

TIM1 PHASE II FORMS*

*List of all TIM1 Phase II Forms and most recent version of each form enclosed.

TIMI PHASE II FORMS

Form Number	Form Type	Title	Status
A. FORMS COMPLETED AT CLINICAL CENTERS			
01	--	Patient Information Sheet	Rev 0 03/03/86 (Kept at clinic)
03	SC01	Screening Form	Rev 0 03/03/86 Rev 1 05/28/86 Rev 2 07/17/86 Rev 3 08/21/86 Rev 4 10/06/86 Rev 5 01/05/87
3A	RF01	Patient Refusal Form	Rev 0 03/03/86
04	AD01	Admission Form	Rev 0 03/14/86
05	TA01	Treatment Assignment Form	Rev 0 03/04/86
5A	TA02	Documentation of Incorrect Treatment Assignment	Rev 0 03/03/86
5F	TA03	Documentation of Loss of RT-PA	Rev 0 08/13/86 (Not keyed)
5G	TA04	Documentation of Use of Back-up Miler	Rev 0 10/07/86 (Not keyed)
06	PP	PTCA Procedures Form	Rev 0 03/03/86 Rev 1 05/28/86 Rev 1 06/13/86 (Instruction update) Rev 1 10/08/86 (Instruction update)
6B	NP01	PTCA Non-Performance Form	Rev 0 03/03/86 Rev 1 05/20/86 Rev 1 09/02/87 (Signature)
7A	VE	Ventriculography Form	Rev 0 03/03/86
7B	CA	Coronary Arteriography Form	Rev 0 03/03/86 Rev 1 04/07/86 Rev 2 07/22/86
7c	cc	Cardiac Catheterization Procedures Form	Rev 0 02/19/86
7G	NC	Cardiac Catheterization Non-Performance Form	Rev 0 02/19/86
8A	RS	Rest/Exercise RVG Shipping Form	Rev 0 03/03/86
10	HD01	Hospital Discharge Form	Rev 0 03/04/86
11	FV	Follow-up Visit Form	Rev 0 03/04/86
12	MV	Missed Visit Form	Rev 0 03/03/86
13	TC	Telephone Contact Form	Rev 0 03/03/86

TIMI PHASE II FORMS (Continued)

Form Number	Form Type	Title	Status
A. FORMS COMPLETED AT CLINICAL CENTERS (Continued)			
14	HP	Subsequent Hospitalization Form	Rev 0 03/03/86
15	DN01	Death Notification Form	Rev 0 03/03/86
16	CD01	Cause of Death Form	Rev 0 03/03/86
19	LD01	Laboratory Data Form	Rev 0 03/14/86
20	BR01	Coagulation Core Laboratory Blood Samples Record Form	Rev 0 08/19/86
21	--	Coagulation Core Laboratory Blood Sample Shipping Form	Rev 0 08/20/86 (Not keyed)
22	NB01	No Blood Samples Record Form	Rev 0 02/19/87
23	RO	Myocardial Infarction Event	Rev 0 03/03/86 Rev 1 07/02/87 (More digits CK) Rev 2 12/08/87
24	HM	Hemorrhagic Event	Rev 0 03/04/86 Rev 1 11/10/86
25	cs	Cardiac Surgery Form	Rev 0 03/03/86 Rev 1 11/10/86
26	TF	Transfusion Record Form	Rev 0 11/10/86
27	SN01	Severe Neurologic Event Form	Rev 0 08/01/88
39	BE	Bicycle Ergometry Test	Rev D 08/12/87
40	ET01	One Year Treadmill Exercise Test	Rev 0 04/02/87
41	NT01	Treadmill Exercise Test Non-Performance Form	Rev 0 03/24/87
B. PRELIMINARY INFORMATION FORMS			
5D	TA00	Telephone Documentation of Treatment	Rev 0 03/04/86
31	PT	Catheterization and PTCA Telephone Documentation	Rev 0 03/03/86 Rev 1 05/20/86 Rev 1 06/13/86 (Skip box change)
32	DT01	Hospital Discharge Telephone Documentation	Rev 0 02/28/86
C. FORMS COMPLETED AT CORE LABS			
7D	IA	Notification of Irregularities in Coronary Angiogram	Rev 0 03/03/86
7E	IV	Notification of Irregularities in Ventriculograms	Rev 0 03/03/86

TIMI PHASE II FORMS (Continued)

Form Number	Form Type	Title	Status
C. FORMS COMPLETED AT CORE LABS (Continued)			
7F	AV	Coronary Arteriography Visual Assessment	Rev 0 03/03/86 (Not used) Draft Rev 1 04/15/86 (Not used) Draft Rev 1 05/01/86 (Not used) Rev 1 05/20/86 Rev 2 08/05/86 Rev 3 04/03/87 (Rhode Island) Rev 4 09/02/87 (Rhode Island)
8B	RA	Rest/Exercise RVG Acknowledgement Receipt Form	Rev 0 03/03/86 (Not used) Rev 1 04/17/86
8C	RD	Rest RVG Data Analysis Report Form	Rev 0 03/03/86 Rev 1 08/08/86
8D	XD	Exercise RVG Data Analysis Report Form	Rev 0 03/03/86 (Not used) Rev 1 04/17/86
D. MMCC AND HERC FORMS			
17	DM01	MMCC Classification of Death	Rev 0 03/03/86 (Not used) Rev 1 01/20/87 (Not used) Rev 2 03/15/88 Rev 2 04/12/88 (Corrected coding) Rev 3 07/08/88
43	RC	Myocardial Infarction	Rev 0 03/03/86 (Not used) Rev 1 10/27/86 Rev 2 08/12/87
44	HC	Hemorrhagic Event Classification	Rev 0 03/04/86 Rev 1 04/28/87
73,83	IR	Individual Reviewer Myocardial Infarction Event	Rev 1 10/27/86 Rev 2 08/12/87
74,84	IC	Individual Reviewer Hemorrhagic Event Classification	Rev 1 04/28/87
77,87	ID	Individual Reviewer Death Classification	Rev 1 10/27/86 (Not used) Rev 1 01/20/87 (Not used) Rev 2 03/15/88 Rev 2 04/12/88 (Corrected coding) Rev 3 07/08/88

TIMI PHASE II
INSTRUCTIONS FOR COMPLETING
TIMI FORM 03
SCREENING FORM

GENERAL INSTRUCTIONS

This form should be completed for all screened patients who meet the inclusion criteria. These patients have a **diagnosis** of suspected **MI** with at least 30 minutes of pain **and** ST segment elevation ≥ 0.1 mV **and** are less than 76 years of **age** and can be treated within **four hours since onset** of symptoms.

The patient should be issued an Identification number (ID No.) from the Patient Identification Number List furnished to **your** clinic. The patient's **identification** number should appear in the **box In the upper** right-hand corner of the first page, as well as in the lower right-hand corner of all pages. The clinic number should appear in the upper right-hand corner of the first page.

If a check mark (✓) is made in **any** space on this form designated as "**STOP**," the patient **is** ineligible for further consideration for entry into the study. Do not complete the rest of the form **and** do not send form to the Coordinating Center.

If a check mark (✓) **is** made in any space on this form designated as "**INEL**," the patient **is** ineligible for randomization in this study. Complete the entire form even if an "**INEL**" item is encountered.

If a check mark (✓) is made in any space on this form designated as "**NOBB**," the patient **is** ineligible for randomization to intravenous beta-blockers. Complete the entire form, even if a "**NOBB**" item is encountered.

Please use black ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use abbreviations unless absolutely necessary, and then use only widely recognized abbreviations. A completed copy of this form should be retained for your files.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [*] preceding the item number on the form.

REFER TO ITEM 3, PAGE 1

Time of qualifying **EKG** taken in either the **TIMI** Clinical Center or referral center.

(OVER)

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION
 SCREENING FORM

TIMI II Form 03
 Rev 5 01/05/87
 5 Pages

Clinic No.				
ID No.				
Form Type	S	C	O	1

PART I: Visit Identification

1. Patient's NAME CODE: _____
2. Screening date: _____
 Month Day Year
- [*] 3. Time of qualifying ECG: *EATIME (calc.)*
- A. Date _____
 Month Day Year
- B. Military time _____
 hours minutes
- [*] 4. Does the patient agree to completion of this form? _____ () (STOP)
 Yes No
5. Sex _____ (1) (2) *SEX*
 Yale Female

[*] 9. Can the time of onset of pain be identified? _____ (1) (STOP)
 Yes No

If **YES**, answer @ and (B).
 If **NO**, skip to item 10.

- (A) Time of onset of pain: *DNTIME (calc)*
 Data: $\frac{DNMO}{Month} - \frac{DNDA}{Day} - \frac{DNVA}{Year}$
 Military time: $\frac{DNHR}{hours} : \frac{DNMN}{minutes}$
TWO+RS (calc)
- (B) Will the time be no greater than 4 hours from onset of pain to treatment? _____ (1) (STOP)
 Yes No

[*] 10. Does an ECG reveal ST segment elevation of at least 0.1mV? _____ (1) (STOP)
 Yes No

PART II: Inclusion Criteria

6. Date of birth: _____
 Month Day Year
7. A, Age _____ *AGE*
- B. Is the patient less than 76 years of age? _____ (1) (STOP)
 Yes No
- [*] 8. Has the patient reported severe ischemic pain of at least 30 minutes duration? _____ (1) (STOP)
 Yes No

If **YES**, answer A through F.
 If **NO**, skip to item 11.

- (A) In which leads? (Check all that apply.)
- | | | | |
|-----------|----------|----------|-------------|
| STEN II | STEN V1 | STEN V4 | STEN I |
| II (1) | V1 (1) | V4 (1) | I (1) |
| STEN III | STEN V2 | STEN V5 | STEN aVL -1 |
| III (1) | V2 (1) | V5 (1) | aVL (1) |
| STEN aVF | STEN V3 | STEN V6 | STEN aVR |
| aVF (1) | V3 (1) | V6 (1) | aVR (1) |
- (B) Is ST segment elevation present in at least two of the three inferior leads (II, III, aVF)? _____ (1) (2) *STENF*
 Yes No

ID No.				
--------	--	--	--	--

[*]10. (Continued)

C Is ST segment elevation present in at least two contiguous leads of the **six precordial leads (V1-V6)?** _____ (1) (2) **STEANT**
 Yes No

D Is ST segment elevation present in leads I and aVL? _____ (1) (2) **STEAVL**
 Yes No

E Is a least one item of **B**, **C** or **@** answered yes? _____ (1) (INEL)
 Yes No

11. Does an ECG reveal:

Q waves of at least 30 msec width and 0.2mV depth? _____ (1) (2) **QWAVES**
 Yes No

If **YES**, answer **A**.
 If **NO**, skip to Item 12.

NO (calc.)

A In which leads? (Check all that apply.)

QII	QVI	QIV	QVI
II (1)	V1 (1)	V4 (1)	I (1)
QIII	QV2	QV5	QAVL
III (1)	V2 (1)	V5 (1)	aVL (1)
QAVC	QV3	QV6	QAVR
aVF (1)	V3 (1)	V6 (1)	aVR (1)

12. Does an ECG reveal ST segment depression of at least 0.1 mV? _____ (1) (2) **STD**
 Yes No

If **YES**, answer **A**.
 If **NO**, skip to item 13.

NO STD (calc.)

A In which leads? (Check all that apply.)

STDII	STDV1	STDV4	STD I
II (1)	V1 (1)	V4 (1)	I (1)
STDIII	STDV2	STDV5	STD aVL
III (1)	V2 (1)	V5 (1)	aVL (1)
STD aVF	STDV3	STDV6	STD aVR
aVF (1)	V3 (1)	V6 (1)	aVR (1)

Part III: Exclusion Criteria

13. Are any of the following exclusion conditions satisfied?

- | | Yes | No |
|--|--------|-----|
| A. Left bundle branch block? _____ | (INEL) | (2) |
| B. Premenopausal? _____ | (INEL) | (2) |
| C. Known advanced or terminal illness? (e.g., Cancer) -- _____ | (INEL) | (2) |
| If YES, name _____ | | |
| D. Known dilated cardiomyopathy? _____ | (INEL) | (2) |
| E. Previous cerebrovascular disease (stroke or TIA)? - _____ | (INEL) | (2) |
| F. Any bleeding disorder or a history of significant gastrointestinal bleeding? _____ | (INEL) | (2) |
| G. Current oral anticoagulant therapy? _____ | (INEL) | (2) |
| H. Prosthetic heart valve? -- _____ | (INEL) | (2) |
| I. Uncontrolled hypertension or SBP > 180 or DBP > 110? _____ | (INEL) | (2) |
| J. Significant surgical procedure within the last two weeks? _____ | (INEL) | (2) |
| K. Prolonged cardiopulmonary resuscitation within the last two weeks? - _____ | (INEL) | (2) |
| L. Previous coronary artery bypass surgery? --- _____ | (INEL) | (2) |
| M. Agitation or lethargy such that Informed consent cannot be obtained? _____ | (INEL) | (2) |
| N. Severe trauma within the last 6 months? - _____ | (INEL) | (2) |
| O. Infusion of any thrombolytic agent for myocardial infarction within the last 2 weeks? - _____ | (INEL) | (2) |
| P. Previous participation in TIMI Phase II? -- _____ | (INEL) | (2) |

ID No. _____

13. (Continued) Yes No
- Q. Unable (physically or psychologically) to participate in the TIMI Study? _____ (INEL)(2)
 If YES, explain _____
- A. Participating in other protocols that would conflict with the TIMI Study? _____ (INEL)(2)
 If YES, explain _____
- S. PTCA within the last six months? _____ (INEL)(2)

14. Are any "INEL" conditions checked on this form? _____ (INEL)(2)
 Yes No

If YES, the patient is ineligible, skip to Part VII.
 If NO, the patient is eligible, complete the rest of this form.

PART IV: Beta-Blocker Exclusion Criteria

15. Are any of the following contraindications for immediate Intravenous metoprolol therapy satisfied?
- Yes No
- A. Current treatment with a beta-blocker (within 48 hours), verapamil (within 24 hours), or diltiazem (within 24 hours)? _____ (NOBB)(2) BBINELA 19.
- B. Ventricular rate at rest consistently < 55 beats per minute? _____ (NOBB)(2) BBINELB
- C. Systolic BP consistently < 100 mm Hg? _____ (NOBB)(2) BBINELC
- D. Hoist rales that do not clear w/ coughing, involving 1/3 or more of the lung fields and interpreted as signs of CHF, or pulmonary edema with consistent chest x-ray findings? _____ (NOBB)(2) BBINELD

15. (Continued) Yes No
- E. Presence of significant first-degree AV block (PR > 0.24 sec), or second- or third-degree block? _____ (NOBB)(2) BBINEL
- F. Implanted pacemaker? _____ (NOBB)(2) BBINEL
- G. Asthma by history, wheezing by physical examination, or chronic obstructive pulmonary disease requiring chronic therapy with corticosteroids or 2 stimulants? _____ (NOBB)(2) BBINELG

[*]16. Are any Ineligible conditions for immediate Intravenous beta-blockers checked? _____ (NOBB)(2) BBINEL
 Yes No

PART V: Risk Determination HIGH RISK (Calc)

17. History of previous MI? _____ (1) (2) BLMT
 Yes No
18. Rales which do not clear on coughing: _____ (1) (2) BLAALC
 Yes No

If YES, answer (A).
 If NO, skip to item 19.

- (A) To what extent? BLEXTENT
- ≤ 1/3 lung fields _____ (1)
- > 1/3 lung fields but not all _____ (2)
- Both entire lung fields _____ (3)
19. Hypotension (systolic pressure < 100 mm Hg) and sinus tachycardia (atrial rate > 100 beats/min)? _____ (1) (2) BLHYPO
 Yes No

ID No. _____

20. Atrial **fibrillation** or flutter? _____ (1) (2) **BLAF**
 Yes No
21. Pulmonary edema? (Rales over-both entire lung fields and severe orthopnea or rales over both entire lung fields and frothy sputum or pulmonary edema on chest X ray) _____ (1) (2) **BLPE**
 Yes No
22. Cardiogenic shock? (Systolic blood pressure < 85 mmHg Interpreted as left ventricular dysfunction with evidence of diminished tissue perfusion on initial evaluation) _____ (1) (2) **BLSHOCK**
 Yes No

PART VII: Administrative Matters

[#] 25. Was this patient randomized? _____ (1) (2)
 Yes No

If **YES**, skip to Item 27.
 If **NO**, answer Items (26) .

- 26 Reason not randomized: (check all that apply)
- A. INEL condition(s) checked (Item 14) _____ (1)
- B. Physician **did not** consent (item 23) _____ (1)
- C. Patient did not consent (Item 24) _____ (1)
- D. ER staff failed to notify **TIMI** personnel. _____ (1)
 Explain _____
- E. **TIMI** personnel could not be located. _____ (1)
 Explain _____
- F. Patient's condition changed before randomization _____ (1)
 Explain _____
- G. Other _____ (1)
 Specify _____

PART VI: Consent

COMPLETE ONLY FOR ELIGIBLE PATIENTS

23. Does the patient's physician consent to randomization of the patient into the **TIMI** Study? _____ (1) (REFUSE)
 Yes No

If **YES**, skip to item 24.
 If **NO**, answer (A) .

(A) Explain _____

Skip to item 25.

24. Does the patient consent to be randomized? _____ (1) (REFUSE)
 Yes No

If **YES**, skip to Item 25.
 If **NO**, answer (A) .

(A) Explain _____

Skip to item 29.

ID No. _____

TIMI PHASE II

INSTRUCTIONS FOR COMPLETING

TIMI FORM 04

ADMISSION FORM

GENERAL INSTRUCTIONS

This form should be completed for all randomized patients. Information collected on this form refers to the **time** and condition of the patient up to the time of rt-PA initiation.

The patient's identification number should appear in the box in the upper right-hand corner of the first page, as well as in the **lower right-hand corner** of all pages. The clinic number should appear in the upper **right-hand** corner of the first page.

Please use black ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use abbreviations unless absolutely necessary and then use only widely recognized abbreviations. A completed copy of this form **should** be retained for your files.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [*] preceding the item number on the form.

REFER TO ITEM 5, PAGE 1

Smoking Status: The objective **is** to determine if the patient **is** currently, or has ever been a cigarette **smoker** -- the figure of 100 **cigarettes is** an arbitrary guideline. If a person has smoked only a handful of cigarettes scattered through his/her lifetime, this individual **is** to be considered a nonsmoker: **i.e.**, answer **"NO."** However, if a patient smoked regularly during any period in his/her **lifetime**, classify that individual as a smoker by answering **"YES."**

REFER TO ITEM 6, PAGE 2

Activity status

Rest = seated or lying in bed

Mild physical activity = walking, etc.

Moderate physical activity = climbing stairs, etc.

Marked physical **activity** = running, etc.

REFER TO ITEM 10C, PAGE 3

Date of prior myocardial infarction

If the date **is** completely unknown, **check** the unknown box and leave the month, day, and year items blank.

Record whatever items of the **date are** known and enter 88 for items not available.

Items Known	Values to be Recorded		
	Month	Day	Year
Year only	88	88	Year
Month and Year only	Month	88	Year

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION
 ADMISSION FORM

TIHI II Form 04
 Rev 0 03/14/86
 6 Pages

Clinic No.									
ID No.									
Form Type	A	D	O	1					

PART I: Identification

1. Patient's NAME CODE: _____
2. Screening date: _____
 Month Day Year

PART II. Background Data

3. Race: *RACE*
- White _____ (1)
 Black _____ (2)
 Hispanic _____ (3)
 Other _____ (4)
4. What is the highest grade of education completed? *EDUCATE*
- No formal education _____ (1)
 Grade 11 or less _____ (2)
 High school graduate _____ (3)
 Some college _____ (4)
 Degree from 4 year college -- (5)
 Some graduate education _____ (6)
 Graduate degree _____ (7)

- [*] 5. Has the patient smoked more than 100 cigarettes in his/her lifetime? _____ (1) (2) *SMOKE*
 Yes NO

If **YES**, answer (A), (B) and (C).
 If NO, skip to Item 6.

[*] 5. (Continued)

- (A) Maximum packs/day: *MAXPACKS*
- < 1/2 pack _____ (1)
 1/2 < packs < 1 _____ (2)
 1 < packs < 2 _____ (3)
 > 2 packs _____ (4)
- (B) Number of years smoked _____ *YRSMOKE*
- (C) Is the patient a current smoker? (Based on three weeks prior to qualifying MI) _____ (1) (2) *CURSMOKE?*
 Yes No

If **YES**, answer (D).
 If **NO**, answer (E).

- (D) Packs/day: *PACKSDAY*
- < 1/2 pack _____ (1)
 1/2 < packs < 1 _____ (2)
 1 < packs < 2 _____ (3)
 > 2 packs _____ (4)

Skip to Item 6.

- (E) How long ago did the patient stop smoking? *STOPSMOK*
- < 3 months _____ (1)
 3 < months < 12 _____ (2)
 1 < years < 5 _____ (3)
 > 5 years _____ (4)

ID No. _____

PART III: Present Illness

THE FOLLOWING QUESTIONS PERTAIN TO THIS QUALIFYING EPISODE.

6. What was the activity at onset of pain?

- Sleeping _____ (1)
 Rest _____ (2)
 Mild physical activity _____ (3)
 Moderate physical activity _____ (4)
 Marked physical activity _____ (5)

ACTONSET

7. Was the Index pain the only chest discomfort suffered during the past 48 hours? --- (1) (2)
 Yes No

INDEX PAIN

If YES, skip to Item 8.

If NO, answer (A)

(A) When were other episodes related to the pain leading to enrollment in TIMI? (check all that apply):

1. < 1 hour _____ (1)
 2. 1 - 2 hours _____ (1)
 3. 3-5 hours _____ (1)
 4. 6 - 11 hours _____ (1)
 5. 12 - 23 hours _____ (1)
 6. 24 - 48 _____ (1)

OTHER EPISD

weeks: the three to the qualifying

- A. None _____ (1) BLPATTA
 B. At rest _____ (1) BLPATTB
 C. Exertional _____ (1) BLPATTC
 D. New onset _____ (1) BLPATTD
 E. Increasing frequency _____ (1) BLPATTE
 F. Variant _____ (1) BLPATTF
 G. At night _____ (1) BLPATTG

9. Has the patient experienced previous chest pain or angina? _____ (1) (2)
 Yes No

CHSTRAIN

If YES, answer (A).

If NO, skip to Item 10.

(A) Angina classification:

- Definite angina _____ (1)
 Probable angina _____ (2)
 Probably not angina _____ (3)
 Not angina _____ (4)

BLANGIN^A
 (calc)

If DEFINITE or PROBABLE answer

(B)

If PROBABLY NOT or NOT skip to Item 10.

(B) Date of onset of angina:

- < 7 days _____ (1)
 8 - 14 days _____ (2)
 15 - 21 days _____ (3)
 22 - 30 days _____ (4)
 31 - 180 days _____ (5)
 6 months - 1 year _____ (6)
 > 1 year _____ (7)

ANGONSET

ANG3WK (calc.)
 PAT3WK (calc.)

ID No. _____

PART xv: Medical History

PRIOR TO CURRENT EPISODE

10. Does the patient have a history of myocardial infarction prior to the current episode? F04BLMI
 (1) (2) (3) (4)
 Defi- No Sus- Un-
 nite spect known

If **DEFINITE** or **SUSPECT** answer (A), (B) and (C). If **NO** or **UNKNOWN**, skip to item 11.

(A) Criteria for Infarction: (answer each item)

	Yes	No	Un- known
1. Patient history _____	(1)	(2)	(3)
2. Physician history _____	(1)	(2)	(3)
3. ECG _____	(1)	(2)	(3)
4. Cardiac enzymes _____	(1)	(2)	(3)

(B) Location (check all areas involved)

1. Anterior _____	(1)	BLMILOC1
2. Inferior _____	(1)	BLMILOC2
3. Lateral _____	(1)	BLMILOC3
4. Posterior _____	(1)	BLMILOC4
5. Unknown _____	(1)	BLMILOC5

(*) (C) Date: _____ - Month - Day - Year - Unknown (1)

11. Has the patient ever experienced any of the following events? (See Manual of Operations for definitions. Answer each item.)

