (Continued)

ITEM	LENGTH	NAME	CODES
8C1	11	L18CP/L18CNP	
8D1	11	L18DP/L18DNP	1 = Yes, 2 - No
8E1	11	L18EP/L18ENP	
8F1	I1	L18FP/L18FNP J	
8G1	11	L18GP/L18GNP	Perfusion grade pre-PTCA = $0, 1, 2, 3$
8H1	11	L18HP/L18HNP	4
811	11	L18IP/L18INP	
8J1	11	L18JP/L18JNP	-Yes, 2 -No
8K1	11	L18KP/L18KNP	
8L1	I1	L18LP/L18LNP	Perfusion grade post-PTCA = $0, 1, 2, 3$
8M1	13	L18MP/L18MNP	<pre>% stenosis pre-PTCA (0 - 100)</pre>
8N1	13	L18NP/L18NNP	% stenosis post-PTCA (0 - 100)
801 8D1	13	L180P/L180NP	Gradient pre-PTCA (mm Hg)
8P1	13 12	L18PP/L18PNP	Gradient post-PTCA (mm Hg)
8Q1	12	L18QP/L18QNP	Outcome code 1 = < 60% initial residual stenosis -
			sustained
			2 = < 60% initial residual stenosis -
			with transient reocclusion
			3 = < 60% initial residual stenosis -
			followed by sustained reocclusion
			4 = Failure to enter vessel
			5 = Failure to reach lesion
			6 = Failure to cross lesion
			7 = Vessel resists dilation
			8 🖛 Equipment failure
			9 = Other
8R1	11	L18RP/L18RNP	Measure code
UNI	11	LIONI / LIONNI	1 = Visual estimate
			2 - Electronic calipers
			3 = Manual caliper
8S1	11	L18SP/L18SNP	1 = full
u		,,	2 = partial
			3 = none
8T1	13	L18TP/L18TNP	Seconds
SU1	11	L18UP/L18UNP	Number of catheters
8V1	F3.1	L1MMP/L1MMNP	mm
8W1	12	L1INP/L1INNP	Number of inflations
8WA1	13	L1SCP/L1SCNP	Seconds
8WB1	13	LLATP/LLATNP	Atmospheres
9A	11	COMPAP/COMPANP	
9B	11	COMPBP/COMPBNP	
9C	11	COMPCP/COMPCNP	
9D	11	COMPDP/COMPDNP	
9E	11	COMPEP/COMPENP	1 = Yes, 2 = No
9F	11	COMPFP/COMPFNP	
9G	11	COMPGP/COMPGNP	
9н	11	COMPHP/COMPHNP	
10	12	FTIMEP/FTIMENP	Minutes

## FORM 6 (REV 1) PTCA Procedures Form (Continued)

ITEM	LENGTH	NAME	CODES
12A	11	DEATHP/DEATHNP	1 = Yes, 2 = No
12B	11	MIP/MINP	1 = Yes, 2 = No
12c	11	SURGP/SURGNP	1 = Yes, 2 = No
14A	11	ANGINANP	<pre>1 = definite angina 2 = probable angina 3 = probably not angina 4 = no angina</pre>
14B	11	CHCNP	0 = 0 1 = I 2 = II 3 = III 4 = IV
14c	11	EPISODNP	1 = Yes, 2 = No
CALCULATED	9 11	PTCASTAT	<pre>1 = Early (&lt; 15 hours) 2 = Protocol PTCA (declared protocol) 3 = Excluding Protocol procedures, PTCA within 15 hours-14 days 4 = No procedure in 14 days</pre>
CALCULATED	9 11	NPREASON	<pre>Reason for Non-Protocol PTCA (defined by Drs. Diver and Bairn) 0 = Emergency PTCA in first 15 hours 1 = Angina 2 = Reinfarction 3 = Positive ETT 4 = Physician request 5 = Clinical deterioration 6 = Delay due to unavailability of OR backup or clinical instability 7 = To faciliate non-cardiac surgery 8 = Error in treatment assignment</pre>

FORM 7C (REV 0) Cardiac Catheterization Procedures Form (Clinic)

There is a set of variables for the protocol/hospital discharge/ first nonprotocol catheterizations.

ITEM	LENGTH	NAME	CODES
2	F10.5	CATHTIME/CTIMEHD/CTIMENP	Time (days) to catheterization
2	12	CATHDAYS	Integer days to first catheterization (on <b>FORM17.SSD)</b>
2	F10.5 F10.5 F10.5 F10.5 F10.5	CPDAY CHDDAY CNP1DAY CNP2DAY CNP3DAY	Days to Protocol cath Days to HD cath Days to first NP cath Days to second NP cath Days to third NP cath
4	11	F7C/F7CHD/F7CNP	1 = form received, 0 = none
5	11	REAS7C	<pre>1 = Ischemia post infarction 2 = Re-infarction 3 = Other</pre>
<b>6A</b> 6B 6C	13 13 13	LVPSBPP/LVPSBPHD/LVPSBPNP LVEDBPP/LVEDBPHD/LVEDBPNP ASBP/ASBPHD/ASBPNP	mm Hg mm Hg mm Hg
6D	13	ADBP#ADBPHD/ADBPNP	mm Hg
12	11	F7CCOMP/F7CHDC/F7CNPC	1 -Yes. 2 = No
13A 13B <b>13C 13D</b> <b>13E</b>	<b>11</b> <b>11</b> 11 11 11	F7CCOMPA/F7CHDCA/F7CNPCA F7CCOMPB/F7CHDCB/F7CNPCB F7CCOMPC/F7CHDCC/F7CNPCC F7CCOMPD/F7CHDCD/F7CNPCD F7CCOMPE/F7CHDCE/F7CNPCE	1 = Yes, 2 = No
14 <b>14A</b> 14B 14c	11 <b>11</b> 11 11	F7COCC/F7CHDOC/F7CNPOC F7COCCA/F7CHDOCA/F7CNPOCA F7COCCB/F7CHDOCB/F7CNPOCB F7COCCC/F7CHDOCC/F7CNPOCC	1 = Yes, 2 = No
15	11	F7CARR/F7CHDARR/F7CNPARR	1 = Yes, 2 = No
<b>16A 16B</b> 16C 16D	<b>I1</b> 11 <b>I1</b> 11	F7CPE/F7CHDPE/F7CNPPE F7CHPO/F7CHDPO/F7CNPPO F7CCA/F7CHDCA/F7CNPCA F7CANA/F7CHDANA/F7CNPANA	1 = Yes, 2 = No

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## FORM 7C (REV 0) Cardiac Catheterization Procedures Form (Clinic)

Three sets of variables corresponding to the first three catheterizations.

ITEM	LENGTH	NAME	CODES
2	F10.5	CTIME1/CTIME2/CTIME3	Days to catheterization
4	11	F7C1/F7C2/F7C3	1 = Protocol, 2 = HD, 3 = Non-Protocol
<b>6A</b> 6B 6C 6D	13 13 13 13	LVPSBP1/LVPSBP2/LVPSBP3 LVEDBP1/LVEDBP2/LVEDBP3 ASBP1/ASBP2/ASBP3 ADBP1/ADBP2/ADBP3	mm Hg mm Hg mm Hg mm Hg
8A 8B	I1 I1	F7CGR1/F7CGR2/F7CGR3 F7CST1/F7CST2/F7CST3	Grade = 0, 1, 2 or 3 % stenosis O-100
9	11	F7CIRA1/F7CIRA2/F7CIRA3	Clinic assessment of IRA 1 = LAD 2 = Diagonal 3 = Circumflex 4 = Obtuse marginal 5 = RCA/RPDA 6 = LMCA
12	11	F7CCOMP1/F7CCOMP2/F7CCOMP3	1 = Yes, 2 = No
<b>13A</b> <b>13B</b> 13c 13D <b>13E</b>	<b>I1</b> <b>I1</b> <b>I1</b> 11 11	F7CCMPA1/F7CCMPA2/F7CCMPA3 F7CCMPB1/F7CCMPB2/F7CCMPB3 F7CCMPC1/F7CCMPC2/F7CCMPC3 F7CCMPD1/F7CCMPD2/F7CCMPD3 F7CCMPE1/F7CCMPE2/F7CCMPE3	1 = Yes, 2 = No
14 14A 14B 14c	11 11 11 <b>11</b>	F7COCC1/F7COCC2/F7COCC3 F7COCCA1/F7COCCA2/F7COCCA3 F7COCCB1/F7COCCB2/F7COCCB3 F7COCCC1/F7COCCC2/F7COCCC3	1 = Yes, 2 = No
15	11	F7CARR1/F7CARR2/F7CARR3	1 = Yes, 2 = No
16A	11	F7CPE1/F7CPE2/F7CPE3	

 16A
 11
 F7CPE1/F7CPE2/F7CPE3

 16B
 11
 F7CHP01/F7CHP02/F7CHP03

 16C
 11
 F7CCA1/F7CCA2/F7CCA3

 16D
 11
 F7CANA1/F7CANA2/F7CANA3
There is a set of variables for the protocol/hospital discharge/ first nonprotocol catheterizations.