	Defi- nite	No	Sus- pect	Un- known
A. Congestive heart failure _____	(1)	(2)	(3)	(4) BLCHF
B. Intermittent cerebral ischemic attack _____	(1)	(2)	(3)	(4) BLICIA
C. Stroke _____	(1)	(2)	(3)	(4) BLSTK
D. Intermittent claudication _____	(1)	(2)	(3)	(4) BLIC

12. Has the patient ever had any of the following diseases or conditions diagnosed? (Answer each question.)

	Yes	No	Un- known
A. Diabetes mellitus _____	(1)	(2)	(3) BLDIAB
B. Hypertension _____	(1)	(2)	(3) BLHYP
C. Peripheral vascular disease _____	(1)	(2)	(3) BLPVD
D. Valvular heart disease _____	(1)	(2)	(3) BLVHD
E. Other cardiac disease _____	(1)	(2)	(3) BLOC
Specify _____			
F. Gastrointestinal disease _____	(1)	(2)	(3) BLGI
G. Hematological disease _____	(1)	(2)	(3) BLHMD
H. Renal disease _____	(1)	(2)	(3) BLRENAL
I. Neurological disease _____	(1)	(2)	(3) BLNEURO
J. Other significant disease _____	(1)	(2)	(3) BLOTHOIS
Specify _____			

ID No. _____

- Yes No Un-
known
13. Was coronary angiography performed within 12 months prior to the current MI? _____ (1) (2) (3)
14. Was percutaneous transluminal coronary angioplasty (PTCA) ever performed? _____ (1) (2) (3)

PART v: Medication

15. Have any of the following drugs or types of drugs patient during the past week prior to admission?

If **YES** is checked, indicate time last dose was _____ name(s) _____

	Yes	No	Time last dose taken		
			< 6 hrs	6-24 hrs	> 24 hrs
A. Long-acting nitrates end oral vasodilators _____	(1)	(2)	(1) BLAXA	(2)	(3)
B. Short-acting nitrates _____	(1)	(2)	(1) BLAXB	(2)	(3)
C1. Metoprolol _____	(1)	(2)	(1) BLAXC1	(2)	(3)
C2. Other beta-blockers _____	(1)	(2)	(1) BLAXC2	(2)	(3)
(C3) Name(s) _____					
D. Calcium channel blockers _____	(1)	(2)	(1) BLAXD	(2)	(3)
(D) name(s) _____					
E. Antirhythmics (other than beta-blockers or calcium channel blockers) _____	(1)	(2)	(1) BLAXE	(2)	(3)
F. Intravenous inotropic agents or pressor agents _____	(1)	(2)	(1) BLAXF	(2)	(3)
G. Cardiac glycosides and oral inotropic agents _____	(1)	(2)	(1) BLAXG	(2)	(3)
H. Diuretics _____	(1)	(2)	(1) BLAXH	(2)	(3)
I. Intravenous vasodilators _____	(1)	(2)	(1) BLAXI	(2)	(3)
J. Antihypertensives (other than diuretics and beta-blockers) _____	(1)	(2)	(1) BLAXJ	(2)	(3)
K. Aspirin _____	(1)	(2)	(1) BLAXK	(2)	(3)
L. Dipyridamole _____	(1)	(2)	(1) BLAXL	(2)	(3)
M. Platelet active agents (other than aspirin and dipyridamole) _____	(1)	(2)	(1) BLAXM	(2)	(3)
N. Methyl xanthines _____	(1)	(2)	(1) BLAXN	(2)	(3)
O. Heparin _____	(1)	(2)	(1) BLAXO	(2)	(3)
P. Anticoagulants (other than heparin) _____	(1)	(2)	(1) BLAXP	(2)	(3)

ID No. _____

PART VI: Physical Exam

THE FOLLOWING ITEMS PERTAIN TO
 THE PHYSICAL EXAM AT THE TIME OF
 CONFIRMING TIMI ELIGIBILITY

16. Height _____ BLHT cm
17. Weight _____ BLWT kg
18. Heart rate BLHR beats/minute
19. Respiratory rate BLRSP respirations/min.
20. Blood pressure: (First recording taken at the time of screening for eligibility)
- A. Systolic _____ BLSP mm Hg
- B. Diastolic _____ BLDP mm Hg
21. Abnormal neck vein distension _____
- | | | |
|------|------|-------|
| Pre- | Ab- | Un- |
| sent | sent | known |
- BLNKVEIN
(1) (2) (3)
22. Heart sounds:
- A. S₃ _____ BLS3 (1) (2) (3)
- B. S₄ _____ BLS4 (1) (2) (3)
- C. Pericardial friction rub -- BLFR (1) (2) (3)
- D. Murmurs _____ BLMUR (1) (2) (3)

If PRESENT, answer **(D)**.

If ABSENT or UNKNQWN, skip to item 23.

22. (Continued)

D. (Continued)

- (D)** Murmur(s) characteristic of the following are present (check all that apply):
- a. Benign systolic ejection _____ (1) BLBSE
- b. Mitral regurgitation -- (1) BLMR
- c. Aortic regurgitation -- (1) BLAR
- d. Ventricular septal rupture _____ (1) BLVSR
- a. Other _____ (1) BLOTHUR
- Specify _____

- | | | |
|--|------|------|
| | Pre- | Ab- |
| | sent | sent |
23. Integument:
- A. Ecchymosis _____ (1) (2) BLECCHY
- B. Hematoma _____ (1) (2) BLHEMP
24. Were other significant findings present? _____ (1) (2)
- Yes No
- If YES, specify _____
- _____
- _____
- _____

ID No. _____

PART VII: Local Laboratory Data

LABORATORY MEASUREMENTS At TIME OF SCREENING FOR ELIGIBILITY

- | | Not
Avail-
able | |
|--|-----------------------|-------------|
| 25. Creatinine _____ <u>BLCREAT</u> _____ mg/dl (1) | | |
| 26. BUN _____ <u>BLBUN</u> _____ <input type="checkbox"/> Ifd1 (1) | | |
| 27. Tot81 bilirubin --- <u>BLBILI</u> _____ mg/dl (1) | | |
| 28. SGOT _____ <u>BLSGOT</u> _____ IU/L (1) | | |
| 29. LDH _____ <u>BLLDH</u> _____ run (1) | | |
| 30. Alkaline phosphatase - <u>BLALPKHS</u> _____ IU/L (1) | | |
| 31. Hematocrit _____ <u>BLHCT</u> _____ % (1) | | |
| 32. Hemoglobin _____ <u>BLHGB</u> _____ gms/dl (1) | | |
| 33. White blood cell count
<u>BLWBC</u> _____ thousands/mm ³ (1) | | |
| 34. Potassium _____ <u>BLK</u> _____ <input type="checkbox"/> Eq/L (1) | | |
| 35. Platelet count
A. <u>BLPLAT</u> _____ thousands/mm ³ (1) | | |
| Only • nauer B if A not available | | |
| B. Adequate on smear _____ (1) (2) (3) | | |
| | Yes | No Unknown |
| 36. Urine protein _____ <u>BLUPROT</u> (1) (2) (3) | Pre
sent | Ab-
sent |
| 37. Urine occult blood _____ <u>BLUCCBLD</u> (1) (2) (3) | Un-
known | |
| 38. Stool guaiac _____ <u>BLGUAIAC</u> (1) (2) (3) | | |

PART VIII: Administrative netters

39. Physician performing physical • xms

Nae _____

TIMI Staff No: --- _ _ _ _ _

40. Research Nurse/Coordinator:

Signature _____

TIMI Staff Nor --- _ _ _ _ _

ID No. | | | | | | | | | |

TIMI PHASE II
INSTRUCTIONS FOR COMPLETING
TIMI FORM 05
TREATMENT ASSIGNMENT FORM

GENERAL INSTRUCTIONS

This form should be completed to document opening the Treatment Allocation Mailer and to evaluate therapy at 24 hours. This form should be completed for all randomized patients. This form is completed at the Clinical Center. The original of this form is sent to the Coordinating Center.

The patient's Identification number should appear in the box in the upper **right-hand** corner of the first page, as well as in the lower **right-hand** corner of all pages. The clinic number should appear in the upper **right-hand** corner of the first page.

Please use black ink to complete this form. For Items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use abbreviations unless absolutely necessary, and then use only widely recognized abbreviations. A completed copy of this form should be retained for your files.

ITEM INSTRUCTIONS: **Items with instructions outlined below have the symbol [*] preceding the item number of the form.**

REFER TO ITEM 3, PAGE 1

Record Treatment Allocation Mailer sequence and patient therapy kit label actually used.

REFER TO ITEMS 11 THROUGH 15. PAGE 3

If the **date is the same** as the date recorded in the **previous item**, check **SAME DATE** and leave DATE blank.

TIMI PHASE 11
 THROMBOLYSIS IN MYOCARDIAL INFARCTION
 TREATMENT ASSIGNMENT FORM

TIMI II Form 05
 Rev 0 03/04/86
 6 Pages

ICL
ICLB

Clinic No.							
ID No.							
Form Type	T	A	O	1			

CHECK

PART I: Identification

1. Patient's NAME CODE: _____

2. Screening date

_____/_____/_____
 Month Day Year

[*] 3. TIMI treatment assignment used:

A. Patient therapy kit number: _____

B. Mailer Sequence Number: _____

4. Was the correct sequence number mailer assigned to this patient? _____ (1) (2)
 Yea No

If NO, Form 5A (Documentation of Incorrect Treatment Assignment) must be completed and submitted with this form.

5. Group assignment (check one):

A. PTCA timing study:

2 hour PTCA _____ (01)
 18-48 hour PTCA _____ (02)
 No PTCA _____ (03)

ASSIGN

PTCA OR P (calc)
BBORP (calc)

5. (Continued)

B. Beta-blocker study:

1. Beta-blocker eligible:

Immediate beta-blocker and 18-48 hour PTCA _____ (04)

Immediate beta-blocker and no PTCA _____ (05)

Deferred beta-blocker and 18-48 hour PTCA _____ (06)

Deferred beta-blocker and no PTCA _____ to 7)

2. Beta-blocker ineligible:

18-48 hour PTCA _____ (08)
 No PTCA _____ to 9)

PART 11: TIMI Treatment

6. Was rt-PA treatment initiated? _____ (1) (2) *TRTIN*
 Yea No

If **YES**, skip to item 7.
 If **NO**, specify the reason in item (A).
 If the patient has died, submit a Death Notification Form.

(A) Died _____ (1)
 Patient refused _____ (2)
 Other (specify below) _____ (3)

Skip to Part III.

ID No.							
--------	--	--	--	--	--	--	--

DOSE ASGN (calc.)

7. rt-PA treatment

A. Dose: _____ RTPA DOSE _____ mg

B. If less than protocol specified dose given, check primary reason: RTPA LESS

Urticaria _____ (01)

Fever of chill 8 _____ (02)

Nausea or vomiting _____ (03)

Bleeding at arterial access _____ (04)

Bleeding at central vein access _____ (05)

Bleeding at other puncture sites _____ (06)

Specify site: _____

Other bleeding _____ (07)

Specify site: _____

Convulsions _____ (08)

Anaphylaxis _____ (09)

Hypotension _____ (10)

Bronchospasm _____ (11)

Death _____ (12)

Other (specify below) _____ (13)

9. Metoprolol treatment

A. Intravenous dose _____ IV DOSE _____ mg

B. If less than protocol specified dose given, check all reasons:

1. Heart rate < 49 beats/minute _____ (1)

2. Systolic blood pressure < 95 mm Hg _____ (1)

3. P-Q interval > 0.26 seconds _____ (1)

4. 2° heart block _____ (1)

5. 3° heart block _____ (1)

6. Worsening dyspnea _____ (1)

7. Cold sweats _____ (1)

8. Wheezing _____ (1)

9. Rales exceeding 1/3 of lung fields _____ (1)

10. Chest x-ray findings of pulmonary edema _____ (1)

11. Death _____ (1)

12. Other (specify below) _____ (1)

C. Oral dose during first 24 hours _____ ORAL DOSE _____ mg

8. Was intravenous metoprolol therapy initiated? _____ (1) Yes _____ (2) No IV MET

If YES, skip to item 9.
If NO, specify the reason in item (A).
If the patient has died, submit a Death Notification Form (TIMI Form 15).

(A) Not assigned to intravenous metoprolol _____ (1)

Died _____ (2)

Patient refused _____ (3)

Other (specify below) _____ (4)

Skip to item 10.

ID No. _____

9. (Continued)

D. If oral metoprolol less than protocol specified dose given, check all reasons:

1. Heart rate < 49 beats/minute _____ (1)
2. Systolic blood pressure < 95 mm Hg _____ (1)
3. P-Q interval > 0.26 seconds _____ (1)
4. 2° heart block _____ (1)
5. 3° heart block _____ (1)
6. Worsening dyspnea _____ (1)
7. cold sweats _____ (1)
8. Wheezing _____ (1)
9. Rales • extending > 1/3 of the way up the lung fields _____ (1)
10. Chest X ray findings of pulmonary edema _____ (1)
11. Death _____ (1)
12. Other (specify below) _____ (1)

10. Heparin bolus: HEP BOL _____ DATE HEP TIME (calc) _____ MILITARY TIME _____ DOSE (USP) _____

[*]11. rt-PA treatment initiation: _____ SAME DATE (1) _____ TIME TIDA TIYR TIHR TIME _____

[*]12. Intravenous beta-blocker initiation: _____ NOT GIVEN INBB (1) _____ INBB TIME (calc) _____

[*]13. Oral beta-blocker initiation: _____ ORAL BBOS (1) _____ ORBB TIME (calc) _____

[*]14. Continuous heparin infusion (start): _____ HEP INF (1) _____ HEP I TIME (calc) _____ RATE (USP/hr) _____

[*]15. rt-PA treatment completed: _____ (1) _____

16. Did the patient receive 8 blood transfusion within the first 24 hours of rt-PA treatment initiation? _____ TF24 (1) (2) Yes No

ID No.							
--------	--	--	--	--	--	--	--

17. Were there any complications within the first 24 hours of rt-PA treatment initiation? _____ (1) (2) **Comp**
 Yes No

If **YES**, answer item (18) and (19). If **NO**, skip to item 20.

18. Complications (check one for each item)

	did not occur	occurred but did not interrupt rt-PA treatment	indication for interruption of rt-PA treatment
A. Urticaria _____	(1)	(2)	(3) CompA
B. Fever or chills _____	(1)	(2)	(3) CompB
C. Nausea or vomiting _____	(1)	(2)	(3) CompC
D. Bleeding at arterial access _____	(1)	(2)	(3) CompD
E. Bleeding at central vein access _____	(1)	(2)	(3) CompE
F. Bleeding at other puncture sites _____	(1)	(2)	(3) CompF
Specify site: _____			
G. Other bleeding _____	(1)	(2)	(3) CompG
Specify site: _____			
H. Convulsions _____	(1)	(2)	(3) CompH
I. Anaphylaxis _____	(1)	(2)	(3) CompI
J. Hypotension _____	(1)	(2)	(3) CompJ
K. Bronchospasm _____	(1)	(2)	(3) CompK
L. Death _____	(1)	(2)	(3) CompL
M. Other _____	(1)	(2)	(3) CompM
Specify: _____			

19. Was rt-PA treatment restarted? _____ (1) (2) (3)
 Yes No Not Stopped

20. Hemodynamic measurements:

Time from rt-PA treatment initiation	Heart Rate, bpm	Not done	Blood Pressure, mm Hg	Not done.
			Systolic Diastolic	
0	<u>HR0</u>	(1)	<u>SBP0</u> <u>DBP0</u>	(1)
30 minutes	<u>HR30</u>	(1)	<u>SBP30</u> <u>DBP30</u>	(1)
60 minutes	<u>HR60</u>	(1)	<u>SBP60</u> <u>DBP60</u>	(1)
90 minutes	<u>HR90</u>	(1)	<u>SBP90</u> <u>DBP90</u>	(1)
120 minutes	<u>HR120</u>	(1)	<u>SBP120</u> <u>DBP120</u>	(1)
150 minutes	<u>HR150</u>	(1)	<u>SBP150</u> <u>DBP150</u>	(1)
180 minutes	<u>HR180</u>	(1)	<u>SBP180</u> <u>DBP180</u>	(1)

ID No. _____

21. Which of the following occurred during the time of rt-PA infusion?

	Yes	No	Time from rt-PA treatment initiation	
	(1)	(2)	hours	minutes
A. Dramatic relief of chest pain _____	RPEVA (1)	(2)	RPEVA	MIN (calc)
B. Dramatic worsening of chest pain _____	RPEVB (1)	(2)	RPEVB	MIN (calc)
C. Rapid normalization of ST segments _____	RPEVC (1)	(2)	RPEVC	MIN (calc)
D. Exacerbation of ST segment abnormality _____	RPEVD (1)	(2)	RPEVD	MIN (calc)
E. Appearance of new arrhythmias or conduction disturbances _____	RPEVE (1)	(2)	RPEVE	MIN (calc)
F. Resolution of arrhythmias or conduction disturbances _____	RPEVF (1)	(2)	RPEVF	MIN (calc)
G. Decreased blood pressure or clinical signs of reduced perfusion _____	RPEVG (1)	(2)	RPEVG	MIN (calc)
H. Increased blood pressure or clinical signs of increased perfusion _____	RPEVH (1)	(2)	RPEVH	MIN (calc)

22. Were there any arrhythmias within the first 24 hours of treatment initiation? — (1) (2) **ARRDY**
 Yes No

If **YES**, answer item 23. If **NO**, skip to 24.

23. Indicate type and appearance of arrhythmias, including catheter-induced arrhythmias. (check all that apply.)

	1	2	3	4	5
	None	Prior to thrombolytic therapy	During thrombolytic therapy	Number of minutes after onset of thrombolytic therapy	After completion of thrombolytic therapy
A. Ventricular tachycardia (≥ 3 beats in a row at a rate > 100 /min) _____	ARRA1 (1)	ARRA2 (1)	ARRA3 (1)	ARRA4	ARRA5 (1)
B. Ventricular fibrillation _____	ARRB1 (1)	ARRB2 (1)	ARRB3 (1)	ARRB4	ARRB5 (1)
C. Bigeminy, trigeminy or quadrigeminy lasting > 1 min. _____	ARRC1 (1)	ARRC2 (1)	ARRC3 (1)	ARRC4	ARRC5 (1)
D. Sinus bradycardia (< 50 /min) _____	ARRD1 (1)	ARRD2 (1)	ARRD3 (1)	ARRD4	ARRD5 (1)
E. Second degree heart block _____	ARRE1 (1)	ARRE2 (1)	ARRE3 (1)	ARRE4	ARRE5 (1)
F. Third degree heart block _____	ARRF1 (1)	ARRF2 (1)	ARRF3 (1)	ARRF4	ARRF5 (1)
G. Accelerated idioventricular rhythm, rate < 100 _____	ARRG1 (1)	ARRG2 (1)	ARRG3 (1)	ARRG4	ARRG5 (1)
H. Other _____	ARRH1 (1)	ARRH2 (1)	ARRH3 (1)	ARRH4	ARRH5 (1)

Specify _____

ID No. _____

24. Assessment of chest pain:

A. Present immediately prior to rt-PA treatment _____ (1) (2)
Yes No

PAINCRE

If YES, skip to C.
If NO, answer B.

B Time of relief of chest pain:

Month - Day - Year

Military time: _____ : _____
hours minutes

Skip to item 25.

C. Present at initiation of thrombolytic therapy - (1) (2)
Yes No

PAININIT

D. Present at conclusion of thrombolytic therapy - (1) (2)
Yes No

PAINCOAC

E. Pain at conclusion Of therapy compared to pain at initiation Of therapy:
Increased _____ (1)
Decreased but still present _____ (2)
Same _____ (3)
None _____ (4)

PAINCOMP

25. Was there evidence of coronary thrombosis Or myocardial infarction within the first 24 hours after initiation of TIMI treatment? _____ (1) (2)
Yes No

If YES, answer A and B.
If NO, skip to Part III.

A Time event occurred:

Month - Day - Year

Military time: _____ : _____
hours minutes

25. (Continued)

B Evidence of coronary thrombosis or myocardial infarction:

- Yes No Unknown
1. Angiographic — (1) (2) (3)
 2. Reappearance Of pain _____ (1) (2) (3)
 3. ECG evidence — (1) (2) (3)
 4. CK evidence — (1) (2) (3)
 5. Other enzymes
• Iov8tod _____ (1) (2) (3)

Submit a Myocardial Infarction Form (TIMI Form 23) to doombt this • writ.

PART III: Administrative Matters.

26. The following items are being submitted to the Coordinating Center with this form.

A. First post treatment ECG _____ (1) (2)
Yes No

27. 18 8 patient therapy kit being sent to the Drug Distribution Center? _____ (1) (2)

29. Research Nurse/Coordinator:

Signature _____

TIMI Staff No: _____

29.	CC USE ONLY
A. ECG _____	Yes8 NO (1) (2)

ID No. _____

TIHI PHASE II
INSTRUCTIONS FOR COMPLETING
TIHI FORM 06
PTCA PROCEDURES FORM

GENERAL INSTRUCTIONS:

This form should be completed to document all PTCA procedures including those required by protocol, emergency or elective during the initial hospitalization or during the follow-up period. Balloon inflation must be documented angiographically at least once. *Either* Form 06 or Form 6B is required for all patients assigned to PTCA. Complete Form 06 if the required PTCA was performed or complete Form 6B if the required PTCA was not performed. The original of this form is sent to the Coordinating Center.

The patient's identification number and form type should appear in the box in the upper right-hand corner of the first page, as well as in the lower right-hand corner of all pages. The clinic number should appear in the upper right-hand corner of the first page.

Please use black ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use abbreviations unless absolutely necessary, and then use only widely recognized abbreviations. A completed copy of this form should be retained for your files.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [#] preceding the item number of the form.

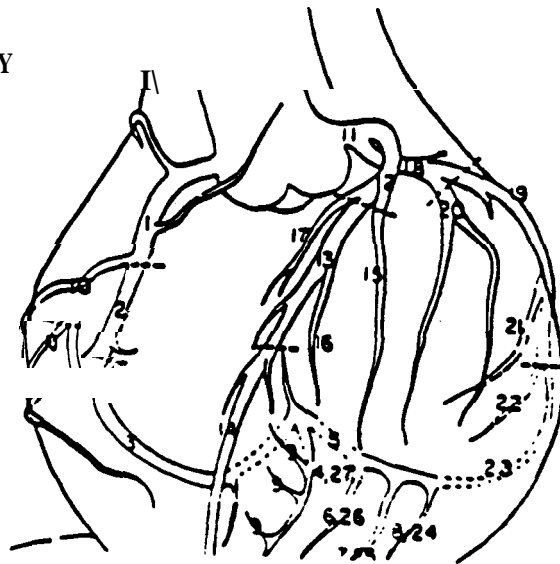
REFER TO ITEM 8B, PAGE 2

Note: If there are two lesions in the same segment of the infarct-related artery, code same site code for "Lesion 1" and "Lesion 2."

Site Codes:

RIGHT CORONARY ARTERY

1. Rox 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.



Site Codes (Continued):

LEFT CORONARY ARTERY

11. LHCA
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. L AV
24. 1st LPL
25. 2nd LPL
26. 3rd LPL
27. LPDA

(OVER)

REFER TO ITEM 8S, PAGE 3

- Full Improvement:
- a) . Post-PTCA < 60% stenosis
 - . and > 20% decrease In stenosis
 - . and perfusion grade 3
 - b) . Post-PTCA < 60% stenosis
 - . and > 20% decrease In stenosis
 - . and change In perfusion grade from 0 or 1 to 2
- Partial Improvement:
- a). Post-PTCA < 60% stenosis or > 20% decrease In **stenosis**)
 - . and perfusion grade 0 or 1 Improves to 2 or 3
 - or perfusion grade 2 Improves to 3
 - or perfusion grade 3 remains 3
 - b) . Post-PTCA > 20% decrease In stenosis
 - . and perfusion grade 2 remains 2
- No Improvement - All Others, e.g.
- a) . Post PTCA perfusion grade 0 or 1
 - b) . Stenosis > 60% and < 20% decrease In **stenosis**
 - c) . Stenosis < 60% or > 20% decrease In stenosis but **perfusion grade worsens** from 3 to 2

REFER TO ITEM 11, PAGE 3

Include any thrombolytic therapy including Protocol rt-PA. This Item should be answered Yes for all patients with two-hour PTCA.

The second **administration** of rt-PA **is** not permitted under **TIMI II** Protocol. The use of thrombolytic agents other than rt-PA to treat TIMI II patients **is** not permitted under Protocol.

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION
 PTCA PROCEDURES FORM

TIMI IS Form 06
 Rev 105/28/86
 5 Pages

#06P/#06NP
 PTCASTAT (calc)

Clinic No.				
ID No.				
Form Type	P	P		

PART I: Identification

1. Patient's NAME CODE: _____

2. Date and time of PTCA: #6TIMEP/#6TIMENP (calc.)

Month Day Year

Military time _____ : _____
 hours minutes

3. PTCA type:

Protocol PTCA _____ (1) #06P
 Non Protocol PTCA _____ (2) #06NP

If Protocol PTCA answer item 3A.
 If Nonprotocol PTCA answer Items
 4 and 5.

3A If Protocol which type
 (check one):

2 hour _____ (1)
 18-48 hour _____ (2)

Skip to Item 6.

4 Was PTCA an emergency or an
 elective procedure? PTCA EENP

Emergency _____ (1)
 Elective _____ (2)

5 What was the indication
 for performing PTCA? REASON NP

Ischemia post infarction _____ (1)
 Re-infarction post infarction _____ (2)
 Other _____ (3)

Specify _____

PART II: Procedure Notes

6. Was PTCA attempted at the
 site of the presumed occlusion
 or stenosis responsible for
 the infarction? SITE 1P/SITE 1N
 Yes No (1) (2)

7. Was PTCA attempted at other
 lesion sites? SITE 2P/SITE 2N
 Yes No (1) (2)

ID No.				
Form Type	P	P		

PART II: Procedure Notes

8. Complete the Information below for each lesion site for which PTCA was attempted.

	Lesion 1	Lesion 2	Lesion 3	Lesion 4
A. Infarct-related artery	L18AP/L18ANP (1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No
[*]B. Site Code	L18BP/L18BNP			
C. Branch vessel Involved	L18CP/L18CNP (1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No
D. Lesion discrete	L18DP/L18DNP (1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No
E. Lesion eccentric	L18EP/L18ENP (1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No
F. Lesion calcified	L18FP/L18FNP (1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No
[*]G. Perfusion grade pre-PTCA	L18GP/L18GNP			
H. Distal embolization during PTCA	L18HP/L18HNP (1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No
I. Dissection during PTCA	L18IP/L18INP (1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No
J. Intimal tear, flap or fissure post-PTCA	L18JP/L18JNP (1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No
K. Thrombosis post-PTCA	L18KP/L18KNP (1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No	(1) (2) Yes No
[*]L. Perfusion grade post-PTCA	L18LP/L18LNP			
M. Percent stenosis pre-PTCA	L18MP/L18MNP			
N. Percent stenosis post-PTCA	L18NP/L18NNP			
O. Gradient pre-PTCA (mm Hg)	L18OP/L18ONP Not Done	(1) Not Done	(1) Not Done	(1) Not Done
P. Gradient post-PTCA (mm Hg)	L18PP/L18PNP (1) Not Done	(1) Not Done	(1) Not Done	(1) Not Done

ID No.									
Form Type	P	P							

8. (Continued)

	Lesion 1	Lesion 2	Lesion 3	Lesion 4
[*]Q. Site outcome code	L18QP/L18QNP			
[*]R. How outcome measured (code)	L18RP/L18RNP			
[*]S. Outcome of PTCA	L18SP/L18SNP (1) (2) (3) Full Par- None tial	(1) (2) (3) Full Par- None tial	(1) (2) (3) Full Par- None tial	(1) (2) (3) Full Par- None tial
T. Total inflation time	L18TP/L18TNP sec.	sec.	sec.	sec.
U. Number of different dilation catheters used	L18UP/L18UNP			
V. Largest balloon size	L18MP/L18MNP mm			
W. Number of inflations	L18IP/L18INP			
8. Maximum duration	L18CP/L18CNP sec.	sec.	sec.	sec.
b. Maximum pressure	L18AP/L18ANP atm.	atm.	atm.	atm.

9. Did PTCA result in any of the following acute complications: (answer = 0/1 item)

- Yes No
- A. Emergency coronary artery bypass surgery (1) (2) COMPAP/COMPANP
- B. Development of total occlusion of infarct artery (1) (2) COMPBP/COMPBNP
- C. Development of total occlusion of branch of infarct-related artery (1) (2) COMPBP/COMPBNP
- D. Development of total occlusion of other major artery (1) (2) COMPBP/COMPBNP
- E. Totally occluded embolization of branches or distal artery (1) (2) COMPBP/COMPBNP
- F. Re-infarction (1) (2) COMPBP/COMPBNP
- G. Death (1) (2) COMPBP/COMPBNP
- H. Other (1) (2) COMPBP/COMPBNP

Specify: _____

10. What was the total elapsed fluoroscopy time? FTI (MFP/FTIME) minutes

11. Was thrombolytic therapy administered during or following the procedure? (1) (2) (3)
Yes No Yes
2 Hr Other
PTCA PTCA

If YES OTHER PTCA, answer (A) through (E).
If YES 2 HRPTCA or No, skip to item 12.

- (A) Name _____
- (B) Dosage _____
- (C) Route: _____ IC (1) IV (2)
- (D) Indication for use:
Embolism following PTCA (1)
Other (2)
Specify _____
- (E) Additional patient therapy kit number: _____

(1)
Not
Used

ID No.					
Form Type	P	P			

12. Did any of the following complications occur within 24 hours after PTCA? (Do not include events checked "Yes" in Item 9.)

- A. Death _____ Yes No (1) (2) DEATHP/DEATHNP
 B. Nonfatal HI _____ (1) (2) MIP/MINP
 C. Emergency surgery _____ (1) (2) SURGP/SURBNP

If YES, complete the appropriate event form.

PART III: PTCA Indications and Medical Therapy

Complete Part III only for Nonprotocol PTCA.

13. Medical therapy prior to PTCA:

- A. Beta-blockers _____ (1) (2)
 Yea No

If YES, answer (1) through (3).
 If NO, skip to B.

- (1) Medication: _____
 (2) Total daily dose: _____ mg
 (3) Were undesirable side effects present at the maximum dose? -- (1) (2)
 Yes No

- B. Calcium channel blockers _____ (1) (2)
 Yea No

If YES, answer (1) through (3).
 If NO, skip to C.

- (1) Medication: _____
 (2) Total daily dose: _____ mg
 (3) Were undesirable side effects present at the maximum dose? -- (1) (2)
 Yes No

13. (Continued)

- C. Nitrates and vasodi-
 Lator _____ (1) (2)
 Yea No

If YES, answer (1) through (3).
 If NO, skip to item 14.

- (1) Medication: _____
 (2) Total daily dose: _____ mg
 (3) Were undesirable side effects present at the maximum dose? -- (1) (2)
 Yea No

14. Angina status prior to PTCA:

- A. Certainty of diagnosis (check one): *ANGINANT*
 Definite angina _____ (1)
 Probable angina _____ (2)
 Probably not angina _____ (3)
 No angina _____ (4)

If DEFINITE or PROBABLE, answer (B) through (D).
 If PROBABLY NOT or NO, skip to item 15.

ID No.							
Form Type	P	P					

14. (Continued)

[*] (B) Canadian Heart Class: CHCNP
 0 _____ (0)
 I _____ (1)
 II _____ (2)
 III _____ (3)
 IV _____ (4)

(C) Episodic rest or prolonged pain? EPISODIC
 _____ (1) (2)
 Yes No

(D) Precipitating factors (check **all that apply**):
 1) Exert ion _____ (1)
 2) Emotion _____ (1)
 3) Meals _____ (1)
 4) Cold weather _____ (1)
 5) Intercourse _____ (1)
 6) Sleep _____ (1)
 7) Rest _____ (1)

15. Exercise test done: _____ (1) (2)
 Yes No

If **YES**, answer 0A through 0C.
 If **NO**, skip to 16.

(A) Maximum pulse: _____ beats/min

0 B Maximum blood pressure (mm Hg):
 1. Systolic _____
 2. Diastolic _____

(C) Exercise machine (check one):
 Treadmill _____ (1)
 Upright bicycle _____ (2)
 Supine bicycle _____ (3)
 Other, specify _____ (4)

16. Was coronary angiography filmed for this PTCA? _____ (1) (2)
 Yes No

If **YES** submit films to the Radiographic Core Lab.

PART IV: Administrative Matters

17. Is the required hospital PTCA report enclosed? _____ (1) (2)
 Yes No

18. PICA Physician:
 Signature _____
 TIMI Staff No: _____

19. Research Nurse/Coordinator:
 Signature _____
 TIMI Staff No: _____

20. FOR CC USE
 Documents received:
 PTCA Report _____ (1) (2)
 Yes No

ID No.									
Form Type	P	P							

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION
 CARDIAC CATHETERIZATION PROCEDURES FORM

TIMI II Form 7C
 Rev 0 02/19/86
 3 Pages

Variables for protocol/hospital discharge / 1st non-protocol catheterizations.

Clinic No.				
ID No.				
Form Type	C	C		

PART I: Identification

1. Patient's NAME CODE: _____

2. Date and time of catheterization:
CATH TIME / CTIM EHD / CTIMENP

Month - Day - Year

Military time _____ : _____
 hours minutes

3. Sequence number: _____

4. Report for: *F7C / F7CHD / F7CNP*

- Protocol PTCA cath _____ (1)
- Protocol predischage cath _____ (2)
- Nonprotocol cath _____ (3)

If Protocol cath skip to item 6.

If Nonprotocol cath answer item (5).

(5) What was the reason for performing this nonprotocol cardiac catheterization?

NP REASON

A. Ischemia post infarction _____ (1)

B. Re-infarction post infarction _____ (2)

C. Other _____ (3)

Specify _____

PART II: Hemodynamics

[*] 6. Left ventricular pressure:

- A. Peak systolic *LVP SBPP / LVPSBPHD / LVPSBPT* _____ mm Hg
- B. End diastolic *LVEDBPP / LVEDBPHD / LVEDBPN* _____ mm Hg

Aortic pressure:

- C. Systolic *ASBP / ASBPHD / ASBPNP* _____ mm Hg
- D. Diastolic *ADBPP / ADBPHD / ADBPNP* _____ mm Hg

ID No.				
Form Type	C	C		

PART III: Procedure Note 8

7. Sequence of ● gloq8m8:
 (indicate the order of the following procedures enter 1, 2, or 3; enter 0 if not done.)
- A. Ventriculography _____
- B. Non-infarct artery _____
- C. Infarct artery _____

8. Angiographers assessment:

- [*]A. Perfusion grade of infarct artery: _____
- B. % Stenosis _____

9. What was the infarct artery?
 (Check one)

- LAD _____ (1)
 Diagonal _____ (2)
 Circumflex _____ (3)
 Obtuse marginal _____ (4)
 RCA or RPDA _____ (5)
 LMCA _____ (6)

10. Was PTCA performed? _____ (1) (2)
 Yes No

If YES, complete PTCA Form (TIMI Form 06).

[*]11. When was sheath removed?

- A. Date: _____ (1)
 Month Day Year Not Removed
- B. Time: _____ : _____
 hours minutes

PART IV: Complications Of Angiography

12. Were there any complications during ● giogrrPhY? _____ (1) (2) F7CComp/F7CHDC/F7CNPC
 Yes No

If YES, answer items 13 through 14.
 If NO, skip to Part V.

13. Vascular non coronary complications: (answer each item)

- A. Arterial thrombosis? _____ (1) (2) F7CCompA/F7CHDCA/F7CNPCF
 Yes No
- B. Arterial dissection? _____ (1) (2) F7CCompB/F7CHDCB/F7CNPCB
- C. Arterial embolus? _____ (1) (2) F7CCompC/F7CHDCC/F7CNPC
- D. Md arterial resultstroke or central nervous system event? _____ (1) (2) F7CCompD/F7CHDCD/F7CNPCD
- E. Was surgery performed for the vascular complication? _____ (1) (2) F7CCompE/F7CHDCE/F7CNPCE

14. Was catheterization complicated by 8 new occlusion of 8 coronary artery or branch vessel? _____ (1) (2) F7CCompF/F7CHDCF/F7CNPCF
 Yes No

If YES, answer A through C.
 If NO, skip to item 15.

ID No.							
Form Type	C	C					

14 (Continued)

PART v: Administrative Matters

Coronary occlusion vex due to the following: ---

17. Angiographer:

- Yes No
 F7C0CCA/F7CHDOCA/F7CNPOCA
 (1) (2)
 F7C0CCB/F7CHDOCB/F7CNPOCB
 (1) (2)
 F7C0CCC/F7CHDOCC/F7CNPOCC
 (1) (2)
- (A) Coronary thrombosis? _____
 (B) Coronary dissection? _____
 (C) Embolization of clot? _____

Signature _____

TIMI Staff No: --- - - - -

18. Research Nurse/Coordinator:

Signature _____

TIMI Staff No: --- - - - -

If YES, answer (C1) through (C4).
 If NO, skip to item 15.

Which artery?

- Yes No
 (C1) Left main _____ (1) (2)
 (C2) LAD _____ (1) (X 2)
 (C3) Circumflex _____ (1) (2)
 (C4) RCA _____ (1) (2)

15 Were there catheter induced arrhythmias requiring
 ● leatrfecl cardioversion
 or defibrillation? _____
 Yes No

F7CAPB/F7CHDARR/F7CNPARR

16 Clinical complications of
 ● nglography: (answer each
 item)

- Yes No
 A. Pulmonary edema _____ (1) (2) F7CPE/F7CHDPE/F7CNPPE
 B. Hypotenaion _____ (1) (2) F7CHPO/F7CHDPO/F7CNAPP
 C. Cardiac arrest _____ (1) (2) F7CCA/F7CHDCA/F7CNPCA
 D. Anaphylaxis due to contrast _____ (1) (2) F7CANA/F7CHDANA/F7CNPANA

ID No.							
Form Type	C	C					

TIMIPHASE II
THROMBOLYSIS IN MYOCARDIAL INFARCTION
CARDIAC CATHETERIZATION PROCEDURES FORM

TIMI II Form 7C
 Rev 0 02/19/86
 3 Pages

Variables corresponding to the first three catheterizations

Clinic No.									
ID No.									
Form Type	C	C							

PART I: Identification

1. Patient's NAME CODE: _____

2. Date and time of catheterization:
CTIME1/CTIME2/CTIME3

 Month Day Year

Military time _____ : _____
 hours minutes

3. Sequence number: _____

4. Report for: *F7C1/F7C2/F7C3*
 Protocol PTCA cath _____ (1)
 Protocol predischage cath _____ (2)
 Nonprotocol cath _____ (3)

If Protocol cath skip to item 6.
 If Nonprotocol cath answer item 5.

5. What was the reason for performing this nonprotocol cardiac catheterization?
- A. Ischemia post infarction _____ (1)
 - B. Re-infarction post infarction _____ (2)
 - C. Other _____ (3)
 Specify _____

PART II: Hemodynamics

- [*] 6. Left ventricular pressure:
- A. Peak systolic _____ *LVP SBP1 / LVP SBP2 / LVP3*
 mm Hg
 - B. End diastolic _____ *LVEDBP1 / LVEDBP2 / LVED*
 mm Hg
- Aortic pressure:
- C. Systolic _____ *ASBP1 / ASBP2 / ASBP3*
 mm Hg
 - D. Diastolic _____ *ADB P1 / ADB P2 / ADB P3*
 mm Hg

ID No.									
Form Type	C	C							

PART III: Procedure Note.

7. Sequence of angiogram
 (indicate the order of the following procedures enter 1, 2, or 3; enter 0 if not done..)

- A. Ventriculography _____
- B. Non-infarct artery _____
- C. Infarct artery _____

8. Angiographers present:

- [*]A. Perfusion grade of infarct artery: F7CGR1/F7CGR2/F7CGR3
- B. % Stenosis F7CST1/F7CST2/F7CST3

9. What was the infarct artery?

- (Check one) F7CIRA1/F7CIRA2/F7CIRA3
- LAD _____ (1)
 - Diagonal _____ (2)
 - Circumflex _____ (3)
 - Obtuse marginal _____ (4)
 - RCA or RPDA _____ (5)
 - LMCA _____ (6)

10. Was PTCA performed? _____ (1) (2)
 Yea No

If YES, complete PTCA Form (TIMI Form 06).

[*]11. When was sheath removed?

- A. Date: _____ (1)
 Month Day Year Not Removed
- B. Time: _____ : _____
 hours minutes

PART IV: Complications of Angiography

12. Were there any complications during angiography? _____ (1) (2) F7CCOMP1/F7CCOMP2/F7CCOMP3
 Yes No

If YES, answer items 13 through 14.
 If NO, skip to

13. Vascular coronary complications: (answer item)

- A. Arterial thrombosis? F7CCMPA1/F7CCMPA2/F7CCMPA3 (1) (2)
F7CCMPB1/F7CCMPB2/F7CCMPB3
- B. Arterial dissection? _____ (1) (2)
- C. Arterial embolus? F7CCMPC1/F7CCMPC2/F7CCMPC3 (1) (2)
- D. Did arterial embolus result in stroke or central nervous system event? F7CCMPD1/F7CCMPD2/F7CCMPD3 (1) (2)
- E. Was surgery performed for the vascular complication? F7CCMPE1/F7CCMPE2/F7CCMPE3 (1) (2)

14. Was catheterization complicated by new occlusion of a coronary artery or branch vessel? F7COCC1/F7COCC2/F7COCC3 (1) (2)
 Yes No

If YES, answer A through C.
 If NO, skip to item 15.

ID No.							
Form Type	C	C					

(Continued)

PART v: Administrative Matters

Coronary occlusion was due to the following:

- A Coronary thrombosis? ^{Yes} (1) ^{No} (2) *F7C0CC01 / F7C0CC02 / F7C0CC03*
 B Coronary dissection? (1) (2) *F7C0CC01 / F7C0CC02 / F7C0CC03*
 C Embolization of clot? (1) (2) *F7C0CC01 / F7C0CC02 / F7C0CC03*

17. Angiographer:

Signature _____

TIMI Staff No: -- _____

18. Research Nurse/Coordinator:

Signature _____

TIMI Staff No: -- _____

If YES, answer (C1) through (C4).
 If NO, skip to item 15.

Which artery?

- | | Yes | No |
|--|-----|-----|
| <input type="radio"/> C1 Left main _____ | (1) | (2) |
| <input type="radio"/> C2 LAD _____ | (1) | (2) |
| <input checked="" type="radio"/> C3 Circumflex _____ | (1) | (2) |
| <input type="radio"/> C4 RCA _____ | (1) | (2) |

15. Were there catheter induced arrhythmias requiring electrical cardioversion or defibrillation? _____

F7CARR1 / F7CARR2 / F7CARR3
 (1) (2)
 Yes No

16. Clinical complications of angiography: (answer each item)

- | | Yes | No |
|--------------------------------------|-----|-----|
| A. Pulmonary edema _____ | (1) | (2) |
| B. Hypotension _____ | (1) | (2) |
| C. Cardiac arrest _____ | (1) | (2) |
| D. Anaphylaxis due to contrast _____ | (1) | (2) |
- F7CPE1 / F7CPE2 / F7CPE3*
F7CHP01 / F7CHP02 / F7CHP03
F7CCA1 / F7CCA2 / F7CCA3
F7CAN1 / F7CAN2 / F7CAN3

ID No.									
Form Type	C	C							

1. Patient's NAME CODE: _____

Clinic No.				
ID No.				
Form Type	A	V	O	

2. Date of arteriography: _____
Month _____ Day _____ Year _____

F7F/F7FHD/F7FNP
F7F1/F7F2/F7F3

3. Sequences: _____

4. Film type: PTCA (1) HD (2) NonProtocol (3)

5. Quality: _____

6. Dominance: Balance (1) Right (2) Left (3) **DOMINANCE**

7. Infarct artery coronary segment: Name _____ Code _____ **ARTERY**

Segment	% Stenosis	Collateral	Segment	% Stenosis	Collateral
1. Prox RCA	_____	_____	17. 1st Septal	_____	_____
2. Mid RCA	_____	_____	18. Prox CX	_____	_____
3. Dist RCA	_____	_____	19. Dist CX	_____	_____
4. RPDA	_____	_____	20. 1st Ob Marg	_____	_____
5. RPLS	_____	_____	21. 2nd Ob Marg	_____	_____
6. 1st RPL	_____	_____	22. 3rd Ob Marg	_____	_____
7. 2nd RPL	_____	_____	23. L TV	_____	_____
8. 3rd RPL	_____	_____	24. 1st LPL	_____	_____
9. Inf. Septal	_____	_____	25. 2nd LPL	_____	_____
10. Ac Marg.	_____	_____	26. 3rd LPL	_____	_____
11. LMCA	_____	_____	27. LPDA	_____	_____
12. Prox LAD	_____	_____	2% Additional Lesion	_____	_____
13. Mid LAD	_____	_____			
14. Dist LAD	_____	_____			
15. 1st Diag	_____	_____			
16. 2nd Diag	_____	_____			

VESSEL (calc)
NOVES (calc)
COLLAT (calc)
DISCAT (calc)

STENRCA (calc.)

STENCA (calc.)

STENLMCA

STENLAD (calc.)

8.

	Lesion 1	Lesion 2	Lesion 3	Lesion 4
	Yes No	Yes No	Yes No	Yes No
A. Suitable? _____	(1) (2)	(1) (2)	(1) (2)	(1) (2)
If No why? Reason 1 _____	_____	_____	_____	_____
If 1b why? Reason 2 _____	_____	_____	_____	_____
B. Balloon filmed? _____	(1) (2)	(1) (2)	(1) (2)	(1) (2)
C. Infarct dilated? _____	(1) (2)	(1) (2)	(1) (2)	(1) (2)

D. Site code _____

F7FPRES1/F7FPRES2/F7FPRES3
F7FPREG1/F7FPREG2/F7FPREG3
F7FPST1/F7FPST2/F7FPST3
F7FPST61/F7FPST62/F7FPST63

	Pre Stenosis	Pre grade	Post Stenosis	Post grade
1. Pre Stenosis _____	PRES1/STENHD/STENNP	_____	POSTST	_____
2. Pre grade _____	PREGR/GRADEHD/GRADENP	_____	POSTGR	_____

SUCCESS (calc)

E. Complications of angioplasty:

1. Dissection _____	(1) (2)	(1) (2)	(1) (2)	(1) (2)
2. Antegrade thrombus _____	(1) (2)	(1) (2)	(1) (2)	(1) (2)
3. Distal embolus _____	(1) (2)	(1) (2)	(1) (2)	(1) (2)
4. Other, specify _____	(1) (2)	(1) (2)	(1) (2)	(1) (2)

F. Success of procedure: **SUCCESS (calc)**

1. Initially successful? _____	(1) (2) (3)	(1) (2) (3)	(1) (2) (3)	(1) (2) (3)
Full Part No	Full Part No	Full Part No	Full Part No	
Yes No	Yes No	Yes No	Yes No	
2. Reocclusion _____	(1) (2)	(1) (2)	(1) (2)	(1) (2)

G. Observations:

1. Hazy lumen _____	(1) (2)	(1) (2)	(1) (2)	(1) (2)
2. Intimal tear _____	(1) (2)	(1) (2)	(1) (2)	(1) (2)
3. Ulcer _____	(1) (2)	(1) (2)	(1) (2)	(1) (2)
4. Aneurysm _____	(1) (2)	(1) (2)	(1) (2)	(1) (2)

H. Additional comments? _____

9. RGL Investigator Signature: _____ 10. RGL Investigator Signature: _____ 11. Date: _____
Month _____ Day _____ Year _____

12. Completed by: _____
Seattle _____ (1)
Rhode Island _____ (2)

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION

TIMI II Form 8A
 Rev 0 03/03/86
 3 Pages

RADIONUCLIDE SHIPPING RECORD
 REST/EXERCISE RVG

Clinic No.				
ID No.				
Form Type	R	S		

PART I: Visit Identification

1. Patient's NAME CODE: _____

2. Date of study: F8ADAYHD/F8ADAY6W (calc)
 Month Day Year

3. Type of study (check one):
 Pre-discharge rest/exercise _____ (1)
 Six week rest/exercise _____ (2)
 Non-Rotool
 Early _____ (3)
 3 month _____ (4)
 6 month _____ (5)
 1 year _____ (6)

4. Were both the rest and exercise portions done? _____ (1) (2)
 Yes No

If NO, answer (A) and (B).
 The rest portion should be performed even if the patient is not able to exercise.

RESTHD/REST6W
 Not Done Done

(A) Rest _____ (1) (2)
 If Rot Done, Reason Not Done

(B) Exercise EXERHD/EXER6W (1) (2)
 If Not Done, Reason Not Done

5. Time of injection of stannous pyrophosphate: _____ : _____
 hours minutes

6. Time of injection of ^{99m}Tc: _____ : _____
 hours minutes

7. Dose injected (mCi): _____

REST
 a. Arterial blood pressure: (check one)

A. Cuff _____ (1)
 Arterial line _____ (2)

8. Systolic _____ mm Hg

C. Diastolic _____ mm Hg

9. Heart rate: _____ bpm

10. Rhythm: (check one)
 NSR _____ (1)
 NSR end ectopy _____ (2)
 AF _____ (3)
 Heart block (2° or 3°) _____ (4)
 Artificial pacemaker _____ (5)
 Other _____ (6)
 Specify _____

ID No.				
Form Type	R	S		

PART II: Data on Magnetic Tape

Check if done and complete necessary data in columns A through F.

	Order on Tape	A Actual Obliquity(°)	B Frame Int. (msec)	C No. of Frames/RR	D No. of Heartbts.	E SYS BP	F HR
11. Field Flood	1	---	---	---	---	---	---
12. Bar Phantom	2	---	---	---	---	---	---
32 Frames or 40m sea:							
13. LLAT	3	---	---	---	---	---	---
14. LPD	4	---	---	---	---	---	---
15. ANT	5	---	---	---	---	---	---
16. LAO BSL1	6	---	---	---	---	---	---
16 Frames:							
17. LAO BSL1 (2 min)	7	---	---	---	---	---	---
16. LAO BSL2 (2 min) a	a	---	---	---	---	---	---
<u>EXERCISE (2min acquisitions)</u>							
19. Stage 1	9	---	---	---	---	---	---
20. Stage 2	10	---	---	---	---	---	---
21. Stage 3	11	---	---	---	---	---	---
22. Stage 4	12	---	---	---	---	---	---
23. Stage 5	13	---	---	---	---	---	---
24. Stage 6	14	---	---	---	---	---	---
25. Stage 7	15	---	---	---	---	---	---
26. Stage 6	16	---	---	---	---	---	---
27. Recovery	17	---	---	---	---	---	---

ID No.							
Form Type	R	S					

PART III: Technical Problems

28. Were there patient motion that interfered with the study? _____ (1) (2)
 Yes No

If **YES**, answer (A) .