ITEM	LENGTH	NAME	CODES	
Rev 0, 1 header Rev 2, 3, 4, <b>#</b> 4	11	F7F/F7FHD/F7FNP	1 - form received, 0 -	none
Rev 0, 1 # 7 Rev 2, 3, 4, # 6	11	DOMNANCE*	1 = balance 2 = right <b>3 =</b> left	
Rev 0, 1 # 5 Rev 2, 3, 4, # 7 Rev 6, #6	12	ARTERY*	<pre>Rev 0, 1, 2, 3 1 = Prox RCA 2 = Mid RCA 3 = Dist RCA 4 = RPDA 5 = RPLS 6 = LMCA 7 = Prox LAD 8 = Mid LAD 9 = Dist LAD 10 = 1st DIAG 11 = 2nd DIAG 12 = Prox CX 13 = Dist CX 14 = OMB 1 15 = OMB 2 16 = LAV 18 = Anterior infarct 19 = Inferior. (or other infarct)</pre>	<pre>Rev 4, 6 1 2 3 4 5,6,7,8,9,10 11 12 13 14 15 16,17 18 19 20 21,22 23,24,25,26,27 29 30</pre>
CALCULATED	11	VESSEL*	1 = RCA (if missing, H 2 = LMCA 9 was used) 3 = LAD 4 = CX	Form 7C item
CALCULATED	11	NOVES*	Number of vessels with stenosis	≥ 60%
CALCULATED	13	STENRCA*	<pre>% stenosis Rev 0, 1, 2, 3: Maximu     to #7-5 Rev 4: Maximum of #7- Rev 6: Maximum of #6-</pre>	<b>1</b> To #7-10
CALCULATED	13	STENLMCA*	% stenosis Rev 0, 1, 2, 3: #7-6 Rev 4: <b>#7-11</b> Rev 6: <b>#6-11</b>	

\*Only available for the <u>first</u> film analyzed by the Core Lab.

#### FORM 7F (REV 0, 1, 2, 3, 4, 6) Coronary Arteriography Visual Assessment (Core Lab)

There is a set of variables for the protocol/hospital discharge/ first nonprotocol catheterizations. (Continued)

ITEM	LENGTH	NAME	CODES
CALCULATED	13	STENLAD*	<pre>% stenosis Rev 0, 1, 2, 3: Maximum of #7-7     to #7-11 Rev 4: Maximum of #7-12 to #7-17 Rev 6: Maximum of #6-12 to #6-17</pre>
CALCULATED to #7-16 REVISIONS 0, 1	13	STENCX*	<pre>% stenosis Rev 0, 1, 2, 3: Maximum of #7-12 Rev 4: Maximum of #7-18 to #7-27 Rev 6: Maximum of #6-18 to #6-27</pre>
#6A #6B	11 13 11 13	<b>PREGR/GRADEHD/GRADENP</b> PREST/STENHD/STENNP POSTGR POSTST	o-3 } If missing, Form 7C <b>#8</b> % was used o-3 %
REVISIONS 2, 3, 4 #8D1	11 13	PREGR/GRADEHD/GRADENP PREST/STENHD/STENNP	0-3 ┟ If missing, Form 7C <b>#8</b> % was used
#8D2	<b>I1</b> 13	POSTGR POSTST	०-3 १
REVISION 6			
#7A1 #7A2	<b>I1</b> 13 <b>I1</b> 13	PREGR/GRADEHD/GRADENP PREST/STENHD/STENNP POSTGR POSTST	O - 3 Form 7C #8 % was used o-3 %
CALCULATED	11	SUCCESS*	<pre>1 = full success 2 = partial success 3 = not successful</pre>
CALCULATED	11	COLLAT*	0 = None, 1 = collaterals to IRA present

\*Only available for the  $\underline{\text{first}}$  film analyzed by the Core Lab.

FORM 7F (REV 0, 1, 2, 3, 4, 6) Coronary Arteriography Visual Assessment (Core Lab)

There is a set of variables for the first three catheterizations.

ITEM	<u>LENGTH</u>	NAME	<u>CODES</u>
Rev 0, 1 header Rev 2, 3, 4 <b>#4</b>	11	F7F1/F7F2/F7F3	1 = Protocol 2 = HD 3 = Non-Protocol
Revisions 0, 1 <b>#6A</b>	11 13	F7FPREG1/F7FPREG2/F7FPREG F7FPRES1/F7FPRES2/F7FPRES	
#6B	11 13	F7FPSTG1/F7FPSTG2/F7FPSTG F7FPSTS1/F7FPSTS2/F7FPSTS	
Revisions 2, 3, 4 <b>#8D1</b>	11 13	F7FPREG1/F7FPREG2/F7FPREG F7FPRES1/F7FPRES2/F7FPRES	
#8D2	11 13	F7FPSTG1/F7FPSTG2/F7FPSTG F7FPSTS1/F7FPSTS2/F7FPSTS	
Revision 6 <b>#7A1</b>	11 13	F7FPREG1/F7FPREG2/F7FPREG F7FPRES1/F7FPRES2/F7FPRES	
#7A2	11 13	F7FPSTG1/F7FPSTG2/F7FPSTG F7FPSTS1/F7FPSTS2/F7FPSTS	

FORM **8A** (REV **0)** Radionuclide Shipping Record • REST/EXERCISE RVG (Clinic)

Data collected at Hospital Discharge (HD) and 6 weeks post study entry (6W)

ITEM	LENGTH	NAME	CODES
2	13	F8ADAYHD, F8ADAY6W	Days from treatment initiation
4A	11	RESTHD, <b>REST6W</b>	1 = Done, 2 = Not done
4B	11	EXERHD, <b>EXER6W</b>	1 = Done, 2 = Not done
17E-18E*	13	RSTSBPHD, <b>RSTSBP6W</b>	Mean resting systolic blood pressure (mm Hg)
19E-26E*	13	EXSBPHD, <b>EXSBP6W</b>	SBP at peak stage during exercise (mm Hg)
27E*	13	RECSBPHD, RECSBP6W	Recovery systolic blood pressure (mm Hg)
17F-18F*	13	RSTHRHD, <b>RSTHR6W</b>	Mean resting heart rate (beats/minute)
19F-26F*	13	EXHRHD, <b>EXHR6W</b>	Exercise heart rate at peak stage (beats/minute)
27F	13	RECHRHD, <b>RECHR6W</b>	Recovery heart rate (beats/minute)
32**	11	STAGEHD, STAGE6W	Stage = 1, 2, 8
33	11	MUGAHD, <b>MUGA6W</b>	1 = Positive 2 = Negative 3 = Indeterminate
34*	11	EXPAINHD, <b>EXPAIN6W</b>	1 -Yes, 2 <b>= No</b>

\*Used only if corresponding items on Form 39 are missing. \*\*Used only if corresponding items on Form 08D are missing. FORM 8C (REV 0, 1) Radionuclide Data Analysis Report • Resting RVG (Core Lab)

Data collected at Hospital Discharge (HD) and 6 weeks (6W) post study entry

ITEM	LENGTH	NAME	CODES
8A	12	RESTEFHD, <b>RESTEF6W</b>	8
8B	F5.2	PFRHD, <b>PFR6W</b>	<b>v/sec</b> (not available on Rev 0)
9A1 9B1 9C1 9D1 9F1 9G1 9H1 911 9J1 9K1	11 11 11 11 11 11 11 11 11 11 11	ANAHD, ANA6W ANBHD, ANB6W ANCHD, ANC6W ANDHD, AND6W ANEHD, ANE6W ANFHD, ANF6W ANGHD, ANG6W ANHHD, ANH6W ANIHD, ANI6W ANJHD, ANJ6W ANKHD, ANK6W	<b>0 - No</b> 1 - Yes
11	I1	RVMIHD, <b>RVMI6W</b>	1 = Yes, 2 = No
<b>11A</b>	I1	RVMIHDA, <b>RVMI6WA</b>	1 = Diffuse, 2 = Local
12A1	F4.1	SDBSEPHD, SDBSEP6W	Mean S.D.
12A2	F4.1	SDASEPHD, SDASEP6W	
12A7	F4.1	SDIFAHD, SDIFA6W	
12A10	F4.1	SDIFLHD, SDIFL6W	
12A11	F4.1	SDPTLHD, SDPTL6W	
12A1	12	RBSEPHD, <b>RBSEP6W</b>	\$
12A2	12	<b>RASEPHD, RASEP6W</b>	
12A7	12	RIFAHD, <b>RIFA6W</b>	
12A10	12	RIFLHD, <b>RIFL6W</b>	
12A11	12	<b>RPTLHD, RPTL6W</b>	
12B4	F4.1	SDABHD, SDAB6W	Mean S.D.
12B5	F4.1	SDANTHD, SDANT6W	
12B6	F4.1	SDAPHD, SDAP6W	
12B8	F4.1	SDINFHD, SDINF6W	
12B9	F4.1	SDPBHD, SDPB6W	
13A1	F3.1	LADPOHD, <b>LADPO6W</b>	Mean S.D.
13A3	F3.1	LADPERHD, <b>LADPER6W</b>	
13B1	F3.1	RCAPOHD, <b>RCAP06W</b>	
13B3	F3.1	RCAPERHD, <b>RCAPER6W</b>	
14A1	13	P01HD, P016W	Number chords (o-100)
14A2	12	P01ANTHD, P01ANT6W	Number of anterior chords (O-60)
14A3	12	P01INFHD, P01INF6W	Number of inferior chords (O-40)
14B1	13	P02HD, P026W	Number of chords (o-100)
14B2	<b>12</b>	P02ANTHD, P02ANT6W	Number of anterior chords (O-60)
14B3	13	P02INFHD, P02INF6W	Number of inferior chords (O-40)

1

#### FORM 8C (REV 0, 1) Radionuclide Data Analysis Report - Resting RVG (Core Lab) (Continued)

ITEM	LENGTH	NAME	CODES
15A1	13	PR1HD, PR16W	Number of chords (o-100)
15A2	12	PR1ANTHD, PR1ANT6W	Number of anterior chords (0-60)
15A3	12	PR1INFHD, PR1INF6W	Number of inferior chords (0-40)
15B1	13	PR2HD, PR26W	Number of chords (o-100)
15B2	12	PR2ANTHD, PR2ANT6W	Number of anterior chords (0-60)
15B3	12	PR1INFHD, PR1INF6W	Number of inferior chords (0-40)

## FORM $\ensuremath{\texttt{8D}}$ (REV 0, 1) Radionuclide Data Analysis Report - Exercise RVG (Core Lab)

Data collected at Hospital Discharge (HD) and 6 weeks (6W) post study entry

ITEM	LENGTH	NAME	CODES
5A	12	BASEEFHD, BASEEF6W	8
5D	13	BASEBSHD, BASEBS6W )	
5E	13	BASEASHD, BASEAS6W	
5F	13	BASEIAHD, BASEIA61	0
5G	13	BASEILHD, BASEIL6W	•
5H	13	BASEPLHD, BASEPL6W	
JII	10	BASEFILLD, BASEFLOW J	
PEAR STAGE C	14	PEAKCHHD, PEAKCH6W ]	
D	13	PEAKBSHD, PEAKBS6W	
Ē	13	PEAKASHD, <b>PEAKAS6W</b>	
F	13	PEAKIAHD, PEAKIA6W	2
G	13	PEAKILHD, PEAKIL6W	0
H	13	PEAKPLHD, PEAKPL6W J	
14A	13	RECEFHD, RECEF6W	
14c	14	RECCHHD, RECCH6W	
14D	13	RECBSHD, RECBS6W	
			٩
14E	<b>I3</b>	RECASHD, RECAS6W	8
14F	13	RECIAHD, RECIA6W	
14G	13	RECILHD, RECIL6W	
14H	13	RECPLHD, <b>RECPL6W</b> t	
15A	13	BESTHD, BEST6W	8
15R 15B	13	WORSTHD, WORST6W	9 8
150	15	WORDTILD, WORDTOW	0
16	11	EFCHGHD, EFCHG6W	<b>1 =</b> fall ≥ 5%
		,	$2 = \text{increase} \geq 5\%$
			<b>3 =</b> no change
17	11	STAGEHD, STAGE6W	Peak stage (l-8)
18	12	EXEFHD, <b>EXEF6W</b>	ê.
1.0	<b>T</b> 1		1 1-11
19	<b>I</b> 1	PSPESVHD, PSPESV6W	1 - Fall
			2 = Increase
			3 = No change
	11	RESULTHD, RESULT6W	1 = Test done, result was negative
CALCULATED	ΤΤ	KEDULTHD, KEDULIOW	
			(good outcome)
			2 = Test done, but not negative and
			not positive
			3 = Test done, result was positive
			4 - Test not done, but patient was alive
			5 = Test not done, patient had died

B - 2 7 <sup>I</sup>

FORM 10 (REV 0) Hospital Discharge Form

ITEM	<u>LENGTH</u>	<u>NAME</u>	CODES
	11	FORM10	1 = Form received
2	13	HDDAY	Days from treatment initiation to hospital discharge
3	11	HDSTAT	1 - Alive, 2 - Dead
5	11	MICONFIR	1 -Yes, <b>2 = No</b>
5A	11 11	MICK MIECG	1 - Yes, 2 - No, 3 - Not done 1 - Yes, 2 <b>=</b> No, 3 - Not done
5B		MIECG	1 105, 2 - NO, 5 NOC done
7	11	CLNCOMHD	1 -Yes, $2 = No$
10	11	CHF	1 -Yes, <b>2 = No</b>
10	13	HDCHFT	Days from treatment initiation to congestive heart failure
11	11	SHOCK	1 = Yes, 2 = No
11	13	HDSHKT	Days from treatment initiation to cardiogenic shock
12	11	VSRUP	1 -Yes, <b>2 - No</b>
12	13	HDVSRUPT	Days from treatment initiation to ventricular septal rupture
13	11	MITRAL	1 = Yes, 2 - No
13	13	HDMITT	Days from treatment initiation to mitral regurgitation
14	11	ARREST	1 = Yes, 2 = No
14	13	HDARSTT	Days from treatment initiation to cardiac arrest
15	11	PAIN	1 -Yes, 2 -No
15	13	HDPNT	Days from treatment initiation to recurrent ischemic pain
16	11	HEMCOM	1 -Yes, <b>2 = No</b>
16A	11	HEMCOMA	1 -Yes, 2 -No
16A	13	HDHEMAT	Days from treatment initiation to hematoma
16B	11	HEMCOMB	1 -Yes, 2 -No
16B	I3	HDHEMBT	Days from treatment initiation to bleeding at puncture site
16C	11	HEMCOMC	1 = Yes, 2 = No
16C	13	HDHEMCT	Days from treatment initiation to ${ t GI}$ bleeding
16D	11	HEMCOMD	1 -Yes, 2 <b>= No</b>
16D	13	HDHEMDT	Days from treatment initiation to significant decrease in hematocrit or hemoglobin
16E	11	HEMCOME	<b>1 = Yes</b> , 2 -No
16E	13	HDHEMET	Days fro-m treatment initiation to transfusion

<u>ITEM</u>	<b>LENGTH</b>	NAME	CODES
16F 16F	11 13	HEMCOMF HDHEMFT	1 = Yes, 2 = No Days from treatment initiation to bleeding requiring surgery
16G 16G	<b>I1</b> 13	HEMCOMG HDHEMGT	1 = Yes, 2 = No Days from treatment initiation to retroperitoneal bleeding
16H 16H	11 13	HEMCOMH HDHEMHT	1 = Yes, 2 = No Days from treatment initiation to intracranial bleeding
161 161	I1 13	HEMCOMI HDHEMIT	1 = Yes, 2 = No Days from treatment initiation to fatal hemorrhage
16J 16J	I1 13	HEMCOMJ HDHEMJT	1 - Yes, 2 - No Days from treatment initiation to thrombocytopenia
16K 16K	11 13	HEMCOMK HDHEMKT	l = Yes, 2 = No Days from treatment initiation to hematuria
16L 16L	11 13	HEMCOML HDHEMLT	<pre>1 = Yes, 2 = No Days from treatment initiation to other bleeding</pre>
17	11	INFCOM	1 - Yes, 2 = No
<b>17A</b> 17A	11 <u>-</u> 13	INFCOMA HDINFAT	<pre>1 = Yes, 2 = No Days from treatment initiation to infection at puncture site</pre>
17B 17B	I1 13	INFCOMB HDINFBT	<pre>l = Yes, 2 -No Days from treatment initiation to infection at other site</pre>
18	11	VASCOM	1 - Yes, 2 = No
18A 18A	11 13	VASCOMA HDVASAT	1 -Yes, 2 = No Days from treatment initiation to arterial embolism
18B 18B	I1 13	VASCOMB HDVASBT	l = Yes, 2 = No Days from treatment initiation to arterial thrombosis
18C 18C	11 13	VASCOMC HDVASCT	l = Yes, 2 = No Days from treatment initiation to venous thrombophlebitis
18D 18D	11 13	VASCOMD HDVASDT	1 -Yes, 2 = No Days from treatment initiation to cerebrovascular accident

<u>ITEM</u>	LENGTH	NAME	CODES
18E 18E	<b>11</b> 13	VASCOME HDVASET	1 = Yes, 2 ≡ No Days from treatment initiation to arterial dissection
18F 18F	<b>11</b> 13	VASCOMF HDVASFT	1 = Yes, 2 = No Days from treatment initiation to other vascular complication
19	11	THRCOM	1 -Yes, 2 -No
19A 19A	<b>11</b> 13	THRCOMA HDTHRAT	<b>l =</b> Yes, 2 <b>- No</b> Days from treatment initiation to <b>pleuritis/</b> pleural effusion
19B 19B	<b>11</b> 13	THRCOMB HDTHRBT	1 -Yes, 2 <b>= No</b> Days from treatment initiation to pericarditis/ pericardial effusion
19C 19C	<b>11</b> 13	THRCOMC HDTHRCT	1 -Yes, 2 <b>= No</b> Days from treatment initiation to hemothorax
19D 19D	<b>I1</b> 13	THRCOMD HDTHRDT	1 <b>= Yes,</b> 2 <b>= No</b> Days from treatment initiation to hemomediastinum
19E 19E	11 13	THRCOME HDTHRET	<pre>1 = Yes, 2 = No Days from treatment initiation to pulmonary embolism</pre>
19F 19F	<b>11</b> 13	THRCOMF HDTHRFT	1 -Yes, 2 <b>- No</b> Days from treatment initiation to other thoracic complication
20	11	OTHCOM	1 = Yes, 2 -No
20A 20A	<b>11</b> 13	OTHCOMA HDOTHAT	<pre>1 = Yes, 2 = No Days from treatment initiation to allergic reaction</pre>
20B 20B	<b>I1</b> 13	OTHCOMB HDOTHBT	<pre>1 = Yes, 2 = No Days from treatment initiation to renal insufficiency</pre>
20c 20c	<b>I1</b> 13	OTHCOMC HDOTHCT	<pre>1 = Yes, 2 = No Days from treatment initiation to liver function abnormalities</pre>
20D 20D	<b>I1</b> 13	OTHCOMD HDOTHDT	1 -Yes, 2 <b>= No</b> Days from treatment initiation to other complication
21	11	SURPRO	1 -Yes, 2 <b>= No</b>

<u>ITEM</u>	LENGTH	NAME	CODES
22 22	11 13	ECARD HDCRDT	1 = Yes, 2 -No Days from treatment initiation to electrical cardioversion/defibrillation
23 23	I1 13	RTCATH HDRCTHT	1 - Yes, 2 - No Days from treatment initiation to right heart catheterization
24 24	I1 13	CARDCATH HDCCTHT	1 = Yes, 2 -No Days from treatment initiation to left heart cardiac catheterization
25 25	I1 13	IABP HDIABT	1 = Yes, 2 = No Days from treatment initiation to intra-aortic balloon counter pulsation
26	11	CARSUR	1 - Yes, 2 = No
26A 26A	I1 13	CABG HDCABGT	1 = Yes, 2 = No Days from treatment initiation to CABG
26B 26B	I1 13	OTHSUR HDOSURT	1 = Yes, 2 = No Days from treatment initiation to other surgery
28 28	I1 13	EPACE HDPACET	1 = Yes, 2 = No Days from treatment initiation to electrical pacing
28A	11	EPACETYP	0 = None, 1 = Temporary, 2 = Permanent,
29 29	I1 13	EPHYS HDEPHST	1 = Yes, 2 = No Days from treatment initiation to electro- physiology studies
30 30	I1 13	OTHSP HDOSPT	1 = Yes, 2 = No Days from treatment initiation to other special procedures

ITEM	LENGTH	NAME	CODES
40A1 40A2 40B1 40B2 40C11 40C12 40C21 40C22 40D1 40D2 40C1 40D2 40C1 40C2 40C2 40C2 40C2 40C2 40C2 40C2 40C2	11 11 11 11 11 11 11 11 11 11	HDRXA HDDRXA HDRXB HDRXC1 HDRXC1 HDRXC2 HDDRXC2 HDDRXC2 HDRXD HDDRXD HDDRXF HDDRXF HDDRXF HDDRXF HDDRXF HDDRXH HDDRXI HDDRXI HDDRXI HDRXI HDDRXL HDRXL HDRXL HDRXL HDRXM HDRXN HDRXN HDRXN HDRXN HDRXN HDRXN HDRXN HDRXN HDRXN HDRXN HDRXN HDRXN HDRXN	1 - Yes, 2 - No In-hospital variables prefixed by "HD." Hospital discharge variables prefixed by "HDD" (missing HDDRXA-HDDRKP if patient died prior to Hospital Discharge).
41 41A	11 11	HEPSTOP HEPDAYS	1 = Yes, 2 = No Days of heparin = 0, 1, 2, 3, 4 or 5
42 42B	11 13	ORALBB10 ORALBBT	1 = Yes, 2 ≖ No Days from treatment initiation to oral beta-blocker therapy

### FORMS 11/12/13

Follow-up Forms (Variables suffixed by "6W" are from the 6-Week Follow-up Visit. and variables suffixed by "YE" are from the 1-Year Visit.)