(A) Which views? (check • II that apply) :

Rest

- 1. LLAT _____ (1)
- 2. LPO _____ (1)
- 3. ANT _____ (1)
- 4. LAO _____ (1)
- 5. Exercise _____ (1)

If **EXERCISE**, answer (B) .

(B) Stage number _____

29. Were there labeling difficulties? _____ (1) (2)
 Yes No

If **YES**, answer (A) .

(A) Specify _____

30. Were there positioning difficulties? _____ (1) (2)
 Yes No

If **YES**, answer (A) .

(A) Specify _____

31. Was there • intra-study cardiac emergency? _____ (1) (2)
 Yes No

If **YES**, answer (A) .

(A) Specify _____

32. Exercise performed for _____ minutes _____
 to stage STAGE HD / STAGE 6U

33. Exercise ECG results: MUGA HD / MUGA 6U
 Positive _____ (1)
 Negative _____ (2)
 Indeterminate _____ (3)

34. Chest pain EXPLAIN HD / EXPLAIN 6U
 _____ (1) (2)
 Yes No

PART IV: Administrative

35. Are the following required ECGs being submitted to the Coordinating Center with this form:

	Yes	No
A. Rest _____	(1)	(2)
B. Peak exercise _____	(1)	(2)
C. Recovery _____	(1)	(2)

36. Radionuclide technologist:

Signature: _____
 TIMI Staff No. _____

37. Research Nurse/Coordinator:

Signature: _____
 TIMI Staff No. _____

38. Date mailed to RNL:

_____/_____/_____
 Month Day Year

39. FOR CC USE ONLY		
	Yes	No
A. Rest _____	(1)	(2)
B. Peak exercise _____	(1)	(2)
C. Recovery _____	(1)	(2)

ID No.	_____	_____	_____	_____	_____
Form Type	R	S	_____	_____	_____

RADIONUCLIDE DATA ANALYSIS REPORT
 RESTING RVG

Clinic No.				
ID No.				
Form Type	R	D		

PART I: Visit Identification

- Patient's NAME CODE: _____
- Date of study: _____
 Month Day Year
- RV sequence:**
 Pre-discharge rest/exercise __ (1)
 Six week rest/exercise -- (2)
 Non-Protocol
 Early _____ (3)
 3 month _____ (4)
 6 month _____ (5)
 1 year _____ (6)
- Arterial blood pressure: (check one)
 A. Cuff _____ (1)
 Arterial line - - - - - (2)
 B. Systolic - - - - - mm Hg
 C. Diastolic - - - - - mm Hg
- Heart rate: _____ bpm

PART II: Quality Control

- Number of views: (check one)
 Complete :
 4 view _____ (4)
 3 views _____ (3)
 Incomplete :
 2 views - - - - - (2)
 1 views - - - - - (1)
- Technical quality: (check one)
 Fully satisfactory - _____ (1)
 Satisfactory for EF and limited RWM analysis (1 or 2 views) _____ (2)
 Satisfactory for EF only -- (3)
 Unsatisfactory _____ (4)

PART III: Results

- Global LV function: **RESTEFAD/RESTEF6**
 A. LVEF _____ %
 B. PFR _____ V/sec

- Regional LV function-Visual analysis :

For each segment, score: Normal = 3,
 Mildly hypokinetic = 2, Severely hypokinetic = 1, Akinetic = 0,
 Dyskinetic = -1. Non-visualized = 9.

Segment Number and Name	Function Score	Aneurysm (No=N, Yes=Y)
A. 1. Basal septal ()	___	___
B. 2. Apical septal ()	___	___
C. 3. Anterolateral ()	___	___
D. 4. Anterobasal ()	___	___
E. 5. Anterior ()	___	___
F. 6. Apical ()	___	___
G. 7. Inferoapical ()	___	___
H. 8. Inferior ()	___	___
I. 9. Posterobasal ()	___	___
J. 10. Inferolateral ()	___	___
K. 11. Posterolateral ()	___	___

- Regional LV function:
 Total LV score (normal = 33) = ()
 Sign Value
- RVTI _____ (1) (2)
 Yes No

If YES, answer (A) .

- Diffuse _____ (1)
 Local _____ (2)

ID No.				
Form Type	R	D		

12. Regional LV function - Quantitative Analysis (1) Processing not possible

Segment Number and Name	Mean S.D.		Regional LVEF (%)
	Sign	Mean	
A. Left anterior oblique view:			
1. Basal septal (11-26) _____ ()	-	-	_____
2. Apical septal (27-42) ---- ()	---	---	_____
7. Inferoapical (43-58) _____ ()	---	---	_____
10. Inferolateral (59-74) --- ()	---	---	_____
11. Posterolateral (75-90) _____ ()	---	---	_____
B. Left lateral view:			
4. Anterobasal (11-26) _____ ()	---	---	_____
5. Anterior (27-42) ----- ()	---	---	_____
6. Apical (43-58) _____ ()	---	---	_____
8. Inferior (59-74) ----- ()	---	---	_____
9. Posterobasal (75-90) _____ ()	---	---	_____
C. Optimal RAO equivalent (check one)			
LLAT --- (1) LPO --- (2)			

13 hyperkinetic segments:
 61-90, -70, Inf

	1		2		3		4	
	Sign	Hypo (S.D.) Value	First	Chord	Sign	Hyper (S.D.) Value	First	Chord
A. If anterior MI: (LAD) _____ ()	---	---	-	-	()	---	---	---
B. If inferior MI: (RCA) ----- ()	---	---	-	-	()	---	---	---

14. Hypokinesis

	1	2	3
Number of Chords	All Chords	(Anterior) Chords 11-70	(Inferior) Chords 61-90
A. > - 1 S.D. _____	-	-	_____
B. > - 2 S.D. _____	-	-	_____

15. Hyperkinesis

A. > + 1 S.D. - - - - -	-	-	_____
B. > + 2 S.D. -----	-	-	_____

PART IV: Administrative Matters

16. RNL technologist signature:

18. Date form completed :

____ - ____ - ____
 Month Day Year

17. RNL investigator signature:

ID	No.						
Form Type	R	D					

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION

TIMI II Form #1
 Rev 1 04/17/86
 2 Pages

RADIONUCLIDE DATA ANALYSIS REPORT
 EXERCISE RVG

Clinic No.				
ID No.				
Form Type	X	D		

PART I: Visit Identification

1. Patient's NAME CODE:

2. Date of study:
 _____ - _____ - _____
 Month Day Year

3. RVG sequence:

- Predischarge rest/exercise _____ (1)
- Six week rest/exercise _____ (2)
- Non-Protocol
- Early _____ (3)
- 3 month _____ (4)
- 6 month _____ (5)
- 1 year _____ (6)

4. Technical quality: (check one)

- Satisfactory _____ (1)
- Limited (LVEF only) _____ (2)
- Unsatisfactory _____ (3)

PART II: Results

	A	B	C	Regional LWV					H	I		
				D	E	F	G	Postero-		New RWM ab	Yes	No
	LVEF	Systolic BP	(% Change) Sign PSP/ESV	Basal Sign Septal	Apical Sign Septal	Infero-apical Sign	Infero-lateral Sign	Postero-lateral Sign				
5. Average Baseline	BASEEFHD/ BASEEF6W			()	()	()	()	()	()	()	()	()
6. Stage 1			()	()	()	()	()	()	()	()	()	()
7. Stage 2			()	()	()	()	()	()	()	()	()	()
8. Stage 3			()	()	()	()	()	()	()	()	()	()
9. Stage 4			()	()	()	()	()	()	()	()	()	()
10. Stage 5			()	()	()	()	()	()	()	()	()	()
11. Stage 6			()	()	()	()	()	()	()	()	()	()
12. Stage 7			()	()	()	()	()	()	()	()	()	()
13. Stage 8			()	()	()	()	()	()	()	()	()	()
14. Recovery			()	()	()	()	()	()	()	()	()	()

ID No.				
Form Type	X	D		

15. Change in regional EF:

Sign Value

A. Best zone (non-MI) _____ ()

B. Worst zone (MI) _____ ()

16. LVEF change (check one): **EFCHGD/EFCHGW**

LVEF fall \geq 5% _____ (1)

LVEF increase \geq 5% _____ (2)

LVEF no change _____ (3)

STAGEHD/STAGEGW

17. Peak exercise stage _____

EXEFHD/EXEFGW

18. Peak exercise LVEF _____ %

19. Pressure volume index - PSP/ESV change (check one):

Fall (decrease from baseline) _____ (1)

Increase (> 35% increase from baseline) _____ (2)

No change (0 - \leq 35% increase) _____ (3)

RESULTHD/RESULTGW (calc)

PART III: Administrative matters

20. RNL technologist:

Signature: _____

21. RNL Investigator:

Signature: _____

22. Date form completed:

_____/_____/_____
 Month Day Year

ID No.					
Form Type	X	D			

TIMI PHASE II
INSTRUCTIONS FOR **COMPLETING**
TIMI FORM 10
HOSPITAL DISCHARGE FORM

GENERAL INSTRUCTIONS

This form should be completed for all randomized patients at hospital discharge. Answer all items for the time period between the Screening Examination and discharge from the hospital or death. This form should cover the entire hospitalization period since entry into the study.

At the time of discharge from the hospital the patient should receive an appointment for Follow-up Visit 1.

The patient's identification number and Form type should appear in the box in the upper right-hand corner of the first page, as well as in the lower right-hand corner of all pages. The clinic number should appear in the upper right-hand corner of the first page.

Please use black ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use **abbreviations** unless absolutely necessary, and then use only widely recognized abbreviations. A completed copy of this form should be retained for your files.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [#] preceding the item number of the form.

REFER TO ITEM 6, PAGE 1

This question calls for clinical judgment to be made by the **TIMI** physician responsible for this patient.

Examples of cardiac enzymes over the course of hospital stay which might suggest **reperfusion** or myocardial salvage include early CK peak or quantitative **CK-MB** in small amounts in spite of presentation ST abnormalities indicating large areas of myocardium in jeopardy.

Examples of ECG evolution which might suggest reperfusion or myocardial salvage include rapid normalization of ST segments, R-wave preservation and failure to develop Q-waves.

REFER TO ITEM 57A, PAGE 9

ECG's are required once daily for the first four days following treatment **initiation**, and prior to discharge.

REFER TO ITEM 578, PAGE 9

To give a full picture of the clinical course at this time it is also requested that a narrative summary accompany this form. It should be less than one double-spaced page in length which describes pertinent clinical features and, in particular, adherence to the TIMI protocol and effects of TIMI therapy.

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION
 HOSPITAL DISCHARGE FORM

TIMI II Form 10
 Rev 0 03/04/86
 9 Pages

Clinic No.					
ID No.					
Form Type	H	D	O	1	

PART I: Visit Identification

- Patient's NAME CODE:

- Date of hospital discharge or death:

HDDAY	---	---	---
Month	Day	Year	
- Current statue of the patient: (Check one)

Alive _____ (1)	HDSTAT
Dead _____ (2)	

If **DEAD**, complete Death Notification Form (TIMI Form 15) and Cause of Death Form (TIMI Form 16) and complete as much of this form as possible.

- Group assignment (check one):
 - PTCA timing study:

2 hour PTCA _____ (01)
18-48 hour PTCA _____ (02)
No PTCA _____ (03)
 - Beta-blocker study:
 - Beta-blocker eligible:

Immediate beta-blocker and 18-48 hour PTCA _____ (04)
Immediate beta-blocker and no PTCA _____ (05)
Deferred beta-blocker and 18-48 hour PTCA _____ (06)
Deferred beta-blocker and no PTCA _____ (07)
 - Beta-blocker ineligible:

18-W hour PTCA _____ (08)
No PTCA _____ (09)

PART II: MI Diagnosis

- Was myocardial infarction confirmed? _____ (1) (2)

Yes	No	
-----	----	--

M I CONFIR
- Were CK-MBCK consistent with an MI? _____ (1) (2) (3)

Yes	No	Not done
-----	----	----------

M I CK
 - Were serial ECGs conclatent with an MI? _____ (1) (2) (3)

Yes	No	Not done
-----	----	----------

M I ECG
- Myocardial salvage
 - Did this patient's course during rt-PA infusion (see Form 05 item 21) suggest reperfusion with myocardial salvage? _____ (1) (2)

Yes	No
-----	----
 - Did cardiac enzymes over the course of hospital stay suggest reperfusion or myocardial salvage (e.g., early CK peak)? _____ (1) (2)

Yes	No
-----	----
 - Did ECG evolution over the course of hospital stay suggest reperfusion or myocardial salvage? _____ (1) (2)

Yes	No
-----	----
 - In the clinical judgment of the TIMI physician responsible for this patient was myocardial infarction interrupted with salvage of jeopardized myocardium? _____ (1) (2)

Yes	No
-----	----

ID No.					
--------	--	--	--	--	--

PART III: Clinical Complications

7. Did any clinical complications occur? _____ (1) (2) **CLNCOMH**
 Yes No

If **YES**, answer Items (8) through (20).
 For these items, if Yes is checked, Indicate date.
 If **NO**, skip to PART IV.

(8) Was there **clinical** or laboratory evidence of myocardial infarction or coronary thrombosis? _____ (1) (2) _____
 Yes No Date of first occurrence
 Month Day Year

If **YES**, answer item (9).
 If **NO**, skip to item (10).

- (9) Evidence:
- 1. Angiographic evidence _____ (1) (2) _____
 - 2. **Pain** _____ (1) (2) _____
 - 3. ECG evidence _____ (1) (2) _____
 - 4. **CK** evidence _____ (1) (2) _____
 - 5. **Other** enzymes elevated _____ (1) (2) _____

Complete Myocardial Infarction Form (TIMI Form 23).

- (10) Congestive heart failure? _____ **CHF** **HDCHF** (calculated)
 (1) (2) _____
- (11) Cardiogenic shock? _____ **SHOCK** **HDSHKT** (calc.)
 (1) (2) _____
- (12) Ventricular septal rupture? _____ **VSAUR** **HDVSAURT** (calc.)
 (1) (2) _____
- (13) Mitral regurgitation? _____ **MITRAL** **HDMITT** (calc.)
 (1) (2) _____
- (14) Cardiac arrest? _____ **ARREST** **HDARSTT** (calc.)
 (1) (2) _____
- (15) Recurrent ischemic pain? _____ **PAIN** **HDPNT** (calc.)
 (1) (2) _____

ID No. _____

⑩ Hemorrhagic complications? _____ Yes No Date of first occurrence
 (1) (2) Hemcom _____ Month Day Year

If YES, answer (A) through (L).
 If NO, skip to item (17).

- (A) Hematoma? _____ (1) (2) HEMCOMA HDHEMAT (calc.)
 Specify site: _____
- (B) Bleeding at puncture site? _____ (1) (2) HEMCOMB HDHEMBT (calc.)
 Specify site: _____
- (C) GI bleeding? _____ (1) (2) HEMCOMC HDHEMCT (calc.)
- (D) Significant decrease in hematocrit or hemoglobin? - (1) (2) HEMCOMD HDHEMDT (calc.)
- (E) Transfusion? _____ (1) (2) HEMCOM E HDHEMET (calc.)
- (F) Bleeding requiring surgery? _____ (1) (2) HEMCOMF HDHEMFT (calc.)
- (G) Retroperitoneal? _____ (1) (2) HEMCOMG HDHEMGT (calc.)
- (H) Intracranial? _____ (1) (2) HEMCOMH HDHEMHT (calc.)
- (I) fatal hemorrhage? _____ (1) (2) HEMCOMI HDHEMIT (calc.)
- (J) Thrombocytopenia? _____ (1) (2) HEMCOMJ HDHEMJT (calc.)
- (K) Hematuria? - _____ (1) (2) HEMCOMK HDHEMKT (calc.)
- (L) Other - _____ (1) (2) HEMCOML HDHEMLT (calc.)
 Specify _____

If (C), (D), (F), (G), (H) or (I) is answered YES complete a Hemorrhagic Event Form (TTMI Form 24). If (E) is answered YES complete a Transfusion Record Form (TTMI Form 26). For (K) and (L) a Hemorrhagic Event Form may also be appropriate.

⑪ Infection? _____ Yea No Date of first occurrence
 (1) (2) INFCOM _____ Month Day Year

If YES, answer (A) and (B).
 If NO, skip to item (18).

- (A) Puncture site? _____ (1) (2) INFCOMA HDINFAT (calc.)
 Specify _____
- (B) Other? _____ (1) (2) INFCOMB HDINFBT (calc.)
 Specify _____

ID No. _____

18 Vascular complications? _____ Yes No _____
 (1) (2) VASCOM
 Date of first occurrence
 Month Day Year

If YES, answer A through F.
 If NO, skip to Item 19.

- A Arterial embolism? _____ (1) (2) VASCOMA HDVASAT (calc)
 - B Arterial thrombosis? _____ (1) (2) VASCOMB HDVASBT (calc)
 - C Venous thrombophlebitis? _____ (1) (2) VASCOMC HDVASCT (calc)
 - D Cerebravascular accident? _____ (1) (2) VASCOMD HDVASDT (calc)
 - E Arterial dissection? _____ (1) (2) VASCOM E HDVASET (calc)
 - F Other? _____ (1) (2) VASCOM F HDVASFT (calc)
- Specify _____

19 Thoracic complications? _____ (1) (2) THRCOM

If YES, answer A through F.
 If NO, skip to item 20.

- A Pleuritis/pleural effusion? _____ (1) (2) THRCOMA HDTHRAT (calc)
 - B Pericarditis/pericardial effusion? _____ (1) (2) THRCOMB HDTHRBT (calc)
 - C Hemothorax? _____ (1) (2) THRCOMC HDTHRET (calc)
 - D Hemomediastinum? _____ (1) (2) THRCOMD HDTHRDT (calc)
 - E Pulmonary embolism? _____ (1) (2) THRCOME HDTHRET (calc)
 - F Other? _____ (1) (2) THRCOM F HDTHRFT (calc)
- Specify _____

20 Other complications? _____ (1) (2) OTHCOM

If YES, answer A through D.
 If NO, skip to item 21.

- A Allergic reactions? _____ (1) (2) OTHCOMA HDOTHAT (calc)
 - B Renal insufficiency? _____ (1) (2) OTHCOMB HDOTHBT (calc)
 - C Liver function abnormalities? _____ (1) (2) OTHCOMC HDOTHE T (calc)
 - D Other? _____ (1) (2) OTHCOMD HDOTHDT (calc)
- Specify _____

ID No. _____

PART IV: Special Procedures

21. Did the patient undergo any special procedures? _____ (1) (2) SURPRD
 Yes No Date of first occurrence
 Month Day Year

If YES, answer items (22) through (30).
 For these items, if yes is checked, indicate date.
 If NO, skip to PART V.

- (22) Electrical cardioversion/defibrillation? _____ (1) (2) ECARD HD ECDT (calc)
 (23) Right heart catheterization? _____ (1) (2) RTCATH HD RCHT (calc)
 (24) Protocol or non-protocol left heart cardiac catheterization? _____ (1) (2) CAAD CATH HD CCTH (calc)

If YES, complete a Cardiac Catheterization Form (TIMI Form 7C) for each catheterization.

- (25) Intra-aortic balloon counter pulsation? _____ (1) (2) IABP HD IABT (calc)
 (26) Cardiac surgery? _____ (1) (2) CARSUR

If YES, answer (A) and (B) and complete Cardiac Surgery Form (TIMI Form 25).
 If NO, skip to item (27).

- (A) Coronary artery bypass? _____ (1) (2) CABG HD CABGT (calc)
 (B) Other? _____ (1) (2) OTH SUR HD OSUR (calc)
 Specify _____

(27) Protocol or non-protocol percutaneous transluminal coronary angioplasty (PTCA)? _____ (1) (2) _____

If YES, complete PTCA Form (TIMI Form 06) for each PTCA.

(28) Electrical pacing? _____ (1) (2) EPACE HD PACET (calc)

If YES answer (A).

- (A) Type: _____ EPACETYP
 Temporary _____ (1)
 Permanent _____ (2)

(29) Electra-physiology studies? _____ (1) (2) (EPHY) (25) HD EPST (calc)
 (30) Other special procedures? _____ (1) (2) (OTH S) (2) HD OSP (calc.)

If YES, answer (A).

(A) Specify: _____

ID No.							
--------	--	--	--	--	--	--	--

PART v: Physical Exam

IF PATIENT DIED, SKIP TO PART VI.

31. Weight: _____ kilograms

32. Heart rate: _____ beats/minute

33. Respiratory rate: respiration/min.

34. Blood pressures

A. Systolic _____ mm Hg

B. Diastolic _____ mm Hg

	Pre- sent	Ab- sent	Un- known
35. Abnormal neck vein distension _____	(1)	(2)	(3)

36. Rales which do not clear on coughing _____ (1) (2) (3)

If PRESENT, answer (A).

- (A) To what extent?
- ≤ 1/3 lung field _____ (1)
 - > 1/3 lung fields but not all _____ (2)
 - Both entire lung fields _____ (3)

- | | Pre-
sent | Ab-
sent | Un-
known |
|-----------------------------------|--------------|-------------|--------------|
| 37. Heart sounds : | | | |
| A. S3 _____ | (1) | (2) | (3) |
| B. S4 _____ | (1) | (2) | (3) |
| C. Pericardial friction rub _____ | (1) | (2) | (3) |
| D. Murmurs _____ | (1) | (2) | (3) |

If PRESENT, answer (D1).
 If ABSENT or UNKNOWN, skip to item 38.

- (D1) Murmur(s) characteristic of the following are present (check all that apply):
- a. Benign systolic ejection _____ (1)
 - b. Mitral regurgitation _____ (1)
 - c. Aortic regurgitation _____ (1)
 - d. Ventricular septal rupture _____ (1)
 - e. Other _____ (1)
- Specify _____

- | | Pre-
sent | Ab-
sent |
|--|--------------|-------------|
| 38. Integument: | | |
| A. Ecchymosis _____ | (1) | (2) |
| B. Hematoma _____ | (1) | (2) |
| 39. Were other significant findings present? _____ | (1) | (2) |
| Yes No | | |
| If Yes, specify: _____ | | |
| _____ | | |
| _____ | | |

ID No. _____

PART VI: Medication History

If PATIENT DIED omit column prescribed at Hospital Discharge.

	1 Prescribed during hospitalization		2 Prescribed at Hospital Discharge	
	Yes	No	Yes	No
40. Have any of the following drugs or types of drugs been prescribed since onset of qualifying MI either during the hospitalization or at hospital discharge?				
A. Long-acting nitrates and oral vasodilators _____	HDRXA (1) (2)		HDDRXA (1) (2)	
B. Short-acting nitrates _____	HDRXB (1) (2)		HDDRXB (1) (2)	
C. Beta-blockers				
C1. Metoprolol _____	HDRXC1 (1) (2)		HDDRXC1 (1) (2)	
C2. Other beta-blockers _____	HDRXC2 (1) (2)		HDDRXC2 (1) (2)	
C3. name(s) _____				
D. Calcium channel blockers _____	HDRXD (1) (2)		HDDRXD (1) (2)	
D1. name(s) _____				
E. Antiarrhythmics (other than beta-blockers or calcium channel blockers) _____	HDRXE (1) (2)		HDDRXE (1) (2)	
F. Intravenous inotropic agents or pressor agents _____	HDRXF (1) (2)		HDDRFX (1) (2)	
G. Cardiac glycosides and oral inotropic agents _____	HDRXG (1) (2)		HDDRXG (1) (2)	
H. Diuretics _____	HDRXH (1) (2)		HDDRXH (1) (2)	
I. Intravenous vasodilators _____	HDRXI (1) (2)		HDDRXI (1) (2)	
J. Antihypertensives (other than diuretics and beta-blockers) _____	HDRXJ (1) (2)		HDDRXJ (1) (2)	
K. Aspirin _____	HDRXK (1) (2)		HDDR XK (1) (2)	
L. Mpyridamole _____	HDRXL (1) (2)		HDDRXL (1) (2)	
M. Platelet active agents (other than aspirin and dipyridamole) _____	HDRXM (1) (2)		HDDR XM (1) (2)	
N. Methyl xanthlner _____	HDRXN (1) (2)		HDDR XN (1) (2)	
O. Heparin _____	HDRXO (1) (2)		HDDR XO (1) (2)	
P. Anticoagulants (other than heparin) _____	HDRXP (1) (2)		HDDR XP (1) (2)	
41. Was the continuous infusion of heparin stopped prior to 5 days after treatment? _____	(1)	(2) HEP STOP		

If YES, answer items (A) and (B). If NO, skip to item 42.

- (A) How many days of continuous heparin infusion were administered before stopping heparin? - HEP DAYS
- (B) Reason for heparin discontinuation:

ID No. _____

42. Did the patient receive oral beta-blocker therapy in the hospital? _____

(1) Yes (2) No ORALBBT/C

42. (Continued)

Was oral beta-blocker therapy interrupted? _____ (1) (2)
 Yes No

If YES, answer B and C.
 If NO, answer A.

If YES, answer D, E and F.
 If NO, skip to item 43.