ITEM	LENGTH	NAME	CODES
Header of Form 11 or Form 12 or Form 13	11	TYPEFU	Most recent contact recorded was 1 = follow-up visit form 2 = missed visit form 3 = telephone contact form 4 = Hospital discharge form 5 = Death 6 = Search agency
Header of Form 11	11	FU6W, FUYR	1 <b>=</b> Follow-up Visit 0 <b>=</b> No Follow-up Visit
Form 11 # 2 or Form 12 # 2 or Form 13 # 2	14	DAYSFU	Days from treatment initiation to most recent contact
Form 11 <b>#</b> 6	11	PHYACT6W, PHYACTYE	1 -Yes, 2 <b>= No</b>
Form 11 # 7	11	HRTCLS6W, HRTCLSYR	<pre>0 = Class 0 1 = Class I 2 = Class II 3 = Class III 4 = Class IV</pre>
Form 11 <b># 9B</b> or Form 12 <b>#</b> 8B	11	CAFV01, CAFV02	1 = Definite
Form 11 <b># 9C</b> or Form 12 <b>#</b> 8C	11	CHFFV01, CHFFV02	2 = No 3 = Suspect 4 = Unknown
Form 11 # <b>9D</b> or Form 12 # 8D	11	PAINFV01, PAINFV02	
Form 11 # 13A # 13B # 13C1 # 13C5 # 13D # 13E # 13F # 13G # 13H # 13I # 13J # 13J # 13J # 13M # 13M # 13M # 13N # 13N # 130 # 13P	11 11 11 11 11 11 11 11 11 11	FURXA6W, FURXAYR FURXB6W, FURXBYR FURXC16W, FURXC1YR FURXC56W, FURXC5YR FURXD6W, FURXDYR FURXE6W, FURXDYR FURXF6W, FURXFYR FURXG6W, FURXFYR FURX16W, FURXHYR FURX16W, FURXIYR FURXL6W, FURXLYR FURXL6W, FURXLYR FURXL6W, FURXLYR FURXM6W, FURXMYR FURXN6W, FURXMYR FURXN6W, FURXNYR FURXO6W, FURXOYR FURXO6W, FURXOYR	1 -Yes, <b>2 = No</b>

#### FORMS 11/12/13 Follow-up Forms (Continued)

ITEM	LENGTH	NAME	CODES
Form 12 # 4 or Form 13 # 4	11	LOCATEFU	At most recent follow-up: 1 = able to locate patient 2 = not able
Form 12 # 4B or Form 13 # 4B	11	CCFU	At most recent follow-up: 1 = want Coordinating Center to help locate patient 2 = no help
Form 12 # 7	12	MISS6W, MISSYR	<pre>1 = patient ill 2 = patient moved 3 = reason related to study design 4 = reason related to clinic 5 = lack of family or physician     support 6 = uncooperative 7 = other 8 = unknown</pre>
Form 12 # 12A	11	SOURCE6W, SOURCEYR	<pre>1 = patient 2 = spouse/significant other 3 = other kin 4 = patient's doctor 5 = patient's employer 6 = hospital chart</pre>

6 = hospit7 = other FORM 14 (REV 0) Subsequent Hospitalization Form (Only Cardiovascular **Rehospitalizations** Extracted)

ITEM	<u>LENGTH</u>	NAME	CODES
2	I4	HOS <u>C</u> DAY	Days to hospitalization for cardiovascular reasons (item <b>#7 =</b> 1) from treatment initiation. If <b># 7 =</b> 0 then HOSCDAY <b>=</b> maximum time to follow-up from Forms <b>11/12/13/14/15.</b>
7	11	CHOSC	Censoring variable: <b>1 =</b> cardiovascular reasons 0 <b>=</b> none
2	14	RHPAINT	Days to first re-hospitalization for definite angina
88	11	RHPAIN	Patient was re-hospitalized for definite angina (used to calculate variables in RPIE file) 1 = Yes 0 = No
2	14	CHFDAY	Days to congestive heart failure from treatment initiation. (Form 10 Item 10 also used). If no CHF, this is time to death or follow-up.
8C	11	CCHF	Censoring variable: 1 = congestive heart failure 0 = none
2	14	ARRDAY	Days from treatment initiation to arrhythmia. If no arrhythmia, this is time to death or follow-up.
8 D	11	CARR	Censoring variable: 1 = arrhythmia 0 = none
	14	STKDAY	Days from treatment initiation to stroke. (Form 28 also used if category = infarction or hemorrhage (1 or 2). If no stroke, this is time to death or follow-up.
8 E	11	CSTK	Censoring variable: 1 = stroke, only if hemorrhage or infarction (on Form 28) or if hospitalized for stroke (Form 14) 0 = none
2	14	HOSPDAY1	Days to first re-hospitalization
2	14	STAY1	Length of stay (days) for first re-hospitalization
6	11	RHEL1	First re-hospitalization was elective 1 = Yes 2 = No

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#### FORM 14 (REV 0) Subsequent Hospitalization Form (Continued)

ITEM	LENGTH	<u>NAME</u>	CODES
8A 8B 8C 8D 8E 8F1 8F2 8F3 8F4 8F5 8G	11	RHMI1 RHANG1 RHCHF1 RHARR1 RHSTK1 RHCATH1 RHPTCA1 RHCABG1 RHPP1 RHOSUR1 RHOTH1	<pre>1 = Yes 2 = No 3 = Suspect 1 = Yes 2 = No 1 = Yes, 2 = No, 3 = Suspect</pre>
2	14	HOSPDAY2	Days to second re-hospitalization
2	14	STAY2	Length of stay (days) for second re-hospitalization
б	11	RHEL2	Second re-hospitalization was elective 1 = Yes 2 = No
8A 8B 8C 8D 8E 8F1 8F2 8F3 8F4 8F5 8G	] 11	RHMI2 RHANG2 RHCHF2 RHARR2 RHSTK2 RHCATH2 RHPTCA2 RHCABG2 RHPP2 RHOSUR2 RHOTH2	<pre>1 = Yes 2 = No 3 = Suspect 1 = Yes 2 = No 1 = Yes, 2 = No, 3 = Suspect</pre>
2	14	HOSPDAY3	Days to third re-hospitalization
2	I4	STAY3	Length of stay (days) for third re-hospitalization
6	11	RHEL3	Third re-hospitalization was elective 1 = Yes 2 = No
8A 8B 8C 8D 8E 8F1 8F2 8F3 8F4 8F5 8G	] 11	RHMI3 RHANG3 RHCHF3 <b>RHARR3</b> RHSTK3 RHCATH3 RHPTCA3 <b>RHCABG3</b> RHPP3 RHOSUR3 RHOTH3	<pre>1 = Yes 2 = No 3 = Suspect 1 = Yes 2 = No 1 = Yes, 2 = No, 3 = Suspect</pre>

#### FORM 14 (REV 0) Subsequent Hospitalization Form (Continued)

ITEM	LENGTH	NAME	CODES
2	I4	HOSPDAY4	Days to fourth re-hospitalization
2	I4	STAY4	Length of stay (days) for fourth re-hospitalization
6	11	RHEL4	Fourth re-hospitalization was elective 1 = Yes 2 = No
8A 8B 8C 8D 8E 8F1 8F2 8F3 8F3 8F4 8F5 8G	11	RHMI4 RHANG4 RHCHF4 RHARR4 RHSTK4 RHCATH4 RHPTCA4 RHCABG4 RHPP4 RHOSUR4 RHOTH4	<pre>1 = Yes 2 = No 3 = Suspect 1 = Yes 2 = No 1 = Yes, 2 = No, 3 = Suspect</pre>
2	14	HOSPDAY5	Days to fifth re-hospitalization
2	14	STAY5	Length of stay (days) for fifth re-hospitalization
6	11	RHEL5	Fifth re-hospitalization was elective 1 = Yes 2 = No
8A 8B 8C 8D 8E 8F1 8F2 8F3 8F4 8F5 8G	11	RHM15 RHANG5 RHCHF5 <b>RHARR5</b> <b>RHSTK5</b> RHCATH5 RHPTCA5 <b>RHCABG5</b> <b>RHCABG5</b> <b>RHPP5</b> RHOSUR5 RHOTH5	<pre>1 = Yes 2 = No 3 = Suspect 1 = Yes 2 = No 1 = Yes, 2 = No, 3 = Suspect</pre>
CALCULATED	11	FORM14_1	Total number of Form 14's received for a patient (only cardiovascular re-hospitalizations)
CALCULATED	11	FORM14_2	1 = Second Form 14 received
CALCULATED	11	FORM14_3	1 = Third Form 14 received
CALCULATED	11	FORM14_4	1 = Fourth Form 14 received
CALCULATED	11	FORM14_5	1 = Fifth Form 14 received

<u>ITEM</u>	<u>LENGTH</u>	NAME	CODES
	11	FORM15	1 = Form received
S	12	F15CAUSE	<pre>Tentative cause of death 1 = Qualifying MI 2 = New MI, confirmed or suspected 3 = Sudden coronary death - arrhythmia suspected 4 = Congestive heart failure 5 = Confirmed cardiac arrhythmia 6 = Peri-operative cardiovascular surgical death 7 = Stroke 8 = Non-cardiac, non-cerebral, atherosclerotic arterial disease 9 = Pulmonary embolism 10 = Non-atherosclerotic heart disease 11 = Neoplastic disease 12 = All other diseases 13 = Non-cardiovascular surgically related death 14 = Homicide, suicide, accident 1s = Unknown</pre>

ITEM	<u>LENGTH</u>	NAME	<u>CODES</u>
	11	FORM16	1 - Form received
16	11	AUTOPSY	1 <b>= Yes,</b> 2 -No

FORM 17 (REV 2, 3) MMCC Death Classification Form

ITEM	<u>LENGTH</u>	NAME	<u>CODES</u>
Header	11	DEATH	l = Patient died (at any time) 0 ■ Patient alive
2	F10.5	DTIME	Time (days) from treatment initiation to death (if missing Form 15 is used). If patient has not died, this is days of follow-up.
2	14	DDAYS	Integer days from treatment initiation to death. If patient has not died, this is days of follow-up.
6A	11	DCOMP	1 = natural causes 2 = complications
6B	11	DHEMORR	1 -Yes, 2 -No
6C	11	DPTCA	1 = Yes, 2 = No
6D	11	DCABG	1 -Yes, 2 <b>- No</b>
6 E	11	DOTHER	1 <b>= Yes,</b> 2 -No
7	11	DCVD	1 = Yes, 2 = No
8A	11	DCARDIAC	1 = Yes, 2 = No
8B/8B1	11	F17MI	0 = No or unknown 1 = Qualifying MI 2 = Recurrent MI
882	11	F17TIME	<pre>If DCOMP = 1:     1 = Before any procedures     2 = After any procedures     3 = No procedures performed</pre>
			<pre>If DCOMP = 2:     1 = Before any complications     2 = After any complications</pre>
8C	11 11 <b>11</b> 11	DPMPFAIL DVENTRUP DARRTH DOTHCAR	1 = Yes, 2 = No
15	F6.1	DICDCODE	ICD code

#### FORM 19 (REV 0) • PARTS 1, 2, 3, 4, 5, 6-15(a-e) Laboratory Data Form

ITEM	LENGTH	NAME	<u>CODES</u>
3	15	ULCK	IV/L
3A 3B 3C 3D 3F 3G 3H 31 <b>3J</b> 3K 3L 3M 3N 30 3P <b>3Q</b> 3R 3S	F10.5 F	CKTIMOOO CKTIM004 CKTIM012 CKTIM012 CKTIM016 CKTIM020 CKTIM024 CKTIM030 CKTIM036 CKTIM042 CKTIM042 CKTIM048 CKTIM072 CKTIM096 CKTIM120 CKTIM144 CKTIM168 CKTIM192 CKTIM216 CKTIM240	Time from treatment initiation (days)
3A 3B 3c 3D 3F 3G 3H 31 <b>3J</b> 3K 3L 3M 3N 30 3P <b>3Q</b> 3R 3S	15 15 15 15 15 15 15 15 15 15 15 15 15 1	CKTOTOOO CKTOTO04 CKTOT008 CKTOT012 CKTOT016 CKTOT020 CKTOT024 CKTOT030 CKTOT036 CKTOT042 CKTOT048 CKTOT048 CKTOT072 CKTOT096 CKTOT120 CKTOT144 CKTOT168 CKTOT192 CKTOT216 CKTOT240	IU/L
6A 7A 8A 9A 10A 11A 12A 13A 14A 15A	15, <b>11</b> 15, <b>11</b> 15, <b>11</b> 15, <b>11</b> 15, <b>11</b> 15, <b>11</b> 15, <b>11</b> 15, <b>11</b> 15, <b>11</b> 15, <b>11</b>	HEP19D01, IVD01 HEP19D02, IVD02 HEP19D03, IVD03 HEP19D04, IVD04 HEP19D05, IVD05 HEP19D06, IVD06 HEP19D07, IVD07 HEP19D08, IVD08 HEP19D09, IVD09 HEP19D10, IVD10	U USP, 1 = IV 2 = Subcu 3 = Both 0 = None

#### FORM 19 (REV 0) • PARTS 1, 2, 3, 4, 5, 6-15(a-e) Laboratory Data Form (Continued)

<u>ITEM</u>	LENGTH	<u>NAME</u>	CODES
6B 7B 8B 9B 10B 11B 12B 13B 14B 15B	<b>14</b> 14 14 14 14 14 14 14 14	ASA19D01 ASA19D02 ASA19D03 ASA19D04 ASA19D05 ASA19D06 ASA19D07 ASA19D08 ASA19D08 ASA19D09 ASA19D10	mg
6C 7c 8C 9C 10C 11C 12C 13c 14C 15c	F4.1 F4.1 F4.1 F4.1 F4.1 F4.1 F4.1 F4.1 F4.1 F4.1 F4.1 F4.1	COU19D01 COU19D02 COU19D03 COU19D04 COU19D05 COU19D06 COU19D07 COU19D08 COU19D09 COU19D10	mg
6D 7D 8D 9D 10D 11D 12D 13D 14D 15D	13 13 13 13 13 13 13 13 13 13 13 13	MET19D01 MET19D02 MET19D03 MET19D04 MET19D05 MET19D06 MET19D07 MET19D08 MET19D09 MET19D10	mg
6E 7E 8E 9E 10E 11E 12E 13E 14E 15E	11 11 11 11 11 <b>11</b> 11 11 11 11	OBBD01 OBBD02 OBBD03 OBBD04 OBBD05 OBBD06 OBBD07 OBBD08 OBBD09 OBBD10	<b>1 =</b> Yes, 2 = No

#### FORM 23 (REV 0, 1, 2) Myocardial Infarction Event Form

ITEM	LENGTH	<u>NAME</u>	CODES
	11	FORM23	1 = At least 1 Form 23 received
	11	F23_1 F23_2 F23_3 F23_4 F23_5	<pre>1 = First Form 23 1 = Second Form 23 1 = Third Form 23 1 = Fourth Form 23 1 = Fifth Form 23</pre>
2	F10.5	MIDATE, MIDATE2, MIDATE3	Time (days) from treatment initiation to classified MI (used only if Form 43 # 2 is missing)
CALCULATED	11	CLINICMI 200171	Total number of Form 23's received for a patient (0, 1, 2,)
3в	11	F23PAIN1 F23PAIN2 F23PAIN3 F23PAIN4 F23PAIN5	Pain indicated on first Form 23 Pain indicated on second Form 23 Pain indicated on third Form 23 Pain indicated on fourth Form 23 Pain indicated on fifth Form 23
	14	F23PNT1 F23PNT2 F23PNT3 F23PNT4 F23PNT5	Days to pain identified above. (Missing if no pain)
CALCULATED	12	PAIN23 14-	Pain indicated on at least one Form 23
CALCULATED	14	PAIN23T / 4.	Time to first recording of pain on Form 23

RECURRENT PAINFUL ISCHEMIC EVENTS (R.P.I.E.) (Defined from Forms 10, 23, 43 and 14)

LENGTH	<u>NAME</u>	CODES
11	RPIEHD	First in hospital R.P.I.E. was 1 = Definite MI 2 = Suspect MI 3 = Pain recorded on Form 10 Item 15 0 = No event
13	RPIEHDT	Time to first in-hospital event (days). If no event, this is missing.
11	RPIE	<pre>First R.P.I.E. was 1 = Definite MI 2 = Suspect MI 3 = Rehospitalized for definite angina (Form 14) 0 = No event</pre>
13	RPIET	Time to first event (days). If no event, this is missing.
11	RPIEAFT	<pre>First R.P.I.E. after hospital discharge was 1 = Definite MI 2 = Suspect MI 3 = Rehospitalized for definite angina (Form 14) 0 = No event</pre>
13	RPIEAFTT	Time to first event after hospital discharge (days). If no event, this is missing.
11	DSMI	1 = Definite or suspect MI 0 = None
13	DSMIT	Time to first definite or suspect MI (days). If no event, this is missing.

There are <u>six</u> "sets" of variables (suffixed by 1, 2, 3, 4, 5 or 6) -- each is based on a different subgroup of events (Form 44 #4A).

- 1. Patient's first <u>maior</u>e n t
- 2. Patient's first major or minor event
- 3. Patient's first major, minor or loss no site event
- 4. Same as #1, but only nonsurgical events\*
- 5. Same as #2, but only nonsurgical events\*
- 6. Same as #3, but only nonsurgical events\*
- 7. Same as #1, but only surgical events
- 8. Same as #2, but only surgical events
- 9. Same as #3, but only surgical events

\* Nonsurgical events: Form 44 # 4B = 2. All loss no site events are nonsurgical.