- A** Reason ineligible for oral beta-blockers (check all that apply)
1. Ventricular rate consistently < 45 beats per minute _____ (1)
 2. Systolic blood pressure consistently < 90 mm Hg _____ (1)
 3. Moist rales that did not clear with cough and involve 1/3 or more of the lung fields, interpreted as a sign of CHF _____ (1)
 4. Pulmonary edema with consistent chest X ray findings _____ (1)
 5. PR Interval > 0.24 seconds _____ (1)
 6. Second degree heart block (except if Permanent pacemaker is in place) _____ (1)
 7. Third degree heart block (except if permanent pacemaker is in place) _____ (1)
 - a. Asthmatic by history _____ (1)
 9. Wheezing on physical examination _____ (1)
 10. Chronic obstructive pulmonary disease under treatment with corticosteroids or beta2 stimulants _____ (1)
 11. Other (specify below) _____ (1)

Skip to Item 43.

B Date oral beta-blocker first prescribed: ORALBBT (calc.)

 Month Day Year

D Date interrupted:

 Month Day Year

- E** Reason Interrupted (Check all that apply):
1. Ventricular rate < 45 beats/minute _____ (1)
 2. Systolic blood pressure < 90 mm Hg _____ (1)
 3. P-R interval > 0.26 seconds _____ (1)
 4. 2° AV block _____ (1)
 5. 3° AV block _____ (1)
 6. Wheezing _____ (1)
 7. Moist rales that did not clear with cough and involve 1/3 or more of the lung fields, interpreted as a sign of CHF _____ (1)
 - a. Pulmonary edema with consistent chest X ray findings _____ (1)
 9. Diarrhea _____ (1)
 10. Dizziness _____ (1)
 11. Rash _____ (1)
 12. Other (specify below) _____ (1)

F Was beta-blocker therapy reinstated? _____ (1) (2)
 Yes No

If YES, answer G.
 If NO, skip to item 43.

G Date reinstated:

 Month Day Year

ID No. _____

TIMI PHASE II
 INSTRUCTIONS FOR COMPLETING
TIMI FORM 11
 FOLLOW-UP VISIT **FORM**

GENERAL INSTRUCTIONS

This **form** should be completed for each randomized patient. This form should be completed during each **of the follow-up visits**. **The permissible** time periods for completing these visits **are given In each** patient's Appointment Schedule. In the event that the **time period for a visit** elapses **without the visit being** completed, a Missed Visit **Form** should be **completed**. This does not apply if the patient is **deceased**.

Unless otherwise **specified**, the Information on this form should cover the period since the patient's last **completed** Follow-up Visit. **If** the present visit is the first completed follow-up visit, the Information **summarized** here should cover the period since the completion of the Hospital Discharge **Form**. If the patient has missed a visit, the Missed Visit **Form** should be reviewed so that all information Included on the Missed Visit **Form** **will** be Included on this completed Follow-up **Visit** **Form**.

For all follow-up visits, blood and urine specimens should be collected at the clinic for local laboratory tests. Additionally, a **12-lead** resting ECG **and a rest/exercise radionuclide** ventricular study should be obtained at the **six** week visit.

A maximal treadmill exercise tolerance test should be performed at the 12 month visit.

The clinic number, the patient's ID No., and Follow-up **Visit** Number (see patient's Appointment Schedule) for this examination should appear in the box In the upper **right-** hand corner of the first page. The patient's ID No. and Follow-up Visit Number should also appear In the boxes In the lower right-hand corner of all pages.

Please use black ink to complete this **form**. For Items which cannot be answered by a check mark (✓), PRINT clearly all responses In the spaces provided. Do not use abbreviations unless absolutely necessary, and then use only widely recognized abbreviations. A completed copy of this form should be retained for your files.

ITEM INSTRUCTIONS: **Items** with Instructions outlined below have the symbol **[*]** preceding the **item** number on the form.

REFER TO ITEM 3, PAGE 1

Follow-up Visit Number	Time Since Entry
01	6 weeks
02	12 months

(OVER)

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION
 FOLLOW-UP VISIT FORM

TIMI II Form 11
 Rev 0 03/04/86
 6 Pages

Clinic No.						
ID No.						
Form Type	F	V				

TYPEFU
 (calc.)
 FU6W/FUYR(calc.)

PART I: Visit Identification

1. Patient's NAME CODE: _____

2. Date of visit:
 Month Day Year
 DAYSFU (calc.)

[*] 3. Follow-up Visit Number: _____

4. Has the patient transferred from another TIMI clinic since the last completed study visit? _____ (1) (2)
 Yes No

If **YES**, answer item (A).

(A) Previous Clinic Name (specify below):

Previous Clinic Number: -- . .

5. Have there been any changes in the patient's place of residence or employment since the Patient's Information Sheet was last completed? -- _____ (1) (2)
 Yes No

If **YES**, the patient's current information should be updated on the Patient Information Sheet which is filed at the clinic.

THE FOLLOWING QUESTIONS REFER TO THE TIME OF THIS TIMI VISIT UNLESS OTHERWISE NOTED. "THE LAST SCHEDULED TIMI CONTACT" REFERS TO THE MOST R&C&NT EVENT (e.g., THE HOSPITAL DISCHARGE OR ME 6 WEEK FOLLOW-UP VISIT OR THE 3 MONTH OR 6 MONTH TELEPHONE CONTACT).

6. Has the patient reached a level of physical activity equal to that prior to the onset of the qualifying TIMI episode? _____ (1) (2)
 Yes No
 PHYACT6W
 PHYACTYR'

[*] 7. Current Canadian Heart Class:
 Class 0 _____ (0)
 Class I - _____ (1)
 Class II _____ (2)
 Class III - _____ (3)
 Class IV _____ (4)
 H1B2CLS6U
 HATCLSYR

8. Is the patient a current cigarette smoker? -- (1) (2)
 Yes No

ID No.						
Form Type	F	V				

Part III: Medical History

THE FOLLOWING QUESTIONS REFER TO THE TIME INTERVAL SINCE THE LAST SCHEDULED TIMI CONTACT UNLESS OTHERWISE NOTED.

9. Has the patient experienced any of the following events?
 (See Manual of Operations for definitions. Answer each item.)

	Defi- nite	No	Sus- pect
A. Myocaraial Infarction _____	(1)	(2)	(3)

If DEFINITE or SUSPECT complete a Myocardial Infarction Form (TIMI Form 23).

B. Cardiac Arrest _____	(1)	(2)	(3)	<i>CAFVO1 / CAFVO2</i>
C. Congestive heart failure _____	(1)	(2)	(3)	<i>CAFVO1 / CAFVO2</i>
D. Angina pectoris _____	(1)	(2)	(3)	<i>PAINFVO1 / PAINFVO2</i>
E. Intermittent cerebral ischemic attack _____	(1)	(2)	(3)	
F. Stroke _____	(1)	(2)	(3)	
G. Intermittent clauaication _____	(1)	(2)	(3)	

10. Have any of the following conditions been diagnosed? (Answer each question.)

	Yes	No
A. Diabetes mellitus _____	(1)	(2)
R. Hypertension _____	(1)	(2)
C. Peripheral vascular aisease _____	(1)	(2)
D. Valvular heart disease _____	(1)	(2)
E. Other cardiac aisease _____	(1)	(2)
Specify _____		
F. Gastrointestinal aisease _____	(1)	(2)
G. Hematological aisease _____	(1)	(2)
H. Renal disease _____	(1)	(2)
I. Neurological disease _____	(1)	(2)
J. Other significant aisease _____	(1)	(2)
Specify _____		

ID No.									
Form Type	F	V							

11. Has **the** patient undergone any of the following procedures?

A. Cardiac catheterization _____ Yea No
 (1) (2)

If **YES**, complete a Cardiac Catheterization Form (TIMI Form 7C) for each catheterization.

B. Percutaneous transluminal coronary angioplasty _____ (1) (2)

If **YES**, complete a PTCA Form (TIMI Form 06) for each PTCA.

C. Cardiac surgery _____ (1) (2)

If **YES**, complete a Cardiac Surgery Form (TIMI Form 25) for each surgery.

D. Other _____ (1) (2)

Specify _____

12. Has the patient been hospitalized since the last TIMI visit (do not include the qualifying TIMI episode)? _____ (1) (2)

If **YES**, answer (A) and complete a Subsequent Hospitalization Form (TIMI Form 14) for each admission.

(A) Number of admissions to the hospital: _____

PART IV: Medication

13. Is the patient currently using any of the following drugs?

			Yes	No	Never
			Started		
A.	Long-acting nitrates and oral vasodilators	_____	FURXAGW/FURXAYR	(1) (2)	FURXAYR
B.	Short-acting nitrates	_____	FURXBGW/FURXBYR	(1) (2)	
C1.	Metoprolol	_____	FURXCLW/FURXC1YR	(1) (2) (3)	

If **YES**, answer (C2). If **NO**, answer (C3) and (C4).
 If **NEVER STARTED**, skip to C5.

(C2) Total daily dose _____ mg

Skip to item C5.

(C3) Date stopped _____ Month _____ Year _____

ID No.							
Form Type	F	V					

13. (Continued)

(C4) Reason stopped (check all that apply):

- 1. Ventricular rate < 45 beats/minute _____ (1)
- 2. Systolic blood pressure < 90 mm Hg _____ (1)
- 3. P-R interval > 0.26 seconds _____ (1)
- 4. 2° AV block _____ (1)
- 5. 3° AV block _____ (1)
- 6. Wheezing _____ (1)
- 7. Moist rales that did not clear with cough and involved 1/3 or more of the lung fields, interpreted as a sign of CHF _____ (1)
- 8. Pulmonary edema with consistent chest X ray _____ (1)
- 9. Diarrhea _____ (1)
- 10. Dizziness _____ (1)
- 11. Rash _____ (1)
- 12. Other (specify below) _____ (1)

C5. Other beta-blockers _____ FURXC6W/FURXC5YR
 (1) (2)
 Yes No

If YES, answer **(C6)** .

(C6) Names _____ FURXD6W/FURXDYR
 Yes No

D. Calcium channel blockers _____ (1) (2)

If YES, answer **(D1)** .

(D1) Name(s) _____

- E. Antiarrhythmics (other than beta-blockers or calcium channel blockers) _____ FURXE6W/FURXEVR
 (1) (2)
- F. Intravenous inotropic agents or pressor agents _____ FURXFGW/FURXFYR
 (1) (2)
- G. Cardiac glycosides and oral inotropic agents _____ FURXG6W/FURXGYR
 (1) (2)
- H. Diuretics _____ FURXH6W/FURXHYR
 (1) (2)
- I. Intravenous vasodilators _____ FURXIGW/FURXIYR
 (1) (2)
- J. Antihypertensives (other than diuretics and beta-blockers) _____ FURXJ6W/FURXIYR
 (1) (2)
- K. Aspirin _____ FURXK6W/ Never Started FURXKYR
 (1) (2) (3)

If NO, answer **(K1)** and **(K2)** .

(K1) Date stopped _____ Month Year

(K2) Reason stopped _____

ID No.							
Form Type	F	V					

13. (Continued)

- | | | | |
|---|------------|-----------|-----------------|
| L. Dipyridamole _____ | Yes
(1) | No
(2) | FURXLLW/FURXLYR |
| M. Platelet active agents (other than aspirin and dipyridamole) _____ | (1) | (2) | FURXMGW/FURXMYR |
| N. Methyl xanthines _____ | (1) | (2) | FURXNGW/FURXNYR |
| O. Heparin _____ | (1) | (2) | FURXOLW/FURXOYR |
| P. Anticoagulants (other than heparin) _____ | (1) | (2) | FURXPGW/FURXPYR |

PART V: Physical Exam

THE FOLLOWING ITEMS PERTAIN TO THE PHYSICAL EXAM AT THE TIME OF THE FOLLOW-UP VISIT

14. Weight _____ Kilograms
15. Heart rate _____ beats/minute
16. Respiratory rate _____ Respirations/min.
17. Blood pressure:
- A. systolic _____ mm Hg
- B. diastolic _____ mm Hg
18. Abnormal neck vein distension _____ (1) (2) (3)
19. Rales after coughing or deep breathing _____ (1) (2) (3)

If PRESENT, answer **(A)**.

- (A)** To what extent?
- < 1/3 lung field _____ (1)
- ≥ 1/3 lung field but not all _____ (2)
- Both entire lung fields _____ (3)

20. Heart sounds:

- | | | | |
|----------------------------------|------|------|-------|
| | Pre- | Ab- | Un- |
| | sent | sent | known |
| A. S ₃ _____ | (1) | (2) | (3) |
| B. S ₄ _____ | (1) | (2) | (3) |
| C. Percardial friction rub _____ | (1) | (2) | (3) |
| D. Murmurs _____ | (1) | (2) | (3) |

If PRESENT, answer **(D)**.

If ABSENT or UNKNOWN, skip to Item 21.

(D) Murmur(s) characteristic of the following are present (check all that apply):

- a. Benign systolic ejection _____ (1)
- b. Mitral regurgitation _____ (1)
- c. Aortic regurgitation _____ (1)
- d. Ventricular septal rupture _____ (1)
- e. Other _____ (1)

Specify _____

21. Were other significant Findings present? _____ (1) (2)
- Yes No

If YES, specify: _____

ID No.							
Form Type	F	V					

TIM1 PHASE II
INSTRUCTIONS FOR COMPLETING
TIM1 FORM 12
MISSED VISIT FORM

GENERAL INSTRUCTIONS

This form should be completed and forwarded to the Coordinating Center as soon as it becomes certain that the patient will not complete the Follow-up Visit within the **permissible** time period given in the patient's Appointment Schedule. If a patient has died, this form should not be completed for the follow-up period in which the death occurred. In this case, the Death Notification Form and Cause of Death Form should be completed and forwarded to the Coordinating Center.

The information on this **form** should cover the period since the patient's last completed visit (either Hospital Discharge Visit or Follow-up Visit), or since the last completed Missed Visit if the patient has missed the previous visit.

The clinic number, the patient's ID No., and Follow-up Visit Number (see patient's Appointment Schedule) for this examination should appear in the box in the upper right-hand corner of the first page. The patient's ID No. and Follow-up Visit Number should also appear in the boxes in the lower right-hand corner of all pages.

Please use black ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use abbreviations unless absolutely necessary, and then use only widely recognized abbreviations. A completed copy of this form should be retained for your files.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [*] preceding the Item number on the form.

REFER TO ITEM 4, PAGE 1

If the clinic has been unable to locate or determine the whereabouts of the patient after attempting to contact the patient's next of kin, referring or private physician, or the patient's employer and has exhausted all available resources, the clinic may request that the Coordinating Center assist in locating the patient. If the clinic requests the services of the Coordinating Center, Item 4 **(*)** should be answered **YES**.

REFER TO ITEM 7, PAGE 2

The patient should be queried at the time of the contact as to the main reason for missing the visit.

It should be noted that even if the patient **is** unwilling to actively participate in the study, the clinic should contact him/her once during the time period of each scheduled follow-up visit. At that time, the patient should be encouraged to continue active participation in the study.

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION
 MISSED VISIT FORM

TIMI II Form 12
 Rev 003/03/86
 3 Pages

Clinic No.					
ID No.					
Form Type	M	V			

TYPEFU
 FUGW/FUYR
 (calc.)

PART I: Visit Identification

1. Patient's NAME CODE _____

5. Is the patient alive? ALIVEFU
 (1) (2) (3)
 Yes No Unknown

2. A. Date of contact: DAY6FU (calc.)

 Month Day Year

If NO, do NOT complete this form. Complete Death Notification Form and Cause of Death Form, instead.

B. Expected date for follow-up visit from Appointment Schedule:

 Month Day Year

6. Was the patient encouraged to continue active participation in the study? _____
 (1) (2) (3)
 Yes No Not Applicable

3. Follow-up Visit Number: _____

[*] 4. Were you able to locate or determine the whereabouts of the patient? LOCATEFU
 _____ (1) (2)
 Yes No

[*] 7. What is the main reason that the patient missed the visit? (Check only one.) MISS6W/MISSYR
 Patient has been ill _____ (01)

If YES, skip to Item 5.
 If NO, answer (A) and (B).

- (A) Did you attempt to contact any of the following sources?
- | | Yes | No | Not Applicable |
|--|-----|-----|----------------|
| 1. Patient _____ | (1) | (2) | (3) |
| 2. Patient's next of kin _____ | (1) | (2) | (3) |
| 3. Reference listed in Patient Information Sheet as likely to know patient's whereabouts _____ | (1) | (2) | (3) |
| 4. Referring or private physician - - | (1) | (2) | (3) |
| 5. Patient's employer - - | (1) | (2) | (3) |

- Moved (distance too far to continue at this clinic) _____ (02)
- Reason related to study design (e.g., study procedures, time commitment) _____ (03)
- Reasons related to clinic (e.g., transportation, clinic facilities, clinic hours, waiting period) _____ (04)
- Lack of support from family and/or private physician _____ (05)
- Uncooperative or unwilling _____ (06)
- Other (specify below) _____ (07)
- Unknown _____ (08)

(B) Do you wish the Coordinating Center staff to assist in locating the patient? CCFU
 _____ (1) (2)
 Yes No

ID No.					
Form Type	M	V			

Part II: Medical History

THE FOLLOWING QUESTIONS REFER TO THE TIME INTERVAL SINCE THE LAST SCHEDULED TIMI CONTACT OR SINCE THE MISSED VISIT FORM WAS LAST COMPLETED.

8. Has the patient experienced any of the following events?
 (See Manual of Operations for definitions. Answer each item.)

	Defi- nite	No	Sus- pect	Un- known
A. Myocardial infarction _____	(1)	(2)	(3)	(4)

If DEFINITE or SUSPECT complete a Myocardial Infarction Event Form (TIMI Form 23).

B. Cardiac arrest _____	(1)	(2)	(3)	(4)
C. Congestive heart failure _____	(1)	(2)	(3)	(4)
D. Angina pectoris _____	(1)	(2)	(3)	(4)
E. Intermittent cerebral ischemic attack _____	(1)	(2)	(3)	(4)
F. Stroke _____	(1)	(2)	(3)	(4)
G. Intermittent claudication _____	(1)	(2)	(3)	(4)

CAFV01/CAFV02
 CHFV01/CHFV02
 PAINFV01/PAINFV02

9. Have any of the following conditions been diagnosed? (Answer each question.)

	Yes	No	Un- known
A. Diabetes mellitus _____	(1)	(2)	(3)
B. Hypertension _____	(1)	(2)	(3)
C. Peripheral vascular disease _____	(1)	(2)	(3)
D. Valvular heart disease _____	(1)	(2)	(3)
E. Other cardiac disease _____	(1)	(2)	(3)
Specify _____			
F. Gastrointestinal disease _____	(1)	(2)	(3)
G. Hematological disease _____	(1)	(2)	(3)
H. Renal disease _____	(1)	(2)	(3)
I. Neurological disease _____	(1)	(2)	(3)
J. Other significant disease _____	(1)	(2)	(3)
Specify _____			

ID No.									
Form Type	M	V							

10. Has the patient undergone any of the following procedures?

	Yes	No	Un- known
A. Cardiac catheterization _____	(1)	(2)	(3)

If **YES**, complete a Cardiac Catheterization Form (TIMI Form 7C) for each catheterization.

B. Percutaneous transluminal coronary angioplasty _____	(1)	(2)	(3)
---	-------	-------	-------

If **YES**, complete a PTCA Form (TIMI Form 06) for each PTCA.

C. Cardiac surgery _____	(1)	(2)	(3)
--------------------------	-------	-------	-------

If **YES**, complete a Cardiac Surgery Form (TIMI Form 25) for each surgery.

D. Other _____	(1)	(2)	(3)
----------------	-------	-------	-------

Specify _____

11. Has the patient been hospitalized since the last TIMI visit (do not include the qualifying TIMI episode)? _____	(1)	(2)	(3)
---	-------	-------	-------

If **YES**, answer **(A)** and complete a Subsequent Hospitalization Form (TIMI Form 14) for each admission.

(A) Number of admissions to the hospital: _____

PART III: Administrative Matters

12. What is the main source of the information reported, in Items 7 - 11?
 (Check one source for each item.)

- PT = Patient
- SPS = Patient's spouse/significant other
- KIN = Patient's next of kin other than spouse
- MD = Referring or patient's private physician
- EMP = Patient's employer
- HC = Hospital chart
- OTHER = Other

	PT	SPS	KIN	MD	EMP	HC	OTHER
	SOURCE	SOURCE	SOURCE	SOURCE	SOURCE	SOURCE	SOURCE
A. Item 7 _____	(1)	(2)	(3)	(4)	(5)	(6)	(7)
B. Item 8 _____	(1)	(2)	(3)	(4)	(5)	(6)	(7)
C. Item 9 _____	(1)	(2)	(3)	(4)	(5)	(6)	(7)
D. Item 10 _____	(1)	(2)	(3)	(4)	(5)	(6)	(7)
E. Item 11 _____	(1)	(2)	(3)	(4)	(5)	(6)	(7)

13. Research Nurse/Coordinator:
 Signature _____

TIMI Staff No: _____

ID No.								
Form Type	M	V	I	C	R	S	O	T

TIM1 PHASE II
INSTRUCTIONS FOR **COMPLETING**
TIM1 FORM 13
TELEPHONE CONTACT FORM

GENERAL INSTRUCTIONS

This form should be completed and forwarded to the Coordinating Center to document a Telephone Follow-up. If a patient has died, this form should not be completed for the **follow-up** period in which the death occurred. In this case, the Death Notification Form and Cause of Death Form should be completed and forwarded to the Coordinating Center.

The information on this form should cover the period since the patient's last study contact.

The clinic number, the patient's ID No., and Follow-up Visit Number (see patient's Appointment Schedule) for this contact should appear in the box in the upper right-hand corner of the first page. The patient's ID No. and Follow-up Visit Number should also appear in the boxes in the lower right-hand corner of all pages.

Please use black ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use abbreviations unless absolutely necessary, and then use only widely recognized abbreviations. A completed copy of this form should be retained for your files.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol **[*]** preceding the item number on the form.

REFER TO ITEM 3, PAGE 1

Telephone Contact Number	Time Since Entry
01	3 months
02	6 months
03	18 months
04	24 months

REFER TO ITEM 4, PAGE 1

If the clinic has been unable to locate or determine the whereabouts of the patient after attempting to contact the patient's next of kin, referring or private physician, or **the** patient's employer and has exhausted all available resources, the clinic may request that the Coordinating Center assist in locating the patient. If the clinic requests the services of the Coordinating Center, Item 4 **(B)** should be answered YES.

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION
 TELEPHONE CONTACT FORM

TIMI 11 Fon 13
 Rev 0 03/03/86
 2 Pages

Clinic	No.				
ID No.					
Form Type	T	C			

TYPEFU
(calc.)

PART I: Visit Identification

1. Patient's NAME CODE: _____

2. Date of contact: DAYSFU (calc.)

 Month Day Year

[*] 3. Telephone Contact Number _____

[*] 4. Were you able to locate or determine the whereabouts of the patient? _____ (1) (2)
 Yes No LOCATEFU

It YES, skip to item 5.
 If NO, answer (A) and (B).

(A) Did you attempt to contact any of the following sources?

- | | | | |
|--|-------|-------------|------------------------|
| | Yes | No | Not
Appli-
cable |
| 1. Patient | _____ | (1) (2) (3) | |
| 2. Patient's next of kin | _____ | (1) (2) (3) | |
| 3. Reference listed in Patient Information Sheet as likely to know patient's whereabouts | _____ | (1) (2) (3) | |
| 4. Referring or private physician | _____ | (1) (2) (3) | |
| 5. Patient's employer | --- | () () () | |

4. (Continued)

(B) Do you wish the Coordinating Center staff to assist in locating the patient? _____ (1) (2)
 Yes No CCFU

5. Is the patient alive? _____ (1) (2) (3)
 Yes No unknown ALIVEFU

If NO, do NOT complete this form. Complete a Death Notification Form and Cause of Death Form, instead.

6. Were you able to contact the patient? _____ (1) (2) (3)
 Yes No Not
 Applicable

ID No.					
Form Type	T	C			

Part II: Health Status

THE FOLLOWING QUESTIONS REFER TO THE TIME INTERVAL SINCE THE LAST SCHEDULED TIMI CONTACT (FOLLOW-UP VISIT, MISSED VISIT, OR TELEPHONE CONTACT).

7. Has the patient been admitted to a hospital since the last TIMI contact (do not include the qualifying TIMI episode)? _____ (1) (2) (3)
 Yes No Unknown

If YES, answer A (A) complete a Subsequent Hospitalization Form (TIMI Form 14) for each admission.

(A) Number of admissions to the hospital: _____

8. Has the patient been seriously ill (but not admitted to a hospital for this illness) since the last TIMI contact (do not include the qualifying TIMI episode)? _____ (1) (2) (3)
 Yes No Unknown

If YES, _____ never@end@.
 If NO or UNKNOWN, skip to item 9.

(A) How long was patient ill? _____ days

08 Was this illness a myocardial infarction or other heart disease? _____ (1) (2) (3)
 Yes No Unknown

If YES, complete a Myocardial Infarction Event Form (TIMI Form 23).
 If NO, answer (C).