ITEM	LENGTH	NAME	CODES
	11	FORM44	1 = At least 1 Form 44 received
Form 44 # 2	F10.5	HEMTIME1-9	Time (days) from treatment initia- tion to event. If no event, then this is days to hospital discharge or death prior to hospital discharge.
Form 44 # 4A	11	HEMSEV1, HEMSEV4, HEMSEV7	0 = none or missing 1 = major
	11	HEMSEV2, HEMSEV5, HEMSEV8	0 = none or missing 1 = major 2 = minor
	11	HEMSEV3, HEMSEV6, HEMSEV9	0 = none or missing 1 = major 2 = minor 4 = loss no site

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#### FORM 24 (REV 0, 1)/44 (REV 0, 1) (Continued)

ITEM	LENGTH	NAME	CODES
Form 44 #8	11	LT24_1-9	<ol> <li>Event occurred within 24 hours of rt-PA initiation</li> <li>Event did not occur within 24 hours of rt-PA initiation</li> <li>Loss no site (question not answered)</li> </ol>
CALCULATED	11	SEVTOT1	Total number of major events for a
CALCULATED	11	SEVTOT2	patient Total number of minor events for a patient
CALCULATED	11	SEVTOT3	Total number of no events for a patient
CALCULATED	11	SEVTOT4	Total number of loss no sites for a patient
Form 44 # 5A,	58 12	HEMPRIM1-9	<pre>0 = no event 1 = gastrointestinal 2 = intracranial 3 = catheter site 4 - other puncture site 5 - genitourinary 6 = retroperitoneal 7 = other 8 = unknown (includes loss no site) 10 = two or more secondary sites</pre>
Form 24 # 13	11	HEMTRNS1-9	1 = yes 2 = no
Form 10 # 2	13	HDDAY	Days from treatment initiation to hospital discharge
Form 17 #6B	11	HEMDEATH	<ol> <li>Death from hemorrhage prior to hospital discharge</li> <li>2 = Other cause of death</li> </ol>
CALCULATED	F10.5	HEMTIME	Time of HERC* event
CALCULATED	11	HEMSEV	Severity of HERC* event 1 = No event 2 = Major 3 = Minor 4 = Loss, no site

\*Most severe, nonsurgical event (defined by M. Terrin for HERC Manuscript).

#### FORM 24 (REV 0, 1)/44 (REV 0, 1) (Continued)

<u>ITEM</u>	LENGTH	NAME	CODES
CALCULATED	12	HEMPRIM	<pre>Site of HERC* event 0 = no event 1 = gastrointestinal 2 = intracranial 3 = catheter site 4 = other puncture site 5 = genitourinary 6 = retroperitoneal 7 = other 8 = unknown (includes loss no site) 10 = two or more secondary sites</pre>

\*Most severe, nonsurgical event (defined by M. Terrin for HERC Manuscript).

#### FORM 25 (REV 0, 1) Cardiac Surgery Form

If more than one event, data from first event is used (except for SURGTIM2)

ITEM	LENGTH	NAME	CODES
	11	FORM25	Number of Form 25's received
2	F10.5	SURGTIME	Days from treatment initiation to first event
2	F10.5	SURGTIM2	Days from treatment initiation to second event
4, 4A	11	SURGREAS	<pre>0 = elective 1 = angina without definite ECG changes 2 = angina with ECG changes 3 - persistent chest pain and ST elevation 4 = other</pre>
5A	11	ANGSTAT	<pre>1 = Definite angina 2 = Probable angina 3 = Probably not angina 4 - No angina</pre>
5B	11	ANGCLAS S	$ \begin{array}{rcl} 0 &=& 0 \\ 1 &=& I \\ 2 &=& II \\ 3 &=& III \\ 4 &=& IV \end{array} $
5 c	11	ANGPAIN	1 = Yes, 2 = No
б	11	F25EXER	1 = Yes, 2 = No
6A	13	F25PULSE	beats/min
6B1	13	F25SYSTO	mm Hg
6B2	13	F25DIAST	mm Hg
7	11	F25CATH	<b>1</b> = Yes, 2 = No
8A/8B	11	LADGRAFT	<pre>1 = LAD/diagonal 2 = other</pre>
8C/8D	11	CXGRAFT	<pre>1 = CX/obtuse marginal 2 = other</pre>
8 E	11	RCAGRAFT	1 = RCA or RPDA 2 = other
8F	11	LMCGRAFT	$\begin{array}{l} 1 = LMCA \\ 2 = other \end{array}$

#### FORM 25 (REV 0, 1) Cardiac Surgery Form (Continued)

If more than one event, data from first event is used (except for **SURGTIM2)** 

<u>ITEM</u>	LENGTH	<u>NAME</u>	CODES
9A 9B 9C 9D	<b>I1</b> <b>I1</b> 11	CONDSAP CONDLIM CONDRIM CONDOTH	1 = Conduit used
10A	11	F25DEATH	Death within 24 hours of CABG 1 = Yes, 2 = No (calculated from events)
10B	11	F25MI	MI within 24 hours of CABG 1 = Yes, 2 = No (calculated from events)
11	11	F25TRANS	1 = Yes, 2 = No (Rev 1 only)

#### FORM 26 (REV 0) Transfusion Report Form

ITEM	LENGTH	NAME	CODES
	11	FORM26	1 - Form received
	F10.5	TRANTIME	Days from treatment initiation to first transfusion (if no transfu- sion, this is days to hospital discharge)
3A 3B 3c 3D	11 11 11 11	F26HEM F26SURG F26ANEM F26OTH	0 = No, l-Yes 0 = No, l = Yes 0 = No, l = Yes 0 = No, <b>l = Yes</b>
4A	F4.1	F26WBU	Number of units. If missing Form 24 <b>#</b> 14A is used.
4B	F4.1	F26PCU	Number of units. If missing Form 24 # 14B is used.
CALCULATED	F5.1	TFUNIT	F26WBU + F26PCU

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FORM 27 (REV **0)** Severe **Neurologic** Event Form

ITEM	LENGTH	NAME	CODES
6	11	ALCOH	Alcohol consumption $1 - \leq 1$ oz 2 = 2-3 oz 3 = 4-5 oz $4 - \geq 6$ oz 5 = unknown
11A	12 12 12 12	EPMO EPDA EPYR EPHR EPMN	Earliest date and time of symptoms
11B	12 12 12 <b>12</b> 12	LPMO LPDA LPYR LPHR LPMN	Latest date and time of symptoms
12A	11 11 <b>11</b> 11 11	ITEM12A ITEM12B ITEM12C ITEM12D ITEM12E ITEM12F	Severe headache Vomiting Seizures Focal deficit Altered mental Coma
13	11	ITEM13	Onset was: 1 = Sudden 2 = Steplike 3 = Gradual 4 = Unknown
14	11	ITEM14	Maximum deficit achieved $1 = \leq 6$ hours 2 - 7-12 hours 3 = 13-24 hours 4 = 25-48 hours 5 = 49-72 hours 6 = > 72 hours 7 = Unknown
15	11	ITEM15	Improvement 1 = Yes, 2 = No, 3 = Unknown
16	11	ITEM16	Change in blood pressure 1 = Yes, 2 <del>=</del> No, 3 = Unknown
16A	11	ITEM16A	Hypotension 1 = Yes, 2 = No, 3 = Unknown
16B	11	ITEM16B	Hypertension 1 = Yes, 2 = No, 3 = Unknown

#### FORM 27 (REV 0) Severe **Neurologic** Event Form (Continued)

<u>item</u>	LENGTH	NAME	CODES
17A <b>17B</b> 17c 17D	11 11 11 11	ITEM17A ITEM17B ITEM17C ITEM17D	Antiplatelet agents Calcium channel blockers Ergotamines IV nitroglycerine 1 = Yes 2 = No
<b>18A</b> <b>18B</b> 18C	11 11 11	ITEM18A ITEM18B ITEM18C	Profound hypotension 3 = Unknown Fluctuations in systolic BP Arrhythmias
19	11	ITEM19	<pre>Verbal response 1 = Oriented and converses 2 - Disoriented/confused 3 = Inappropriate words 4 = Incomprehensible sounds 5 = None 6 = Untested</pre>
20	11	ITEM20	Eye opening 1 = Spontaneous 2 = To speech 3 - To pain 4 = None 5 = Untested
21	11	ITEM21	Motor response 1 = Obeys 2 - Localizes 3 = Withdraws 4 = Abnormal flexion 5 = Abnormal extension 6 - None 7 - Untested
46	11	ITEM46	CT scan evidence of lesion 1 - Yes, 2 - No, 3 = Unknown, 4 = Not done
46A 46B 46C 46D 46E 46F 46G 46H	11 11 11 11 11 11 11 11	ITEM46A ITEM46B ITEM46C ITEM46D ITEM46E ITEM46F ITEM46G ITEM46H	Deep <b>lacunar</b> infarction Cortical infarction Larger infarction Mottled hemorrhagic infarction Subarachnoid hemorrhage Intraparenchymal hemorrhage Watershed area infarction More than one infarction
53	11	ITEM53	Recovery <b>1</b> = Full, no deficit 2 = Partial, minor residual 3 = Partial, major residual 4 = Comatose 5 = Deceased

FORM 28 (REV 0) Severe Neurologic Event Classification Form

ITEM	LENGTH	NAME	CODES
2	16	F28DATE	Date of event
3A 3B 3c 3D	11 11 <b>11</b> 11	ITEM3A ITEM3B ITEM3C ITEM3D	Infarction Hemorrhage TIA Other
4A 4B 4c 4D 4E 4F	12 12 12 12 12 12 11	ITEM4A ITEM4B ITEM4C ITEM4D ITEM4E ITEM4F	Primary cerebral site Other cerebral Other cerebral Other cerebral Other cerebral More than 5 sites <b>1 = Yes</b> , 2 = No
<b>5A</b> 5B 5c 5D <b>5E</b> 5F	12 12 12 12 12 12 11	ITEM5A ITEM5B ITEM5C ITEM5D ITEM5E ITEM5F	Primary vascular territory Other vascular Other vascular Other vascular Other vascular More than 5 territories 1 = Yes, 2 = No
6	11	ITEM6	Hours to onset $1 = \leq 12$ hours 2 = 12-23 hours 3 = 24-71 hours $4 = \geq 72$ hours
7A 7B 7c 7E	11 11 11 11	ITEM7A ITEM7B ITEM7C ITEM7E	Lacune Embolism Thrombosis Unknown
8A 8B 8C 8D	11 11 11 11	ITEM8A ITEM8B ITEM8C ITEM8D	Subdural Parenchym Subarachnoid Epidural $1 = Yes$ 2 = No
9A 9B 9C 9D	11 11 11 11	ITEM9A ITEM9B ITEM9C ITEM9D	Subdural Parenchym Subarachnoid Epidural $1 = Yes$ 2 = No
10	11	ITEM10	Hemorrhage in infarct 1 = Yes 2 <b>=</b> No

# FORM 28 (REV 0) Severe Neurologic Event Classification Form (Continued)

<u>ITEM</u>	LENGTH	<u>NAME</u>	CODES	
11A 11B 11C 11D 11E 11F	11 11 11 11 11 11	ITEM11A ITEM11B ITEM11C ITEM11D ITEM11E ITEM11F	t-PA Heparin controlled Heparin not documented Coumadin controlled Coumadin not documented Embolism	1 = Primary
11F 11G 11H 11I 11J 11K 11L 11L 11M 11N	11 11 11 11 11 11 11 11 11	ITEM11G ITEM11H ITEM111 ITEM11J ITEM11K ITEM11L ITEM11M ITEM11N	Hypotension Hypertension Trauma Aortic balloon pump PTCA Surgery Vascular malformation Other	2 = Secondary 3 = Not at all
CALCULATED	11 I1	STKCAT	Type of neurological events 1 = Hemorrhage 2 = Infarct	5:

2 = Infarct 3 = TIA 4 = Subdural

ITEM	LENGTH	NAME	CODES
5	11	<b>PTO1DONE</b>	Protocol Cath Done <b>1 =</b> Yes, 2 <b>=</b> No
5	11	PTO2DONE	Hospital Discharge Cath Done 1 <b>- Yes,</b> 2 <b>-</b> No
9	11	PTCADONE	Protocol PTCA Done 1 = Yes, 2 = No, 3 = Attempted
10	12	PTCAREAS	Reasons why Protocol PTCA was not performed <b>1</b> - Patient deceased 2 = Patient refused 3 = Physician refused <b>4</b> = Emergency CABG 5 = Emergency PTCA

5 = Emergency PTCA 6 - Other emergency procedure

- 7 = Total occlusion 8 = Stenosis < 60%
- **9 =** Distal lesions
- 10 = Lesion too long (> 20 mm) 11 - Lesion involves bifurcation
- of major coronary branches
- 12 = Tortuous proximal vessel 13 = Infarct related lesion is in LMCA
- 14 = Stenosis > 70% in LMCA 15 = Closure of IRA at the site
- of stenosis would result in severe hemodynamic collapse
- 16 = Bleeding complications
- 17 = Complication of catheterization
- 18 = Cath lab not available 19 = PTCA physician not available
- 20 = Surgical backup not available
- 21 = Other

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#### FORM 39 (REV 0) Bicycle Ergometry Test Form (Clinic) Data collected at Hospital Discharge (HD) and 6 weeks (6W)

ITEM	LENGTH	NAME	<u>CODES</u>
5	12	REASHD, <b>REAS6W</b>	<pre>Reason for stopping test 1 = Chest pain 2 = ST-segment change 3 = Arrhythmia • supraventricular 4 = Arrhythmia • ventricular 5 = Hypertension 6 = Hypotension 7 = Fatigue/exhaustion 8 = Dyspnea 9 = Dizziness 10 = Poor motivation 11 = Physician's request 12 = Patient completed protocol 13 = Adequate HR achieved 14 = Claudication</pre>
6A 6B 6C 6D 6E 6F	<b>I1</b> <b>I1</b> <b>I1</b> <b>I1</b> 11 11	NITRTHD, NITRT6W BBHD, BB6W CABLCKHD, CABLCK6W ANTIAHD, ANTIA6W DIURETHD, DIURET6W DIGITHD, DIGIT6W	1 -Yes, 2 = No
7	14	BTIMEHD, BTIME6W	Seconds
8	14	LEVELHD, LEVEL6W	kpm
9	13	PMAXHRHD, <b>PMAXHR6W</b>	8
10A*	13 13 13	RSTHRHD, <b>RSTHR6W</b> RSTSBPHD, <b>RSTSBP6W</b> RSTDBPHD, <b>RSTDBP6W</b>	beats/minute mm Hg mm Hg
10B*	13 13 13	EXHRHD, <b>EXHR6W</b> EXSBPHD, <b>EXSBP6W</b> EXDBPHD, <b>EXDBP6W</b>	beats/minute mm Hg mm Hg
10C*	13 13 13	RECHRHD, <b>RECHR6W</b> RECSBPHD, <b>RECSBP6W</b> RECDBPHD, <b>RECDBP6W</b>	beats/minute mm Hg mm Hg
11*	11	EXPAINHD, EXPAIN6W	1 = Yes, 2 = No
11A	11	PAINTHD, <b>PAINT6W</b>	0 = No pain, 1 = angina, 2 = atypical chest pain
12 12A	I1 13	SBPDECHD, <b>SBPDEC6W</b> SBPMCHHD, <b>SBPMCH6W</b>	<b>1 =</b> Yes, 2 = No mm Hg
13* 13A*	11 13	HRDECHD, <b>HRDEC6W</b> HRMCHHD, <b>HRMCH6W</b>	1 -Yes, 2 <b>= No</b> beats/minute

#### FORM 39 (REV 0) Bicycle Ergometry Test Form (Clinic) Data collected at Hospital Discharge (HD) and 6 weeks (6W) (Continued)

<u>ITEM</u>	LENGTH	<u>NAME</u>	<u>CODES</u>
14A 14B <b>14C 14D</b>	11 11 11 11	LBBBHD, <b>LBBB6W</b> RBBBHD, <b>RBBB6W</b> LVHHD, <b>LVH6W</b> STEHD, <b>STE6W</b>	1 -Yes, 2 <b>- No</b>
15	11	RSTSTDHD, <b>RSTSTD6W</b>	1 = Yes, 2 = No
16	11	EXSTDHD, <b>EXSTD6W</b>	1 -Yes, 2 -No
18A 18B	F3.1 11 F3.1 11	EXSTDDHD, <b>EXSTDD6W</b> EXCFHD, <b>EXCF6W</b> RECSTDHD, <b>RECSTD6W</b> RECCFHD, <b>RECCF6W</b>	mm 1, 2 or 3 mm 1, 2 or 3
20 21 22 23A 23B		LEADSHD, <b>LEADS6W</b> STDLDHD, <b>STDLD6W</b> EXSTEHD, <b>EXSTE6W</b> STEQHD, <b>STEQ6W</b> STENQHD, <b>STENQ6W</b>	Number of leads Number of leads <b>1 = Yes, 2</b> -No mm mm
24A	11	IPVCNHD, <b>IPVCN6W</b> IPVCRHD, <b>IPVCR6W</b> IPVCEHD, <b>IPVCE6W</b> IPVCRCHD, <b>IPVCRC6W</b>	
24B	11	FPVCNHD, FPVCN6W FPVCRHD, FPVCR6W FPVCEHD, FPVCE6W FPVCRCHD, FPVCRC6W	1 = Yes
24C	11	VCPNHD, VCPN6W VCPRHD, VCPR6W VCPEHD, VCPE6W VCPRCHD, VCPRC6W	I = Ies
24D	11	VTCHNDH, VTCHN6W VTCHRHD, VTCHR6W VTCHEHD, VTCHE6W VTCHRCHD, VTCHRC6W	

\*If missing or not available Form 8A is used.

#### FORM 40 (REV **0,1)** One Year Treadmill Exercise Test Form

ITEM	LENGTH	NAME	CODES
	11	FORM40	1 - Form received
2	I4	F40DAYS	Days to 1 year exercise test
5	12	REASYR	<pre>Primary reason for stopping test 1 = Chest pain 2 = ST-segment change 3 = Arrythmia - supraventricular 4 = Arrythmia - ventricular 5 = Hypertension 6 = Hypotension 7 = Fatigue/exhaustion 8 = Dypsnea 9 = Dizziness 10 = Poor motivation 11 = Physician's request 12 = Patient completed protocol 13 = Adequate HR achieved 14 = Claudication</pre>
	14	TTIMEYR	Seconds
	12	FSTAGEYR	<pre>Final exercise stage     1 - 0     2 = 1/2     3 = I     4 = II     5 = III     6 = IV     7 = V     8 = VI     9 = VII</pre>
9	13	PMAXHRYR	ક
10A	13 13 13	RSTHRYR RSTSBPYR RSTDBPYR	beats/minute mm Hg mm Hg
10B	13 13 13	<b>EXHRYR</b> EXSBPYR EXDBPYR	beats/minute mm <b>Hg</b> mm Hg
10C	13 13 13	RECHRYR RECSBPYR RECDBPYR	beats/minute mm Hg mm Hg
11	11	EXPAINYR	1 = Yes, 2 = No
12 13 14	I1 I1 I3	PAINTYR SBPDECYR SBPMCHYR	1 <del>=</del> Angina, 2 = Atypical 1 -Yes, 2 -No mm Hg

#### FORM 40 (REV 0, 1) One Year Treadmill Exercise Test Form (Continued)

<u>ITEM</u>	LENGTH	NAME	CODES	
<b>15A</b> 15B 15c 15D	11 11 11 11	LBBBYR RBBBYR LVHYR STEYR	1 -Yes, 2 = No	
16 17 18	11 F3.1 13	RSTSTDYR STDMCHYR EXSTDYR	1 =Yes, 2 <b>- No</b> mm 1 <b>- Yes, 2 - No</b>	
19A 19B	F3.1 11 F3.1 11	EXSTDDYR EXCFYR RCSTDDYR RECCFYR	mm 1, 2 or 3 mm 1, 2 or 3	
20	11	ONSTGYR	Exercise stage (0-7)	
21	12	STDLDYR	Number of leads	
22	11	EXSTEYR	1 = Yes, 2 = No	
23A 23B	F3.1 F3.1	STEQYR STENQYR	mm mm	
CALCULATED	11	RESULTYR	<pre>1 = Severe ischemia (Definit 2 = Ischemia supplie 3 = Normal Dr. Cha 4 = Non-diagnostic If result could not be assessed of to missing data, the clinic inter was used (Items 27 and 28)</pre>	ed by aitman) lue