(C) Name the patient's illness: _____

PART III: Administrative Matters

9. What is the main source of the information reported, in Items 7 and 8? (Check one source for each item.)

- PT = Patient
- SPS = Patient's spouse/significant other
- KIN = Patient's next of kin other than spouse
- MD = Referring or patient's private physician
- EMP = Patient's employer
- HC = Hospital chart
- OTHER = Other

	PT	SPS	KIN	MD	EMP	HC	OTHER
A. Item 7 _____	(1)	(2)	(3)	(4)	(5)	(6)	(7)
B. Item 8 _____	(1)	(2)	(3)	(4)	(5)	(6)	(7)

10. Research Nurse/Coordinator:

Signature _____

TM Staff No: _____

ID	No.								
Form T&e	T	C							

TIMI PHASE II
INSTRUCTIONS FOR COMPLETING
TIMI FORM 14
SUBSEQUENT HOSPITALIZATION FORM

GENERAL INSTRUCTIONS

Complete this form for each admission to the hospital. **This** form should be submitted to the Coordinating **Center as soon as possible.**

The clinic number, the patient's ID No., and Form Type should appear in the box **in** the upper right-hand corner of the first page. For Form Type enter the event sequence number from the patient's Appointment Schedule. The patient's ID No. and **Form** Type should also appear in the box in the lower right-hand corner of all pages.

Please use black ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. A completed copy of this form should be retained for **your** files.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [•] preceding the item number on the form.

REFER TO ITEM 10. PAGE 2

All documents submitted to the Coordinating Center in conjunction with this form should be masked and identifiers removed.

A Hospital Discharge summary and/or a narrative summary, which is less than one **double-**spaced page in length describing pertinent clinical features, assessment, and therapy for this admission should accompany this form for all hospitalizations which do not require completion of an additional form. If an additional event form (myocardial infarction, cardiac catheterization, PTCA, cardiovascular surgery) **is** required, attach the hospital discharge summary to that form.

TIMI PHASE 11
 THROMBOLYSIS IN MYOCARDIAL INFARCTION
 SUBSEQUENT HOSPITALIZATION FORM

TIMI II Form 14
 Rev 0 03/03/86
 2 Pages

Form 14-1...5 (calc.)

Clinic No.					
ID No.					
Form Type	H	P			

PART I: Visit Identification

1. Patient's NAME CODE:

2. Dates of hospitalization:

A. Admitted:

HOSCDAY STKDAY
 CHEDAY HOSPODAY1...5 } calc.
 ARRDAY STAY1...5
 Month Day Year

B. Discharged or died:

Month Day Year

3. Name and address of hospital:

Hospital: _____

Address: _____

4. Diagnosis:

A. Admission: _____

B. Discharge: _____

5. The hospitalization was or will be reported on: (check one)

- Follow-up Visit Form _____ (1)
- Missed Visit Form _____ (2)
- Telephone Contact Form _____ (3)
- Cause of Death Form _____ (4)

If Follow-up, Missed Visit or Telephone Contact Form answer **A**.

(A) Visit or Contact No. _____

6. Is this hospitalization elective? _____ (1) (2)
 Yes No

PART II: Physician Assessment

7. Is the cause for this hospitalization cardiovascular? - (1) (2)
 Yes No **CHOSC (calc) CREAS1**

If **YES**, answer item **8**.
 If **NO**, skip to item 9.

8 What was the cardiovascular reason for this hospitalization? (answer each item)

Definite No Suspect
 A. MI _____ (1) (2) (3) **AHMI 7...**

If **DEFINITE** or **SUSPECT** complete a Myocardial Infarction Event Form (TIMI Form 23).

B. Angina pectoris --- (1) (2) (3) **AHAN61**

C. Congestive heart failure _____ (1) (2) (3) **RCHF 1, CCHF (calc)**

ID No.					
Form Type	H	P			

8 (Continued)

- | | | | | | |
|-----------------------------|-------|---------------|-----|--------------|---------------------------|
| | | Defi-
nite | No | Sus-
pect | |
| D. Arrhythmia | _____ | (1) | (2) | (3) | RHARR1...5
CAAR (calc) |
| E. Stroke | _____ | (1) | (2) | (3) | RHSTK1...5
CSTK (calc) |
| F. Cardiovascular procedure | _____ | (1) | (2) | | |

If **DEFINITE** answer (F1) to (F5).

- (F1) Coronary angiography _____ (1) (2) Yes No RH CATH1...5

If **YES**, complete a Cardiac Catheterization Form (TIMI Form 7C).

- (F2) PTCA _____ (1) (2) Yes No RHPTCA1...5

If **YES**, complete a PTCA Form (TIMI Form 06).

- (F3) CABG _____ (1) (2) Yes No RHCABG1...5

If **YES**, complete Cardiac Surgery Form (TIMI Form 25).

- (F4) Permanent pacemaker implantation _____ (1) (2) Yes No RHPP1...5

- (F5) Other cardiac surgery _____ (1) (2) Yes No RHOSUR1...5

Specify: _____

- | | | | | | |
|--------------------|-------|---------------|-----|--------------|------------|
| | | Defi-
nite | No | Sus-
pect | |
| c. Other (specify) | _____ | (1) | (2) | (3) | RHOTH1...5 |

9. What was the noncardiovascular reason for this hospitalization? (answer each item)

- | | | | |
|---------------------|-------|-----|-----|
| | | Yes | No |
| A. Gastrointestinal | _____ | (1) | (2) |
| B. Renal | _____ | (1) | (2) |
| C. Hematopoietic | _____ | (1) | (2) |
| D. Hepatobiliary | _____ | (1) | (2) |
| E. Neurologic | _____ | (1) | (2) |
| F. Pulmonary | _____ | (1) | (2) |
| G. Musculoskeletal | _____ | (1) | (2) |
| H. Genito-urinary | _____ | (1) | (2) |
| I. Malignancy | _____ | (1) | (2) |
| J. Elective surgery | _____ | (1) | (2) |
| K. Other | _____ | (1) | (2) |

Specify _____

PART III: Administrative Matters

- [*]10. Is the required Hospital Discharge Summary and/or Narrative Summary being submitted? _____ (1) (2) Yes No

11. Research Nurse/Coordinator:

Signature _____

TIMI Staff No: _____

FOR COORDINATING CENTER USE ONLY	
12. Documents received:	
A. Hospital discharge summary and/or Narrative summary	____ (1) (2) Yes No

ID No.	_____
Form Type	H P _____

TIMI PHASE II
INSTRUCTIONS FOR **COMPLETING**
TIHI FORM 15
DEATH NOTIFICATION FORM

GENERAL INSTRUCTIONS

This form should be completed and returned to the Coordinating Center within 48 hours after notification of the patient's death. Within 30 days after notification of death, the Cause of Death **Form** should also be completed.

The **clinic** number and the patient's Identification number should appear in the box in the upper right-hand corner of the first page, as well as in the lower **right-hand** corner of both pages.

Please use black ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use abbreviations unless absolutely necessary, and then use only widely recognized abbreviations. A completed copy of this form should be retained for your files.

ITEM INSTRUCTIONS: Items **with** instructions outlined below have the symbol **[*]** preceding the item number on the form.

REFER TO ITEM 4, PAGE 1

Answer NO if the patient **died** while sleeping and there **is** no indication of the cause of death.

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION
 DEATH NOTIFICATION FORM

TIMI II Form 15
 Rev 0 03/03/86
 2 pages

Clinic	No.				
ID No.					
Form Type	D	N	O	1	

PART I: Death Information

1. Patient's NAME CODE (See Patient Information Sheet):

2. Date this form completed:

____ - ____ - ____
 Month Day Year

3. Date of death:

____ - ____ - ____
 Month Day Year

[*] 4. Is there any preliminary information available on the cause of death? _____ (1) (2)
 Yes No

If YES, answer Items 5 and 6.
 If NO, skip to Item 7.

5 What was the tentative underlying (basic) cause of death? (Check only one.)

F15CAUSE

A. Atherosclerotic Cardiovascular Disease

Qualifying myocardial infarction _____ (01)

New myocardial infarction, confirmed *or* suspected _____ (02)

Sudden coronary death - arrhythmia suspected (less than one hour ha onset of symptoms) _____ (03)

Congestive heart failure, without new infarct _____ (04)

Confirmed cardiac arrhythmia, without new infarct _____ (05)

Peri-operative cardiovascular surgical death (catherization, angiography, peripheral vascular surgery, PTCA, etc., ⁸⁸ well ⁸⁸ heart surgery) _____ (06)

Stroke _____ (07)

Non-cardiac, non-cerebral, atherosclerotic arterial disease _____ (08)

6 (Continued)

B. Non-atherosclerotic Cardiovascular Disease

Pulmonary embolism _____ (09)

Non-atherosclerotic heart disease (cardiomyopathy, myocarditis, valvular disease, rheumatic heart disease, bacterial endocarditis, ^{to J} _____ (10)

C. Other

Neoplastic disease _____ (11)

All other diseases (pulmonary, infectious, hepatic, GI, renal, metabolic, etc.) _____ (12)

Non-cardiovascular surgically related death (abdominal, orthopedic, etc.) _____ (13)

Homicide, suicide, accident _____ (14)

D. Unknown _____ (15)

ID No.					
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TIM1 PHASE II

INSTRUCTIONS FOR COMPLETING
TIM1 FORM 16
CAUSE OF DEATH FORM

GENERAL INSTRUCTIONS

This form should be completed and forwarded to the Coordinating Center when the death certificate and autopsy report become available. If these are not available within 30 days of notification of the patient's death, this form should be submitted without these documents.

Please review carefully all of the data available regarding this death, that is, hospital records, autopsy report, death certificate, terminal **ECGs**, etc. Note that the underlying (or basic) cause of death should be given and if the death was attributed to cardiovascular disease the immediate (or final step in the disease process) cause of death should be given. Copies of any documentation should be forwarded along with this form to the Coordinating Center.

The clinic number and the patient's Identification number should appear in the box in the upper right-hand corner of the first page. The patient's ID No. should also appear in the box in the lower right-hand corner of all other pages.

Please use black Ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use abbreviations unless absolutely necessary, and then use only widely recognized abbreviations. A completed copy of this form should be retained for your files.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [*] preceding the item number on the form.

REFER TO ITEM 6, PAGE 2

More than one item may be checked, but an explanation should be contained in the Physician's Summary.

REFER TO ITEM 6A, PAGE 2

Sudden unexpected or unobserved death does not **usally** apply to hospitalized patients.

REFER TO ITEM 8, PAGE 3

This list Includes only the most frequent immediate cause of death relating to coronary heart disease. More than one item may be checked, but an explanation should be contained in the Physician's Summary.

(OVER)

THROMBOLYSIS IN MYOCARDIAL INFARCTION
CAUSE OF DEATH FORM

Clinic No.					
ID No.					
Form Type	C	D	O	I	

PART I: Identifying Information

1. Patient's NAME CODE (See Patient Information Sheet):

2. Date this form completed:

____ - ____ - ____
Month Day Year

3. Date of death:

____ - ____ - ____
Month Day Year

4. Has the Death Notification Form (Form 15) been submitted? _____ (1) (2)
Yes No

If NO, complete and forward a Death Notification Form to the Coordinating Center.

PART II: Cause of Death

5. What was the underlying (basic) cause of death? (Check only one.)

A. Atherosclerotic Cardiovascular Disease _____ (1)

If checked, skip to Item 6.

B. Non-atherosclerotic Cardiovascular Disease _____ (2)

If checked, skip to Item 7.

C. Non-cardiovascular Disease _____ (3)

If checked, skip to Item 7.

D. Unknown _____ (4)

If checked, skip to Item 7.

ID No.					
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PART III: Hospitalization

9. Since the last completed study visit has the patient been hospitalized for any reason not associated with the terminal event? _____ (1) (2)
 Yes No

If YES, answer Item (10) and complete Subsequent Hospitalization Forms (TIMI Form 14).
 If NO, skip to Item 11.

(10) What were the reasons for hospitalization?

Yes No

A. MI _____ (1) (2)

B. Acute coronary insufficiency _____ (1) (2)

If YES, to either A or B, complete Myocardial Infarction Event Form (TIMI Form 23).

C. Other _____ (1) (2)
 Specify: _____

PART IV: Circumstances of Death

[*]11. Did the patient die in a hospital (other than qualifying TIMI hospitalization)? _____ (1) (2)
 Yes No

If YES, complete Subsequent Hospitalization Form (TIMI Form 14).

12. Was the death witnessed? _____ (1) (2) (3)
 Yes No Unknown

13. At the time of the onset of the fatal event, the patient was: (Answer only one)

At home _____ (01)

At work, other than home _____ (02)

At a public place, other than work _____ (03)

Hospitalized _____ (04)

Unknown _____ (05)

Other _____ (06)

Specify: _____

14. At the time of the onset of the death event, the patient was: (Answer only one.)

Asleep _____ (01)

Awake but sedentary _____ (02)

Engaged in light physical activity _____ (03)

Engaged in heavy physical activity _____ (04)

Unknown _____ (05)

ID No. _____

PART V: Resource Materials

15. Were any of the following sources of information used to help you arrive at the conclusion stated above?

Yes No

- A. History (1) (2)
- B. Physical examination (1) (2)
- C. ECG(s) (1) (2)
- D. Blood test(s) (1) (2)
- E. Chest X-ray (1) (2)
- F. Pulmonary scan (1) (2)
- G. Pulmonary angiography (1) (2)
- H. Autopsy (1) (2)
- I. Other (1) (2)

Specify: _____

J. Lack of evidence of any other cause of death (1) (2)

16. Was an autopsy performed? (1) (2) Autopsy
 Yes No

[*]17. Are the following resource materials available and are they being submitted with this form?

All resources documenting this event must be submitted.

Yes No

- A. Death certificate (1) (2)
- B. Autopsy report (1) (2)
- C. ECG(s) (1) (2)
- D. Final Hospital Summary (1) (2)
- E. Physician's Summary (1) (2)
- F. Other (1) (2)

Specify: _____

PART VI: Administrative Matters

18. Research Nurse/Coordinator:

Signature _____

TIMI Staff No: _____

19. FOR COORDINATING CENTER USE ONLY

Yes No

- A. Death Certificate (1) (2)
- B. Autopsy Report (1) (2)
- C. ECG(s) (1) (2)
- D. Final Hospital Summary (1) (2)
- E. Physician's Summary (1) (2)
- F. Other (1) (2)

Specify _____

ID No. _____

MORBIDITY AND MORTALITY CLASSIFICATION COMMITTEE DEATH CLASSIFICATION FORM
FULL HHCC REVIEW

Clinic No.					
ID No.					
Form Type	D	M	O	1	

DEATH (calc)

PART I: Identifying Information

1. Patient's NAME CODE:

2. Date of death:

DTIME (calc)
DDAYS (calc)

Month Day Year

Military time: - - : - - (1)
Hours Minutes Unknown

PART II: Death Classification

3. Classification decision (check one):

Final _____ (1)
Pending _____ (2)

If **FINAL**, continue with item 4.
If **PENDING**, skip to Item 12.

4. Was this death observed? --- (1) (2)
Yes No

5. Interval to death from the onset of agonal symptoms (for observed deaths) or from the last time the deceased was seen alive (for unobserved deaths):

(1 hour _____ (1)
> 1 hour but ≤ 24 hours ---- (2)
> 24 hours _____ (3)

6. Complications.

A. Did this death occur as the result of natural causes or as a result of treatment complications (check one)?

Natural causes _____ (1) DCOMP
Complications _____ (2)

If **COMPLICATIONS**, continue with items 6B-6E.
If **NATURAL CAUSES**, skip to item 7.

B. Was this death caused by hemorrhage? _____ (1) (2)
Yes No DHEMORR
HEMDEATH

If **YES**, continue with item 6B1-6B5.
If **NO**, skip to item 6C.

Is this hemorrhagic death attributable to:

Yes No
1. rt-PA _____ (1) (2)
2. Heparin _____ (1) (2)
3. Antiplatelet agents - (1)(2)
4. Oral anticoagulants - (1)(2)
5. Other TIMI II therapies _____ (1) (2)

Specify, _____

C. Did this death occur as a consequence of PTCA? - (1) (2) DPTCA
Yes No

If **YES**, provide date of PTCA associated with death.

Month Day Year

ID No.					
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6. (Continued)

Yes No

D. Did this death occur as a consequence of Coronary Artery Bypass Graft (CABG) Surgery? _____ (1) (2) DCABG

E. Was this death caused by complications other than those of PTCA, CABG surgery, or hemorrhage? _____ (1) (2) DOTHER

Specify complications (e.g., catheter induced aortic dissection, drug reaction, etc.)

7. Did this patient die of cardiovascular disease? _____ (1) (2) DCVD
 Yes No

If YES, continue with item 8.
 If NO, skip to item 10.

8. Cardiovascular disease deaths.

A. Did this patient die of cardiac disease? _____ (1) (2) DCARDIAC
 Yes No

If YES, continue with item 8B.
 If NO, skip to item 9.

B. Did this patient die of acute myocardial infarction? _____ (1) (2)
 Yes No

If YES, continue with items 8B1 and 8B2.
 If NO, skip to Item 8C.

8. (Continued)

B. (Continued)

1. The fatal acute myocardial infarction was:

The TIMI Qualifying myocardial infarction _____ (1)

A recurrent myocardial infarction _____ (2)

Unknown _____ (3)

FITMI

2. When did the myocardial infarction occur?

Before any procedures _____ (1)

After any procedures _____ (2)

No procedures performed _____ (3)

FITTIME

C. The fatal cardiac disease was: (Check all that apply)

Pump failure _____ (1)

Ventricular rupture _____ (1)

Arrhythmia _____ (1)

Other _____ (1)

Specify, _____

DPMP FAIL

DVENTRUP

DARRTH

DOTHCAR

Skip to item 11.

9. Non-cardiac, cardiovascular deaths.

A. In which vascular bed was the fatal event (check one)?

Cerebral _____ (1)

Peripheral _____ (2)

B. Specify the fatal cardiovascular event (e.g., esentric embolism with Infarction, rupture of an aneurysm in the Circle of Willis)

Skip to item 11.

ID No. _____

TIMI PHASE II
INSTRUCTIONS FOR COMPLETING
TIMI FORM 19
LABORATORY DATA FORM

GENERAL INSTRUCTIONS

This form should be completed for all randomized patients. This form is completed to document the CK and hematologic measurements, and medications taken from baseline until hospital discharge. Entries should be made daily.

This form should be submitted to the Coordinating Center in conjunction with the Hospital Discharge Form.

The patient's identification number should appear in the box in the upper right-hand corner of the first page, as well as in the lower right-hand corner of all pages. The clinic number should appear in the upper right-hand corner of the first page.

Please use black ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use abbreviations unless absolutely necessary, and then use only widely recognized abbreviations. A completed copy of this form should be retained for your files.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [*] preceding the item number of the form.

REFER TO PART III ITEMS 4 THROUGH 15, PAGES 2 THROUGH 7

The APTT "Upper Limit Normal" refers to the control value against which the patient's APTTs are to be compared. The "Hospital's Highest" refers to the number of seconds after which the hematology laboratory stops timing the APTT. Record APTT in whole numbers (i.e., ... 042, 043, 044, ...) of seconds. Do not record decimal points for APTT.

Start with calendar Day 1, the day thrombolytic therapy was initiated. Day 1 will usually not cover 24 hours of treatment as therapy usually will have begun after 00:00. Subsequent calendar days will cover 24 hours of therapy each day until the day of the event which will not cover 24 hours of treatment as events will usually not occur at 23:59.

Enter zero for any medication not taken.

Once a day's laboratory data have been completely reported, leave the remaining lines for that day blank. Attach additional pages if necessary.

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION
 LABORATORY DATA FORM

TIMI II Form 19
 Rev 0 03/14/86
 7 Page8

Clinic No.					
ID No.					
Form Type	L	D	O	1	

PART I: Identification

1. Patient's NAME CODE:

2. Date form started:

____/____/____
 Month Day Year

PART II: CK Measurements

3. Upper limit of normal ULCK IU/L

First 24-Hour Period	Protocol Time	Not Done	Month	Date Day	Year	Military Time	Total CK (IU/L)
a.	Retreatment	(1)	CKTIM000				CKTOT000
b.	4 hrs.	(1)	CKTIM004				CKTOT004
c.	8 hrs.	(1)	CKTIM008				CKTOT008
d.	12 hrs.	(1)	CKTIM012				CKTOT012
e.	16 hrs.	(1)	CKTIM016				CKTOT016
f.	20 hrs.	(1)	CKTIM020				CKTOT020
g.	24 hrs.	(1)	CKTIM024				CKTOT024
Second 24-Hour Period							
h.	6 hrs.	(1)	CKTIM030				CKTOT030
i.	12 hrs.	(1)	CKTIM036				CKTOT036
j.	18 hrs.	(1)	CKTIM042				CKTOT042
k.	24 hrs.	(1)	CKTIM048				CKTOT048
l.	Day 3	(1)	CKTIM072				CKTOT072
m.	Day 4	(1)	CKTIM096				CKTOT096
n.	Day 5	(1)	CKTIM120				CKTOT120
o.	Day 6	(1)	CKTIM144				CKTOT144
p.	Day 7	(1)	CKTIM168				CKTOT168
q.	Day 8	(1)	CKTIM192				CKTOT192
r.	Day 9	(1)	CKTIM216				CKTOT216
s.	Day 10	(1)	CKTIM240				CKTOT240

ID No.					
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7. Second day.

Date: _____
 Month Day Year

IVD02

- A. Total Daily Heparin Dose (U USP): HEP19D02 IV (1) Subcu (1)
- B. Total daily aspirin dose: ASA19D02 mg
- C. Total daily coumadin dose: COU19D02 mg
- D. Total daily metoprolol dose (oral) MET19D02 mg
- E. Other beta-blocker (oral) _____ (1) (2) 0BBD02
 Yes No

If **YES**, answer (E1) and (E2).

- (E1) Name _____
- (E2) Total daily dose: _____

	1		2		3		4		5			
	Military Hours	Time Minutes	APTT (seconds)	Not Done	PT/control (seconds)	Not Done	Hemoglobin (gms/dl)	Not Done	Hematocrit %	Not Done	Platelet Count thousands/mm ³	Not Done
F.	_____	_____	_____	(1)	_____/____	(1)	_____	(1)	_____	(1)	_____	(1)
G.	_____	_____	_____	(1)	_____/____	(1)	_____	(1)	_____	(1)	_____	(1)
H.	_____	_____	_____	(1)	_____/____	(1)	_____	(1)	_____	(1)	_____	(1)
I.	_____	_____	_____	(1)	_____/____	(1)	_____	(1)	_____	(1)	_____	(1)
J.	_____	_____	_____	(1)	_____/____	(1)	_____	(1)	_____	(1)	_____	(1)
K.	_____	_____	_____	(1)	_____/____	(1)	_____	(1)	_____	(1)	_____	(1)
L.	_____	_____	_____	(1)	_____/____	(1)	_____	(1)	_____	(1)	_____	(1)
M.	_____	_____	_____	(1)	_____/____	(1)	_____	(1)	_____	(1)	_____	(1)

8. Third day.

Date: _____
 Month Day Year

IVD03

- A. Total Daily Heparin Dose (U USP): HEP19D03 IV (1) Subcu (1)
- B. Total daily aspirin dose: ASA19D03 mg
- C. Total daily coumadin dose: COU19D03 mg
- D. Total daily metoprolol dose (oral) METD03 mg
- E. Other beta-blocker (oral) _____ (1) (2) 0BBD03
 Yes No

If **YES**, answer (E1) and (E2).

- (E1) Name _____
- (E2) Total daily dose: _____

	1		2		3		4		5			
	Military Hours	Time Minutes	APTT (seconds)	Not Done	PT/control (seconds)	Not Done	Hemoglobin (gms/dl)	Not Done	Hematocrit %	Not Done	Platelet Count thousands/mm ³	Not Done
F.	_____	_____	_____	(1)	_____/____	(1)	_____	(1)	_____	(1)	_____	(1)
G.	_____	_____	_____	(1)	_____/____	(1)	_____	(1)	_____	(1)	_____	(1)
H.	_____	_____	_____	(1)	_____/____	(1)	_____	(1)	_____	(1)	_____	(1)

ID No. _____

9. Fourth day. Date: _____
 Month Day Year

IVD04

- A. Total Daily Heparin Dose (U USP): HEP19D04 IV (1) Subcu (1)
- B. Total daily aspirin dose: ASA19D04 mg
- C. Total daily coumadin dose: COU19D04 mg
- D. Total daily metoprolol dose (oral) MET19D04 mg
- E. Other beta-blocker (oral) _____ (1) (2) **0BBD04**
 Yes No

If **YES**, answer **E1** and **E2**.