ITEM	LENGTH	<u>NAME</u>	CODES
	11	FORM41	<b>l =</b> Form received
3	12	F41REAS	<ol> <li>Resting angina</li> <li>Other cardiac disease</li> <li>Peripheral vascular disease</li> <li>Musculoskeletal reasons</li> <li>Patient refused</li> <li>Moved/lost to follow-up</li> <li>Treadmill test performed within past three months</li> </ol>
			<pre>a = Different test performed (not Bruce</pre>

- 12 = Other

FORM 43 (REV 1) MMCC Myocardial Infarction Event Classification Form

Only events that were <u>classified</u> as an event, i.e., must have Form 43 #4 = 1 or Form 17 # 8B1 = 2, or Form 15 # 5 = 2 (if Form 17 missing)

ITEM	LENGTH	<u>NAME</u>	CODES
	11	FORM43	1 = At least one Form 43 received
2 (or Form 17 #2 if Form 17 #8B1 = 2, or Form 15 #2 if Form 17 is missing and Form 15 #5 = 2)	F10.5	MIDATE	Time (days) from treatment initiation to first recurrent MI (if no MI then this is days to death or follow-up)
(same as MIDATE)	F10.5	MIDATE2	Time (days) from treatment initiation to second recurrent MI (if no second MI then this is missing)
(same as MIDATE)	F10.5	MIDATE3	Time (days) from treatment initiation to third recurrent MI (if no third MI then this is missing)
CALCULATED	14	MIDAYS	Integer days to first recurrent MI
CALCULATED	11	MITYPE	<pre>0 = no MI 1 = recurrent MI (Form 43 #4 = 1, or Form 17 # 8B1 =     2, or Form 17 # 8B1 is missing and     Form 15 #5 = 2)</pre>
CALCULATED	11	MMCCMI	Total number of <u>classified</u> nonfatal MI's (Form 43) for a patient (0, 1, 2,)
CALCULATED	11	FATALMI	1 = Yes, 0 = No
CALCULATED	11	NONFATMI	1 = Yes, 0 = No

#### FORM 43 (REV 2) MMCC Myocardial Infarction Event Classification Form

Only events that were <u>classified</u> as an event, i.e., must have Form 43 #5D = 1 or Form 43 # 6 A = 1, or Form 17 #8B1 = 2 or Form 15 #5 = 2 (if Form 17 missing))

<u>ITEM</u>	LENGTH	NAME	CODES
	11	FORM43	1 = At least one Form 43 received
2 (or Form 17 #2 if Form 17 #8B1 = 2 or Form 15 #2 if Form 17 is missing and Form 15 #5 = 2)	F10.5	MIDATE	Time (days) from treatment initiation to first recurrent MI (if no MI then this is days to death or follow-up)
(same as MIDATE)	F10.5	MIDATE2	Time (days) from treatment initiation to second recurrent MI (if no second MI then this is missing)
(same as MIDATE)	F10.5	MIDATE3	Time (days) from treatment initiation to third recurrent MI (if no third MI then this is missing)
CALCULATED	14	MIDAYS	Integer days to first recurrent MI
4	11	F43TIME	1 = < 18 hours $2 = \ge 18$ hours If Rev 1, assigned a "2" If no MI, assigned a "0"
CALCULATED	11	MITYPE	<pre>0 = No MI 1 = Recurrent MI (Form 43 #5D = 1 or Form 43 #6A = 1,</pre>
CALCULATED	11	MMCCMI	Total number of classified nonfatal MI's (Form 43) for a patient (0, 1, 2,)
CALCULATED	11	FATALMI	0 = No, 1 = Yes
CALCULATED	11	NONFATMI	0 = No, 1 = Yes

#### QUALIFYING ECG FILE

LENGTH	NAME	CODES
11	FILEECG	1 = ECG received
12	ECGNUM	ECG number
16 17 17	SEQNUM MEANRR PRINTER	Sequence number Mean RR interval (msec) PR interval (msec)
17 17 17 17 17 17 17 17 17 17 17 17	QAMPLI QAMPLIII QAMPLAVR QAMPLAVR QAMPLAVF QAMPLAVF QAMPLV1 QAMPLV2 QAMPLV3 QAMPLV4 QAMPLV5 QAMPLV6	• Q amplitude
17 17 17 17 17 17 17 17 17 17 17 17	RAMPLI RAMPLIII RAMPLAVR RAMPLAVR RAMPLAVF RAMPLV1 RAMPLV2 RAMPLV3 RAMPLV4 RAMPLV5 RAMPLV6	R amplitude
17 17 17 17 17 17 17 17 17 17 17 17	STDVLI STDVLII STDVLAVR STDVLAVR STDVLAVF <b>STDVLV1</b> STDVLV2 STDVLV3 STDVLV4 <b>STDVLV4</b> STDVLV6	• ST deviation (+ value = ST elevation - value = ST depression)

#### FILE GT Coagulation Core Lab Data (RED TUBES ONLY)

LENGTH	<u>NAME</u>	CODES
15 15 <b>15</b> 15	PLSPRER PLS50MNR PLS5HRR PLS8HRR	Blank if missing
13 13 13 13	FIBPRER FIB50MNR FIB5HRR FIB8HRR	Blank if missing
<b>15</b> 15 15 15	TPAPRER TPA50MNR TPA5HRR TPA8HRR	Blank if missing
17 17 <b>17</b> 17	FDPPRER FDP50MNR FDP5HRR FDP8HRR	Blank if missing
<b>15</b> 15 15 15	ALPPRER ALP50MNR ALP5HRR ALP8HRR	Blank if missing

#### FILE LV

#### CONTRAST LEFT VENTRICULOGRAPHY

LENGTH	NAME	CODES
11	DISCAT	1 = Single LAD 2 = Multi LAD 3 = Single RCA 4 = Multi RCA 5 = Undefined
11	FLV01	<pre>1 = LV data available for protocol catheterization 0 = no data</pre>
14	EDV	End diastolic volume
14	ESV	End systolic volume
14	STKV	Stroke volume
F5.1	CO	Cardiac output
14	RVGEF01	Ejection fraction
F10.4	POSLAD	Hypokinesis single vessel LAD
F10.4	POMLAD	Hypokinesis multiple vessel LAD
F10.4	POSRCA	Hypokinesis single vessel RCA
F10.4	POMRCA	Hypokinesis multiple vessel RCA
F10.4	PERSLAD	Hyperkinesis single vessel LAD
F10.4 F10.4	PERMLAD PERSRCA	Hyperkinesis multiple vessel LAD Hyperkinesis single vessel RCA
F10.4	PERMRCA	Hyperkinesis multiple vessel RCA
110.1	FERMICA	Nyperkinebib multiple vebbel kek
12	YEAR01	
12	MONTH01	Date of protocol cath
12	DAY01	
F10.4	НҮРО	Hypokinesis protocol
F10.4	HYPER	Hyperkinesis protocol
13	ONESD	Length of segment with hypokinesis more than -1 SD (NL1L)
13	TWOSD	Length of segment with hypokinesis more than -2 SD (NL2L)
13	CHORDS	Length of segment with akinesis or dyskinesis (NLOL)
11	FLVHD	1 = LV data available for HD catheterization 0 = no data
14	EDVHD	End diastolic volume
14	ESVHD	End systolic volume
14	STKVHD	Stroke volume
F5.1	COHD	Cardiac output
14	RVGEFHD	Ejection fraction
F10.4	POSLADHD	Hypokinesis single vessel LAD
F10.4	POMLADHD	Hypokinesis multiple vessel LAD
F10.4	POSRCAHD	Hypokinesis single vessel RCA
F10.4	POMRCAHD	Hypokinesis multiple vessel RCA
F10.4	PRSLADHD	Hyperkinesis single vessel LAD
F10.4	PRMLADHD	Hyperkinesis multiple vessel LAD
F10.4	PRSRCAHD	Hyperkinesis single vessel RCA
F10.4	PRMRCAHD	Hyperkinesis multiple vessel RCA

#### FILE LV

## CONTRAST LEFT VENTRICULOGRAPHY (Continued)

LENGTH	NAME	<u>CODES</u>
12	YEARHD	
12	MONTHHD	Date of HD cath
12	DAYHD	
F10.4	HYPOHD	Hypokinesis HD
F10.4	HYPERHD	Hyperkinesis HD
13	ONESDHD	Length of segment with hypokinesis more than -1 SD (NL1L)
13	TWOSDHD	Length of segment with hypokinesis more than -2 SD (NL2L)
13	CHORDSHD	Length of segment with akinesis or dyskinesis (NLOL)
11	FLVNP	<pre>1 = LV data available for non-protocol catheterization 0 = no data</pre>
14	EDVNP	End diastolic volume
14	ESVNP	End systolic volume
14	STKVNP	Stroke volume
F5.1	CONP	Cardiac output
14	RVGEFNP	Ejection fraction
F10.4	POSLADNP	Hypokinesis single vessel LAD
F10.4	POMLADNP	Hypokinesis multiple vessel LAD
F10.4	POSRCANP	Hypokinesis single vessel RCA
F10.4	POMRCANP	Hypokinesis multiple vessel RCA
F10.4	PRSLADNP	Hyperkinesis single vessel LAD
F10.4	PRMLADNP	Hyperkinesis multiple vessel LAD
F10.4	PRSRCANP	Hyperkinesis single vessel RCA
F10.4	PRMRCANP	Hyperkinesis multiple vessel RCA
12	YEARNP	
12	MONTHNP	Date of non-protocol cath
12	DAYNP	
F10.4	HYPONP	Hypokinesis non-protocol
F10.4	HYPERNP	Hyperkinesis non-protocol
13	ONESDNP	Length of segment with hypokinesis more than -1 SD (NL1L)
13	TWOSDNP	Length of segment with hypokinesis more than -2 SD (NL2L)
13	CHORDSNP	Length of segment with akinesis or dyskinesis (NLOL)