- E1** Name _____
- E2** Total daily dose: _____

	1	2	3	4	5	
F.	Military Time Hours Minutes	APTT (seconds) Not Done	PT/control (seconds) Not Done	Hemoglobin Not (gms/dl) Done	Hematocrit Not % Done	Platelet Count thousands/a& Not Done
G.	_____	_____ (1)	_____/____ (1)	_____.____ (1)	_____.____ (1)	_____ (1)
H.	_____	_____ (1)	_____/____ (1)	_____.____ (1)	_____.____ (1)	_____ (1)

10. Fifth day. Date: _____
 Month Day Year

IVD05

- A. Total Daily Heparin Dose (U USP): HEP19D05 IV (1) Subcu (1)
- B. Total daily aspirin dose: ASA19D05 mg
- C. Total daily coumadin dose: COU19D05 mg
- D. Total daily metoprolol dose (oral) MET19D05 mg
- E. Other beta-blocker (oral) _____ (1) (2) **0BBD05**
 Yes No

If **YES**, answer **E1** and **E2**.

- E1** Name _____
- E2** Total daily dose: _____

	1	2	3	4	5	
F.	Military Time Hours Minutes	APTT (seconds) Not Done	PT/control (seconds) Not Done	Hemoglobin Not (gms/dl) Done	Hematocrit Not % Done	Platelet Count thousands/a& Not Done
G.	_____	_____ (1)	_____/____ (1)	_____.____ (1)	_____.____ (1)	_____ (1)
H.	_____	_____ (1)	_____/____ (1)	_____.____ (1)	_____.____ (1)	_____ (1)

ID No. _____

11. Sixth day. Date: _____
 Month Day Year

- A. Total Daily Heparin Dose (U USP): HEP19D06 IV (1) Subcu (1)
- B. Total daily aspirin dose: ASA19D06 mg
- C. Total daily coumadin dose: COU19D06 mg
- D. Total daily metoprolol dose (oral) MET19D06 mg
- E. Other beta-blocker (oral) _____ (1) (2) OBBD06
 Yes No

If **YES**, answer (E1) and (E2) .

- (E1) Name _____
- (E2) Total daily dose: _____

	1		2		3		4		5			
	Military Hours	Time Minutes	APTT (seconds)	Not Done	PT/control (seconds)	Not Done	Hemoglobin (gms/dl)	Not Done	Hematocrit %	Not Done	Platelet Count thousands/mm ³	Not Done
F.	_____	: _____	_____	(1)	/ _____	(1)	_____	(1)	_____	(1)	_____	(1)
G.	_____	: _____	_____	(1)	/ _____	(1)	_____	(1)	_____	(1)	_____	(1)
H.	_____	: _____	_____	(1)	/ _____	(1)	_____	(1)	_____	(1)	_____	(1)

12. Seventh day. Date: _____
 Month Day Year

- A. Total Daily Heparin Dose (U USP): HEP19D07 IV (1) Subcu (1)
- B. Total daily aspirin dose: ASA19D07 mg
- C. Total daily coumadin dose: COU19D07 mg
- D. Total daily metoprolol dose (oral) MET19D07 mg
- E. Other beta-blocker (oral) _____ (1) (2) OBBD07
 Yes No

If **YES**, answer (E1) and (E2) .

- (E1) Name _____
- (E2) Total daily dose: _____

	1		2		3		4		5			
	Military Hours	Time Minutes	APTT (seconds)	Not Done	PT/control (seconds)	Not Done	Hemoglobin (gms/dl)	Not Done	Hematocrit %	Not Done	Platelet Count thousands/mm ³	Not Done
F.	_____	: _____	_____	(1)	/ _____	(1)	_____	(1)	_____	(1)	_____	(1)
G.	_____	: _____	_____	(1)	/ _____	(1)	_____	(1)	_____	(1)	_____	(1)
H.	_____	: _____	_____	(1)	/ _____	(1)	_____	(1)	_____	(1)	_____	(1)

ID No. _____

13. Eighth day. Date: _____
 Month Day Year

IV D08
 IV (1) Subcu (1)

- A. Total Daily Heparin Dose (U USP): HEP19 D08
- B. Total daily aspirin dose: ASA19 D08 mg
- C. Total daily coumadin dose: COU19 D08 mg
- D. Total daily metoprolol dose (oral) MET19 D08 mg
- E. Other beta-blocker (oral) _____ (1) (2) OBB D08
 Yes No

If YES, answer (E1) and (E2).

(E1) Name _____

(E2) Total daily dose: _____

	1		2		3		4		5	
	Military Time	APTT	Not	PT/control	Not	Hemoglobin Not	Hematocrit Not	Platelet Count	Not	
	Hours	Minutes	(seconds) Done	(seconds) Done	Done	(gms/dl) Done	% Done	thousands/am3	Done	
F.	_____	_____	_____ (1)	_____/_____	_____ (1)	_____ (1)	_____ (1)	_____	_____ (1)	_____
G.	_____	_____	_____ (1)	_____/_____	_____ (1)	_____ (1)	_____ (1)	_____	_____ (1)	_____
H.	_____	_____	_____ (1)	_____/_____	_____ (1)	_____ (1)	_____ (1)	_____	_____ (1)	_____

14. Ninth day. Date: _____
 Month Day Year

IV D09
 IV (1) Subcu (1)

- A. Total Dally Heparin Dose (U USP): HEP19 D09
- B. Total daily aspirin dose: ASA19 D09 mg
- C. Total daily coumadin dose: COU19 D09 mg
- D. Total daily metoprolol dose (oral) MET19 D09 mg
- E. Other beta-blocker (oral) _____ (1) (2) OBB D09
 Yes No

If YES, answer (E1) and (E2).

(E1) Name _____

(E2) Total daily dose: _____

	1		2		3		4		5	
	Military Time	APTT	Not	PT/control	Not	Hemoglobin Not	Hematocrit Not	Platelet Count	Not	
	Hours	Minutes	(seconds) Done	(seconds) Done	Done	(gms/dl) Done	% Done	thousands/mm ³	Done	
F.	_____	_____	_____ (1)	_____/_____	_____ (1)	_____ (1)	_____ (1)	_____	_____ (1)	_____
G.	_____	_____	_____ (1)	_____/_____	_____ (1)	_____ (1)	_____ (1)	_____	_____ (1)	_____
H.	_____	_____	_____ (1)	_____/_____	_____ (1)	_____ (1)	_____ (1)	_____	_____ (1)	_____

ID No. _____

15. Tenth day. Date: ___ Month ___ Day ___ Year

- A. Total Daily Heparin Dose (U USP): HEPI9D10 IV (1) Subcu (1)
- B. Total daily aspirin dose: ASA19D10 mg
- C. Total daily coumadln dose: COU19D10 mg
- D. Total dally metoprolol dose (oral) MET19D10 mg
- E. Other beta-blocker (oral) (1) (2) OBBD10
 Yes No

If **YES**, answer **E1** and **E2**.

E1 Name _____

E2 Total daily dose: _____

	1		2		3		4		5	
	Military Time	APTT	Not	PT/control	Not	Hemoglobin	Hematocrit	Not	Platelet Count	Not
	Hours	Minutes	(seconds) Done	(seconds) Done	(seconds) Done	(gms/dl) Done	% Done	% Done	thousands/&	Done
F.	___	___	___ (1)	___/___ (1)	___ (1)	___ (1)	___ (1)	___ (1)	___	___ (1)
G.	___	___	___ (1)	___/___ (1)	___ (1)	___ (1)	___ (1)	___ (1)	___	___ (1)
H.	___	___	___ (1)	___/___ (1)	___ (1)	___ (1)	___ (1)	___ (1)	___	___ (1)

PART IV: Administrative Matters

16. Additional pages are included for the following measurements:

- A. CK _____ Yes No
 (1) (2)
- B. Hematologic and medication = (1)(2)

17. Research Nurse/Coordinator:

Signature _____

TIMI Staff No: _____

ID No. _____

TIMI PHASE II
INSTRUCTIONS FOR COMPLETING
TIMI FORM 23
MYOCARDIAL INFARCTION EVENT FORM

GENERAL INSTRUCTIONS

This form should be completed to document myocardial infarction and/or coronary thrombosis events occurring as complications after the course of thrombolytic therapy for TIMI patients and during follow-up. Include details of nonprotocol thrombolytic therapy in the narrative. In addition, complete this form if nonprotocol thrombolytic therapy was administered any time during the initial hospitalization or follow-up. This form is completed in addition to, not in place of a DER and a case report. This form is completed at the Clinical Center. The original of this form is sent to the Coordinating Center as soon as possible upon occurrence of a myocardial infarction and/or coronary thrombosis.

The patient's identification number should appear in the box in the upper right-hand corner of the first page, as well as in the lower right-hand corner of all pages. The clinic number should appear in the upper right-hand corner of the first page.

Please use black ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use abbreviations unless absolutely necessary, and then use only widely recognized abbreviations. A completed copy of this form should be retained for your files.

ITM INSTRUCTIONS: Items with instructions outlined below have the symbol [*] preceding the item number of the form.

REFER TO ITEM 7, PAGE 2

- A) Narrative summary must explicitly present this event with information, from the attending physician. A general hospital discharge summary will not suffice.
- B) Include ECG(s) collected at the time of this event as well as immediately before, and in the course of convalescence if available.

6. Other enzymes: Record highest value associated with this (suspected) myocardial infarct Ion.

	Yes	No	Date			Highest Value	Upper Limits of		Specify Units
			Month	Day	Year		Lab	Normal Range	
A. SGOT _____ (1) (2)									
B. LDH _____ (1) (2)									
C. Other (specify below) _____ (1) (2)									

7. Was nonprotocol thrombolytic therapy administered? _____ (1) (2)
 Yes No

If YES, answer (A) through (C).

- (A) Name _____
- (B) Dosage _____
- (C) Route _____ IC (1) IV (2)

PART IV: Administrative Matters

[*] 8. Were any of the following tests or documents completed in conjunction with this event?

Narrative summary and event ECGs are required for all patients.

- | | | |
|--|-----|----|
| | Yes | No |
| A. Required Narrative Summary _____ (1) (2) | | |
| B. Angiography report (Required if angiography is performed)- (1) (2) | | |
| C. Required ECG(s) _____ (1) (2) | | |
| D. Lab reports of other enzymes (Required if other enzymes are measured) _____ (1) (2) | | |
| Specify _____ | | |

FOR COORDINATING CENTER USE ONLY	
10. Documents received:	
	Yes No
A. Narrative summary _____ (1) (2)	
B. Angiography report -- (1) (2)	
C. ECG(s) _____ (1) (2)	
D. Mher _____ (1) (2)	

9. Research Nurse/Coordinator:

Signature _____

TIMI Staff No: _____

TIMI PHASE II
INSTRUCTIONS FOR COMPLETING
TIMI FORM 24
HEMORRHAGIC EVENT FORM

GENERAL INSTRUCTIONS

This form should be completed to document hemorrhagic events occurring as complications in the course of TIMI therapy. In order to be of sufficient gravity to require completion of this form, these events should be associated with at least one of the following: reduction in heparin dose; transfusion of blood cells; transfusion of clotting factors; transfusion of platelets; treatment with drugs to reverse thrombolytic effects; treatment with drugs to reverse anticoagulant effects; intracranial hemorrhage; gastrointestinal hemorrhage; 3 gm/dl reduction in hemoglobin; or, other life-threatening hemorrhagic event. This form is completed in addition to, not in place of a DER and a case report. This form is completed at the Clinical Center. The original of this form is sent to the Coordinating Center as soon as possible upon occurrence of a hemorrhagic event.

The patient's identification number should appear in the box in the upper right-hand corner of the first page, as well as in the lower right-hand corner of all pages. The clinic number should appear in the upper right-hand corner of the first page.

Please use black ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use abbreviations unless absolutely necessary, and then use only widely recognized abbreviations. A completed copy of this form should be retained for your files.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [*] preceding the item number of the form.

REFER TO ITEM 8B, PAGE 1

Identify only one primary site by number code from item 8A.

REFER TO ITEM 11, PAGE 1

Drugs comprising these specific categories are listed in the Manual of Operations, Chapter 13, Procedures for Completing Study Examinations, Exhibit 13-2, Drug List.

REFER TO ITEM 15, PAGE 2

A narrative summary for this event is required.

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION
 HEMORRHAGIC EVENT FORM

TIMI 11 Form 24
 Rev 1 11/10/86
 2 Pages

Clinic No.	_____
ID No.	_____
Form Type	H M _____

PART I: Event Identification

1. Patient's NAME CODE: _____

2. Date hemorrhage first noted:

 Month Day Year
 Hillitary time: _____ : _____
 Hours Minutes

3. Was heparin either temporarily or permanently discontinued as part of treatment for this event? _____ (1) (2)
 Yes No

4. Weight: _____ kg.

5. Height: _____ cm.

6. Age: _____ years

7. sex: _____ (1) (2)
 Male Female

Part II: Circumstances and Treatment

[*]8A. Site(x) of hemorrhage: Answer each item

- | | Yes | No |
|---------------------------------|-----|-----|
| 1. Gastrointestinal _____ | (1) | (2) |
| 2. Intracranial _____ | (1) | (2) |
| 3. Catheterization site _____ | (1) | (2) |
| 4. Other puncture site(s) _____ | (1) | (2) |
| 5. Genitourinary _____ | (1) | (2) |
| 6. Retroperitoneal _____ | (1) | (2) |
| 7. Other, specify _____ | (1) | (2) |

8. Unknown _____ (1) (2)

- B. 1. Primary site _____
 2. Specify _____

9. Were any of these sites Instrumented (e.g. Foley catheter, cystoscopy, bronchoscopy, N-G tube, etc.)? _____ (1) (2)
 Yes No

If YES, answer A and B.
 If NO, skip to item 10.

A Describe Instrumentation:
 Instrument: _____

B Date applied:

 Month Day Year

10. Number of Punctured vessels and number of bleeding vessels:

	Number Punctured	Number With Major Bleeding
Arteries _____	_____	_____
Veins _____	_____	_____

Explain fully in narrative.

[*]11. In the week prior to this event, the patient received:

- | | Yes | No |
|--|-----|-----|
| Aspirin _____ | (1) | (2) |
| Dipyridamole _____ | (1) | (2) |
| Anticoagulants (other than heparin) _____ | (1) | (2) |
| Platelet active agents (other than aspirin and dipyridamole) _____ | (1) | (2) |

Explain fully in narrative.

ID No.	_____
--------	-------

TIMI PHASE II
INSTRUCTIONS FOR COMPLETING
TIMI FORM 25
CARDIAC SURGERY FORM

GENERAL INSTRUCTIONS

This form should be completed to document coronary artery by-pass graft surgery (**CABG**) performed during the initial hospitalization or during the follow-up period.

The patient's identification number should appear in the box in the upper right-hand corner of the first page, as well as in the lower right-hand corner of all pages. The clinic number should appear in the upper right-hand corner of the first page.

Please use black ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use abbreviations unless absolutely necessary, and then use only widely recognized abbreviations. A completed copy of this form should be retained for your files.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol **[*]** preceding the Item number of the form.

REFER TO ITEM 5B, PAGE 2

Anginal symptoms are divided into four categories of severity according to criteria established by the Canadian Cardiovascular Society.

Class 0: No angina

Class I: "Ordinary physical activity does not cause . . . angina, such as walking and climbing stairs. Angina with strenuous or rapid or prolonged exertion at **work** or recreation."

Class II: "Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal **conditions.**"

Class III: "Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing one flight of stairs in normal conditions and at normal pace. "

Class IV: "Inability to carry on any physical activity without discomfort -- anginal syndrome may be present at rest."

REFER TO ITEM 12, PAGE 3

.. operations report **is** required.

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION
 CARDIAC SURGERY FORM

TIMI 11 Form 25
 Rev 1 11/10/86
 3 Pages

Clinic No.							
ID No.							
Form Type	C	S					

FORM 25 (calc.)

PART I: Event Identification

1. Patient's NAME CODE:

2. Date and time of surgery:

SUAGTIME, SURGTIM2 (calc.)

Month Day Year

Military times: ----- : -----
 Hours Minutes

PART 11: Procedure Notes

3. Medical therapy prior to surgery:

A. Beta-blockers: ----- (1) (2)
 Yes No

If YES, answer 1 through 3.
 If NO, skip to 3R.

- 1 Medication: _____
- 2 Total daily dose: _____ mgs
- 3 Were undesirable side effects present at the maximum dose? --- (1) (2)
 Yes No

3. (Continued)

B. Calcium channel blockers: ----- (1) (2)
 Yes No

If YES, answer 1 through 3.
 If NO, skip to 3C.

- 1 Medication: _____
- 2 Total daily dose: _____ mgs
- 3 Were undesirable side effects present at the maximum dose? --- (1) (2)
 Yes No

C. Nitrates and vasodilators: ----- (1) (2)
 Per NO

If YES, answer 1 through 3.
 If NO, skip to 4.

- 1 Medication: _____
- 2 Total daily dose: _____ mgs
- 3 Were undesirable side effects present at the maximum dose? --- (1) (2)
 Yes No

ID No.							
--------	--	--	--	--	--	--	--

4. Was surgery an emergency or an elective procedure?

SURGERY

Emergency _____ (1)
 Elective _____ (2)

If EMERGENCY, answer A.

(A) What was the indication for the procedure?

Episodic rest or prolonged angina without definite ECG changes _____ (1)

Episodic rest or prolonged angina with ECG changes including ST depression $\geq .1mV$, T wave inversion, pseudonormalization of T waves or transient ST elevation $\geq .1mV$ _____ (2)

Persistent chest pain and new sustained ST elevation $\geq .1mV$ suggestive of reinfarction _____ (3)

Other (specify) _____ (4)

5. Angina status prior to surgery:

ANGSTAT

A. Certainty of diagnosis (check one):

Definite angina _____ (1)
 Probable angina _____ (2)
 Probably not angina _____ (3)
 No angina _____ (4)

If DEFINITE or PROBABLE, answer B through D.
 If PROBABLY NOT OR NO, skip to item 6.

(*) B Canadian Heart Class:

ANGCLASS

0 _____ (0)
 I _____ (1)
 II _____ (2)
 III _____ (3)
 IV _____ (4)

5. (Continued)

(C) Episodic rest or prolonged pain? _____ (1) (2) ANGPAIN
 Yes No

(D) Precipitating factors (check all that apply):

1) Exertion _____ (1)
 2) Emotion _____ (1)
 3) Meals _____ (1)
 4) Cold weather _____ (1)
 5) Intercourse _____ (1)
 6) Sleep _____ (1)
 7) Rest _____ (1)

6. Exercise test done: _____ (1) (2) F25EXER
 Yes No

If YES, answer A through C.
 If NO, skip to 7.

(A) Maximum pulse rate: F25PULSE
 _____ beats/min

(B) Maximum blood pressure (mm Hg):
 1. Systolic F25PRESS
 2. Diastolic _____

(C) Exercise machine (check one):
 Treadmill _____ (1)
 Upright bicycle _____ (2)
 Supine bicycle _____ (3)
 Other, specify _____ (4)

ID No. _____

7. Was coronary angiography performed for this surgery? F25CATH
 (1) (2)
 Yes No

If YES, complete 8 Cardiac Catheterization Form (TIMI Form 7C).

8. Arteries grafted:

	Yes	No	
A. LAD _____	(1)	(2)	} LADGRAFT
B. Diagonal _____	(1)	(2)	
C. Circumflex _____	(1)	(2)	} CXGRAFT
D. Obtuse marginal _____	(1)	(2)	
E. RCA or RPDA _____	(1)	(2)	RCAGRAFT
F. LMCA _____	(1)	(2)	LMCGRAFT

9. Conduits used (check all that apply):

A. Saphenous vein(s) _____ (1) COND SAP

B. Left internal mammary artery _____ (1) CON D LIM

C. Right internal mammary artery _____ (1) CON D R IM

D. Other _____ (1) CON D OTH

Specify _____

10. Did any of the following complications occur within 24 hours after surgery?

	Yes	No	
A. Death _____	(1)	(2)	F25DEATH
B. Nonfatal MI _____	(1)	(2)	F25MI

If YES, complete the appropriate event form.

11. Did the patient receive 8 transfusion of either whole blood or packed cells? _____ (1) (2) F25TRANS
 Yes No

If YES, complete a Transfusion Report Form (TIMI Form 26).

PART III: Administrative Matters

[*]12. Is the required operation report enclosed? _____ (1) (2)
 Yes No

13. Research Nurse/Coordinator:
 Signature _____
 TIMI Staff No: --- - - - -

14. FOR COORDINATING CENTER USE ONLY

Documents received:

	Yes	No
Operation Report _____	(1)	(2)

ID No. _____

TIMI PHASE II
INSTRUCTIONS FOR COMPLETING
TIMI FORM 26
TRANSFUSION REPORT FORM

GENERAL INSTRUCTIONS

This form should be completed to document transfusion of either whole blood or packed red blood cells at any time during the course of the **TIMI** hospitalization. Complete only one form per patient.

The patient's identification number should appear in the box in the upper right-hand **corner** of the first page, as well as in the lower right-hand **corner** of all pages. The clinic number should appear in the upper right-hand corner of the first page.

Please use black ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use abbreviations unless absolutely necessary, and then use only widely recognized abbreviations. A completed copy of this form should be retained for your files.

ITEM INSTRUCTIONS: Items with Instructions outlined below have the symbol **[*]** preceding the Item number of **the** form.

REFER TO ITEM 5, PAGE 1

Record date, time and units for each transfusion of whole blood and/or packed red blood cells.

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION
 TRANSFUSION REPORT FORM

TIMI II Form 26
 Rev 0 11/10/86
 1 Page

Clinic No.					
ID No.					
Form Type	T	F	O	1	

PART I: Event Identification

1. Patient's NAME CODE: _____
2. Date of first transfusion:
 TRANTIME

 Month Day Year

PART II: Reason for Transfusion

3. Reason for transfusion (check all that apply):
- A. Hemorrhagic event _____ (1) F26HEM
 - B. Surgery _____ (1) F26SURG
 - C. Presenting anemia _____ (1) F26ANEM
 - D. Other _____ (1) F26OTH
- Specify _____
4. Products, if YES, specify number of Units: (answer each item)
- | | Yes | No | UNITS |
|-----------------------|-----|-----|--------|
| A. Whole blood _____ | (1) | (2) | F26WBU |
| B. Paaked cells _____ | (1) | (2) | F26PCU |
- TFUNIT (calc.)

[*] 5. Blood transfusion record

	Month	Date		Year	Military Time		Units	
		Day	Year		Hours	Minutes	Whole Blood	Packed Cells
a)	_____	_____	_____	_____	_____	_____	_____	_____
b)	_____	_____	_____	_____	_____	_____	_____	_____
c)	_____	_____	_____	_____	_____	_____	_____	_____
d)	_____	_____	_____	_____	_____	_____	a	_____
e)	_____	_____	_____	_____	_____	_____	*	_____
f)	_____	_____	_____	_____	_____	_____	*	_____
g)	_____	_____	_____	_____	_____	_____	*	_____
h)	_____	_____	_____	_____	_____	_____	*	_____
i)	_____	_____	_____	_____	_____	_____	*	_____
j)	_____	_____	_____	_____	_____	_____	*	_____
k)	_____	_____	_____	_____	_____	_____	*	_____
l)	_____	_____	_____	_____	_____	_____	a	_____
m)	_____	_____	_____	_____	_____	_____	*	_____
n)	_____	_____	_____	_____	_____	_____	*	_____
o)	_____	_____	_____	_____	_____	_____	*	_____

PART III: Administrative Matters

6. Research Nurse/Coordinator:
- Signature _____
- TIMI Staff No: -- _____

ID No.					
--------	--	--	--	--	--

TIM1 PHASE II
INSTRUCTIONS FOR COMPLETING
TIM1 FORM 27
SEVERE NEUROLOGIC EVENT FORM

This form should be completed for all randomized patients with a severe neurological event during the study period. This form should cover the entire period since entry into the study.

If a response needs clarification please make comments identified as to item(s) on a separate sheet of paper. The form and comments will be reviewed on a prearranged telephone call from the Coordinating Center with a **consulting** neurologist either Dr. Dr. Thomas R. Price or Dr. Michael A. Sloan.

The patient's identification number and Form type should appear in the box in the upper right-hand corner of the first page, as well as in the lower right-hand corner of all pages. The clinic number should appear in the upper right-hand corner of the first page.

Please use black ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use abbreviations unless absolutely necessary, and then use only widely recognized abbreviations. A completed copy of this form should be retained for your files.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [*] preceding the item number of the form.

REFER TO ITEM 9. PAGE 2

The patient will be considered to have had a TIA if, in the absence of other specific (contradicting) information, the patient states that a physician has made the diagnosis of transient ischemic attacks (TIA) in the past or if the patient reports a history which meets criteria for **TIA** including duration of event less than 24 hours, focal location within the distribution of a carotid or **vertibro-**basilar system, and absence of other cause for the event.

REFER TO ITEM 11A. PAGE 4

The earliest possible time is the time of onset of the first symptoms or signs compatible with a severe **neurologic** event. This could be headache alone. Usually this will be the time a focal deficit is first noticed. When a patient is asleep or unconscious and awakens with obvious signs of a focal deficit the earliest possible time is the time of loss of consciousness or going to sleep.

(OVER)

REFER TO ITEM 30. PAGE 17

Visual fields are abnormal if there is a homonymous quadratic, unilateral **hemi-**anopic or bilateral hemianopic visual field defect.

REFER TO ITEM 31. PAGE 12

From the best reports charted, identify the type of language deficits. If there is doubt about the type of deficit or the type cannot be determined answer "other."

REFER TO ITEM 37. PAGE 14

Count the total number of each of the imaging studies listed. Non-invasive carotid studies include B mode ultrasound, direct doppler, duplex doppler, **oculoplethysmo-**graphy and periarbital doppler. Enter zero for studies not done.

REFER TO ITEM 38. PAGE 14

The dates and times in Item **38A-F** should be in chronological order. After the last study (MRI or CT), leave lines blank.

REFER TO ITEM 42. PAGE 15

Rapid onset refers to severe **neurologic** events with time from onset to maximum deficit of 10 minutes or less (same as for sudden in Item 13, page 5).

REFER TO ITEM 43. PAGE 16

Loss of consciousness is present for any patients who are less than alert (any category other than alert -- see Item 22, page 8).

(OVER)

SEVERE NEUROLOGIC EVENT FORM

Clinic No.						
ID No.						
Form Type	S	N	O	1		

Identifying Information

- Patient's NAME CODE:
- Date of event:
 Month Day Year

PART 11: Prior Conditions

- Handedness:
 - Right (1)
 - Left (2)
 - Ambidextrous or switched (3)
 - Unknown (4)
- Has this patient ever been treated for or diagnosed to have cancer? (1) (2) (3)
 Yes No Unknown

If **NO** or **UNKNOWN**, skip to item 5.

A. If **YES**, specify type of cancer: _____

- Is there evidence of central nervous system infection, brain tumor, trauma or metabolic condition (such as uremic coma) existing prior to or at the time of the neurologic event contributing to the neurologic symptoms or signs? (1) (2)
 Yes No

If **YES**, specify: _____

ID No.						
--------	--	--	--	--	--	--

6. What was this patient's average daily alcohol consumption prior to entry into **TIMI**?

ALCOH

- \leq 1 oz (1)
- 2-3 oz (2)
- 4-5 oz (3)
- \geq 6 oz (4)
- Unknown (5)

7. Past history of migraines? (1) (2) (3)
 Yes No Unknown

a. Past history of seizures? (1) (2) (3)
 Yes No Unknown

* 9. A. Has the patient ever had a **TIA**? (1) (2) (3)
 Yes No Unknown

If **NO** or **UNKNOWN**, skip to item 10.

B. How long ago was the most recent episode?

- 1 - 7 days ago (1)
- a - 30 days ago (2)
- 1 - 6 months ago (3)
- Over 6 months ago (4)
- Unknown (5)

C. Total number of **TIAs**?

- One (1)
- 2 - 5 (2)
- 6 - 50 (3)
- > 50 (4)
- Unknown (5)

ID No. | | | | | | | |

* 9. (Continued)

D. Vascular territory of past **TIAs**: (check all that apply)

- 1. Right carotid (1)
- 2. Left carotid (1)
- 3. Vertebral-basilar (1)
- 4. Multiple territories (1)
- 5. unknown (1)

E. Prior **TIA** in **same** territory as present

neurologic signs and symptoms? ----- (1) (2) (3)
 Yes No **Unknown**

10. A. Has the patient ever had a stroke

before this event? (1) (2) (3)
 Yes No **Unknown**

If **NO** or **UNKNOWN**, skip to item 11.

B. How long ago?

- 1 - 7 days ago (1)
- 8 - 30 days ago (2)
- 1 - 6 months ago (3)
- Over 6 months ago** (4)
- Unknown** (5)

C. Number of strokes?

- One** (1)
- 2 - 5** (2)
- > 5** (3)
- Unknown** (4)

D. **Type of strokes**: (check all that apply)

- 1. **Embolic** (1)
- 2. **Ischemic** (1)
- 3. **Intracerebral hemorrhage** (1)
- 4. **Subarachnoid hemorrhage** (1)
- 5. **Unknown** (1)

ID No. | | | | | | | | | |

16. Was documented change in blood pressure a possible precipitator of this event? ----- (1) (2) (3) *Item 6*
 Yes No Unknown .

If **YES**, answer items A and B.
 If **NO** or **UNKNOWN**, skip to item 17.

	Yes	No	Unknown
A. Hypotension -----	(1)	(2)	(3) <i>Item 6A</i>
B. Hypertension -----	(1)	(2)	(3) <i>Item 6B</i>

17. Medications

A. Had this patient taken antiplatelet agents within 48 hours of the event? ----- (1) (2) (3) *Item 17A*
 Yes No Unknown

If **YES**, answer items A1 and A2.
 If **NO** or **UNKNOWN**, skip to item 17B.

A1. Agent: _____

A2. Total daily dose: ----- - - - mg

B. Had this patient taken calcium channel blockers within 24 hours of the event? ----- (1) (2) (3) *Item 17B*
 Yes No Unknown

If **YES**, answer items B1 and B2.
 If **NO** or **UNKNOWN**, skip to item 17C.

B1. Agent: _____

B2. Total daily dose: ----- - - - mg

ID No. | | | | | | |

18. (Continued)

C. Within four hours of the event did the patient experience arrhythmias (e.g., ventricular tachycardia, **atrial** fibrillation, etc.) causing reduced cardiac output? ----- (1) (2) (3) *Item 18c*
 Yes No Unknown

If **YES**, answer items C1.
 If **NO** or **UNKNOWN**, skip to item 19.

C1. Specify any arrhythmias:

PART IV: Examination

19. Verbal response (aphasics may be untestable):

Oriented and converses appropriately ----- (1) *Item 19*
 Disoriented and/or confused ----- (2)
 Inappropriate words ----- (3)
 Incomprehensible sounds ----- (4)
None ----- (5)
 Untested ----- (6)

20. Eye opening:

Spontaneous ----- (1) *Item 20*
To speech ----- (2)
To pain ----- (3)
None ----- (4)
Untested ----- (5)

ID No.		H			H
--------	--	---	--	--	---

"21. Motor response:

- Obeys (1)
- Localizes (2)
- Withdraws (3)
- Abnormal **flexion** (4)
- Abnormal extension (5)
- None (6)
- Untested (7)

170m2

22. Degree of alertness:

- Alert (1)
- Lethargic or drowsy (2)
- Stupor** (3)
- Coma** (4)

23. A. Remainder of **neurologic exam**:

- Normal (1)
- Abnormal, focal or **lateralizing** (2)
- Abnormal, multifocal (3)
- unknown (4)

If NORMAL or UNKNOWN, skip to 24

*B. Related to current event? ----- (1) (2) (3)
 Yes No Unknown

24. Weakness:

- None (1)
- Left hemiparesis (2)
- Right hemiparesis (3)
- Bilateral hemiparesis (4)
- unknown (5)

If NONE OR UNKNOWN, skip to 25.

*A. Related to current event? ----- (1) (2) (5)
 Yes No Unknown

ID No. | | | | | | | |

25. Is one muscle group weaker than the others? ----- (1) (2) (3)
Yes No Unknown

If **YES**, answer A and B.
If **NO** or **UNKNOWN**, skip to item 26.

A. Severity:

Slight ----- (1)
Moderate ----- (2)
Marked ----- (3)

B. Most affected muscle group: _____

26. Ataxia:

Absent ----- (1)
Left sided ----- (2)
Right sided ----- (3)
Both sides ----- (4)
Unknown ----- (5)

If **ABSENT** or **UNKNOWN**, skip to 27.

*A. Related to present event? (1) (2) (3)
Yes No Unknown

27. Extraocular movements:

Normal ----- (1)
Abnormal ----- (2)
Untested ----- (3)

If **NORMAL** or **UNTESTED**, skip to 28.

A. Gaze abnormalities: _____

*B. Related to present event? (1) (2) (3)
Yes No Unknown

ID No. | | | | | | | |

*30. Visual fields:

Normal (1)
Abnormal (2)
Untested (3)

If **NORMAL** or **UNTESTED**, skip to 31.

A. **Visual** field abnormality: _____

*B. Related to present event? ----- (1) (2) (3)
Yes No Unknown

*31. A. Language:

Normal (1)
Broca (2)
Wernicke (3)
Global (4)
Anomic (5)
Other (6)
unknown (7)

*B. Related to present event? ----- (1) (2) (3)
Yes No Unknown

32. Dysarthria:

Absent (1)
Present (2)
Unknown (3)

If **ABSENT** or **UNKNOWN**, skip to 33.

*A. Related to present event? ----- (1) (2) (3)
Yes No Unknown

ID No. | | | | | | | |

PART V: Central Nervous System (CNS) Imaging Studies

*37. Number of CNS imaging studies:

- A. Computer Assisted Tomography (CT) -----
- B. Magnetic resonance (MRI) -----
- C. Non-invasive carotid studies -----
- D. Cerebral angiography -----
- E. Other, specify -----

*38. Timing of CT at MRI studies?

	Month	Day	Year	24 Hour Clock	Study	
					MRI	CT
A.	___	___	___	___ : ___	(1)	(2)
B.	___	___	___	___ : ___	(1)	(2)
C.	___	___	___	___ : ___	(1)	(2)
D.	___	___	___	___ : ___	(1)	(2)
E.	___	___	___	___ . ___	(1)	(2)
F.	___	___	___	___ : ___	(1)	(2)

39. Was there marked clinical deterioration or exacerbation of symptoms between any two CT or MRI studies? (1) (2)
 Yes No

If **YES**, answer 40.
 If **NO**, skip to 41.

ID No. | | | | | | | |

40. Between which two studies did the patient experience the morbid determination?

- A-B (1)
- B-C (2)
- C-D (3)
- D-E (4)
- E-F (5)

PART VI: Final Summary.

Taking into account all of the available information, is there evidence of:

Yes No Unknown

- 41. A deficit that lasted more than 24 hours or until death intervened? (1) (2) (3)
- *42. Rapid onset? (1) (2) (3)
- *43. Loss of consciousness? (1) (2) (3)
- 44. Focal brain deficit due to this event? ----- (1) (2) (3)

If **YES**, answer A through I.
 If **NO** or **UNKNOWN**, skip to 45.

ID No.					
--------	--	--	--	--	--

44. (Continued)

	Yes	No	Unknown
*A. Lacunar in type?	(1)	(2)	(3)

If NO , skip to 44B.

(1) Pure motor hemiparesis	(1)	(2)	(3)
(2) Pure sensory	(1)	(2)	(3)
(3) Dysarthria clumsy hand	(1)	(2)	(3)
(4) Ataxic hemiparesis	(1)	(2)	(3)
(5) Other, specify	(1)	(2)	(3)

B. **Sensory** motor only?

C. Hemichorea?

D. Aphasia only?

E. Visual field defect only?

F. Other hemisphere deficit, specify

G. Bilateral brainstem-cerebellar?

H. Unilateral brainstem-cerebellar (not
lacunar)?

I. **Other, specify**

45. Lumbar puncture evidence of hemorrhage? ---- (1) (2) (3) (4)
Yes No Unknown Not Done

ID No.			H				H	
--------	--	--	---	--	--	--	---	--

- | | Yes | No | Unknown | Not Done |
|--|-------|-------|---------|----------|
| 50. Surgical evidence of stroke? ----- | (1) | (2) | (3) | (4) |
| 51. For deaths, autopsy evidence of stroke? ---- | (1) | (2) | (3) | (4) |

If neither 50 nor 51 **YES**, skip to 52.

- | | Yes | No | Unknown |
|--------------------------------------|-------|-------|---------|
| A. Subarachnoid hemorrhage ----- | (1) | (2) | (3) |
| B. Intraparenchymal hemorrhage ----- | (1) | (2) | (3) |
| C. Ischemic stroke ----- | (1) | (2) | (3) |

If **NO** or **UNKNOWN**, skip to 52.

- | | | | |
|---------------------------|-------|-------|-------|
| (1) Lacuna ----- | (1) | (2) | (3) |
| (2) Embolic ----- | (1) | (2) | (3) |
| (3) Atherosclerotic ----- | (1) | (2) | (3) |
| (4) Other ----- | (1) | (2) | (3) |

52. Death occurred within 24 hours of event? ----- (1) (2) (3)

53. Recovery:

- | | | |
|--------------------------------------|-------|--------------|
| Full, no deficit ----- | (1) | <i>Items</i> |
| Partial, minor residual ----- | (2) | |
| Partial, major residual ----- | (3) | |
| Comatose ----- | (4) | |
| Deceased ----- | (5) | |

ID No. | | | | | | | |

SEVERE **NEUROLOGIC** EVENT CLASSIFICATION FORM

STHEAT (case)

Clinic	No.	111-1	
I.D.	No.	111-	1-1
Form	Type	1	1

PART I: Identifying Information

1. Patient's NAME CODE:

2. Date of event: F28DATE
 Month Day Year

3. Was this a severe neurologic event?
- | | Yes | No |
|-------------------------------------|-----|------------|
| A. Infarction | (1) | (2) ITEM3A |
| B. Hemorrhage | (1) | (2) ITEM3B |
| C. Transient ischemic attack | (1) | (2) ITEM3C |
| D. Other | (1) | (2) ITEM3D |
| E. No severe neurologic event | (1) | (2) ITEM3 |

If NO SEVERE NEUROLOGIC EVENT, skip to item 12.

PART II: Location

4. Cerebral Site Codes:
- | | | |
|--|---------|--------|
| A. Primary | — — | ITEM4A |
| B. Other | — — | ITEM4B |
| C. Other | — — | ITEM4C |
| D. Other | — — | ITEM4D |
| E. Other | - - | ITEM4E |
| F. Are more than five cerebral sites involved? | (1) (2) | ITEM4F |
| | Yes No | |

I.D. No.	1	1	1	1	1	1	1
----------	---	---	---	---	---	---	---

9. Extension(s) of hemorrhage:

	Yes	No	
A. Subdural	(1)	(2)	ITEM 9A
B. Parenchymatous	(1)	(2)	ITEM 9B
C. Subarachnoid space	(1)	(2)	ITEM 9C
D. Epidural space	(1)	(2)	ITEM 9D
E. None	(1)	(2)	ITEM 9E

10. Did hemorrhage occur in an infarct? (1) (2) ITEM 10

11. Casual factors:

	Primary	Secondary	Not at all	
A. t-PA	(1)	(2)	(3)	ITEM 11A
B. Heparin controlled according to PTT	(1)	(2)	(3)	ITEM 11B
C. Heparin not documented to be controlled according to PTT	(1)	(2)	(3)	ITEM 11C
D. Coumadin controlled according to PT	(1)	(2)	(3)	ITEM 11D
E. Coumadin not documented to be controlled according to PT	(1)	(2)	(3)	ITEM 11E
F. Embolism	(1)	(2)	(3)	ITEM 11F
G. Hypotension	(1)	(2)	(3)	ITEM 11G
H. Hypertension	(1)	(2)	(3)	ITEM 11H
I. Trauma	(1)	(2)	(3)	ITEM 11I
J. Aortic balloon pump	(1)	(2)	(3)	ITEM 11J

I.D. No.				-			-		
----------	--	--	--	---	--	--	---	--	--

11. (Continued)

	Primary	Secondary	Not at all	
K. PTCA	(1)	(2)	(3)	ITEMI1K
L. Surgery	(1)	(2)	(3)	ITEMI1L
L1. Specify _____				
M. Vascular malformation	(1)	(2)	(3)	ITEMI1M
M1. Specify _____				
N. Other	(1)	(2)	(3)	ITEMI1N
N1. Specify _____				

12. Reasons for classification:

A. Rationale _____

B. Other Comments _____

PART III: Administration

13. Date form completed - - - - -
Month Day Year

14. Signature of neurologist: _____

I.D. No.		-			-			-	
----------	--	---	--	--	---	--	--	---	--

TIMI PHASE II
INSTRUCTIONS FOR COMPLETING
TIMI FORM 40
ONE YEAR TREADMILL EXERCISE TEST

GENERAL INSTRUCTIONS

This form should be completed to document the One Year Treadmill Test.

The patient's identification number should appear in the box in the upper right-hand corner of the first page, as well as in the lower right-hand corner of all pages. The clinic number should appear in the upper right-hand corner of the first page.

Please use black ink to complete this form. For items which cannot be answered by a check mark (✓), PRINT clearly all responses in the spaces provided. Do not use **abbreviations** unless absolutely necessary, and then use only widely recognized **abbreviations**. A **completed** copy of this form should be retained for your **files**.

REFER TO ITEMS 27 AND 28, PAGE 4

TIMI Phase II One Year Exercise Treadmill Test response categories:

Bruce Stage	a	85 X HR	ECG Changes	Angina	Exercise Response
< 2	Yes		Marked	Yes	Severe
< 2	Yes		Moderate	Yes	Severe
< 2	Yes	5	Marked	No	Severe
< 2	Yes		Moderate	No	Ischemic
< 2	Yes		No	Yes	Severe
< 2	Yes		No	No	Normal
< 2	No		Marked	Yes	Severe
< 2	No		Moderate	Yes	Severe
< 2	No		Marked	No	Severe
< 2	No		Moderate	No	Ischemic
< 2	No		No	Yes	Severe
< 2	No		No	No	Non Diag
> 3	Yes		Marked	Yes	Ischemic
1 3	Yes		Moderate	Yes	Ischemic
> 3	Yes		Marked	No	Ischemic
> 3	Yes		Moderate	No	Ischemic
> 3	Yes		No	Yes	Ischemic
> 3	Yes		No	No	Normal
> 3	No		Marked	Yes	Ischemic
> 3	No		Moderate	Yes	Ischemic
> 3	No		Marked	No	Ischemic
> 3	No		Moderate	No	Ischemic
1 3	No		No	Yes	Ischemic
> 3	No		No	No	Normal

A. Moderate ECG changes (any one of 3 criteria)

1. **STD** \geq 1 mm horizontal or down sloping
2. **STD** \geq 1.5 upsloping
3. **STE** \geq 1 in non Q only if **Bruce Stage** \geq 3

B. Marked ECG changes (any one of 3 criteria)

1. **STD** \geq 1.5 horizontal or down sloping
2. **STD** \geq 2.0 upsloping
3. **STE** \geq 1 in non Q If **Bruce Stage** \leq 2

(OVER)

6. Is the patient taking any of the following cardiovascular medications?
- | | Yes | No |
|---|-------|-------|
| A. Nitrates (within two hours) _____ | (1) | (2) |
| B. Beta-blockers (within 24 hours) _____ | (1) | (2) |
| C. Calcium blockers (within 24 hours) _____ | (1) | (2) |
| D. Antiarrhythmics (within 24 hours) _____ | (1) | (2) |
| E. Diuretics (within 12 hours) _____ | (1) | (2) |
| F. Digitalis (within seven days) _____ | (1) | (2) |

7. Total treadmill time: 71 min 45 sec
_____ secs.

8. Final stage entered (check one): F5 STAGE YR
- | | |
|-----------|------|
| 0 _____ | (01) |
| 1/2 _____ | (02) |
| I _____ | (03) |
| II _____ | (04) |
| III _____ | (05) |
| IV _____ | (06) |
| V _____ | (07) |
| VI _____ | (08) |
| VII _____ | (09) |

9. Percent maximum heart rate achieved: 95%
_____ %

10. Vital signs at:

- A. Rest: 95 HR YR 120/80/60 YR / 120/80/60 YR
Heart Rate Systolic BP Diastolic BP
- B. Peak exercise: 160 HR YR 160/90/60 YR, 160/90/60 YR
Heart Rate Systolic BP Diastolic BP
- C. Three minutes recovery: 100 HR YR 120/80/60 YR, 120/80/60 YR
Heart Rate Systolic BP Diastolic BP

11. Did chest pain occur during ETT? EXPLAIN YR
_____ (1) (2)
Yes No

If YES, answer item (12).
If NO, skip to item 13.

(1) Type of chest pain: PAIN YR
Angina _____ (1)
Atypical chest pain _____ (2)

13. Did a fall in the systolic blood pressure occur during exercise? SBP DEC YR
_____ (1) (2)
Yes No

If YES, answer item (14).
If NO, skip to item 15.

(14) By how much? 60 BPM CH YR
_____ mmHg

15. Did the resting ECC show any of the following:

- | | Yes | No |
|--|-------|-------|
| A. LBBB _____ | (1) | (2) |
| B. RBBB _____ | (1) | (2) |
| C. LVH _____ | (1) | (2) |
| D. ST-segment elevation (> 1 mm) _____ | (1) | (2) |

16. Was there abnormal ST-segment depression at rest? RST STD Y
_____ (1) (2)
Yes No

If YES, answer item (17).
If NO, skip to item 18.

(17) How much? _____ mm 60 BPM CH YR

ID No. _____

18. Did **ischemic** ST-segment depression (≥ 1 mm below baseline) occur during or following exercise? _____ (1) (2) **EXSTDYR**
 Yes No

If **YES**, answer items (19) through (21). If **NO**, skip to Item 22.

(19) Maximum depth (below baseline) and configuration of **ischemic** ST-segment depression:
 (1 = upsloping, 2 = horizontal, 3 = downsloping)

		Depth	Configuration (1, 2, or 3)
A. During exercise	_____	<u>EXSTDYR</u> mm	<u>EXCFYR</u>
B. During recovery	_____	<u>RCSTDYR</u> mm	<u>RECCFYR</u>

(20) Exercise stage at the onset of ischemic (≥ 1 mm) ST-segment depression (0-7): _____ ONSTBYR

(21) Number of leads with **ischemic** (≥ 1 mm) ST-segment depression: _____ STOLDYR

22. Did ST-segment elevation (≥ 1 mm above baseline) occur during or following exercise? _____ (1) (2) **EXSTEYR**
 Yes No

If **YES**, answer item (23). If **NO**, skip to item 24.

(23) If **YES**, what was the maximum ST-segment elevation according to the following?

A. Q-wave lead	_____	<u>STEQYR</u> mm
B. Non Q-wave lead	_____	<u>STENQYR</u> mm

24. Did any of the following arrhythmias occur during the study? (Check all that apply)

	None	Rest	Exercise	Recovery
A. Isolated ($< 10/\text{min}$) PVCs	(1)	(1)	(1)	(1)
B. Frequent ($\geq 10/\text{min}$) PVCs	(1)	(1)	(1)	(1)
C. Ventricular couplets	(1)	(1)	(1)	(1)
D. Ventricular tachycardia	(1)	(1)	(1)	(1)

25. Borg **Scale** Level of Perceived Exertion: _____

26. Is this test part of an exercise thallium study? _____ (1) (2)
 Yes No

ID No. _____

[*] 27. Did the patient experience an ischemic response? _____ (1) (2)
 Yes No

[*] 28. Did the patient experience a severe ischemic response? - (1) (2)
 Yes No

29. Were angiography performed? - (1) (2)
 Yes No

If YES, answer (A) and complete Follow-up Cardiac Catheterization Procedures Form (TIMI Form 7C).

If NO, and item 28 is YES answer item 30.

If NO and item 28 is No, skip to item 31.

(A) Date of angiography:

____ Month ____ Day ____ Year

Skip to item 31.

30. Reason one year cardiac catheterization following severe ischemic response was not performed (check one):

Exercise treadmill test performed prior to June 1988 -- (1)

Prior catheterization performed within past 3 months _____ (2)

Patient refused _____ (3)

Specify _____

Physician refused _____ (4)

Specify _____

Other _____ (5)

Specify _____

If reason 2 is checked answer (A) and complete Follow-up Cardiac Catheterization Procedures Form (TIMI Form 7C).

(A) Date of prior procedure:

____ Month ____ Day ____ Year

[*] 31. Required ECGs are attached:

	Yes	Not Available
A. Rest _____	(1)	(2)
B. Exercise _____	(1)	(2)
C. Recovery _____	(1)	(2)

32. Research Nurse/Coordinator:

Signature _____

TIMI Staff No: _____

COORDINATING CENTER USE ONLY

33. Required ECGs:

	Yes	No
A. Rest _____	(1)	(2)
B. Exercise _____	(1)	(2)
C. Recovery _____	(1)	(2)

RESULT/R (calc.)

ID No. _____

TIMI PHASE II
 THROMBOLYSIS IN MYOCARDIAL INFARCTION

TIMI II Form 41
 Rev 1 12/07/88
 1 Page

TREADMILL EXERCISE TEST NON-PERFORMANCE FORM

Clinic No.					
ID No.					
Form Type	N	T	O	1	

1. Patient's NAME CODE: _____ m m - - -

2. Date of one year contact: _____ - Month - Day - Year -

3. Reason for not performing treadmill exercise test.

F41PEAS

- Patient hat resting angina _____ (01)
- Other cardiac disease reasons (CABG, CHF, etc.) _____ (02)
- Peripheral vascular disease _____ (03)
- Musculoskelctal reasons (amputation, leg problem, back problem, arthritis) _____ (04)
- Patient refused (unwilling, uncooperative, missed appointment) _____ (05)
- Moved or lost to follow-up _____ (06)
- Treadmill exercise test performed within past 3 months _____ (07)
- Different txtrclst test performed (not a Bruce Protocol Study) _____ (08)
- Physician refusal _____ (09)
- Protocol violation (physician oversight) _____ (10)
- No funds for payment of procedure _____ (11)
- Other _____ (12)

Sptclfy _____

4. Research Nurse/Coordinator

Signature _____

TIMI Staff No: _____

TIMI PHASE II
THROMBOLYSIS IN MYOCARDIAL INFARCTION

TIMI II Form 43
Rev 2 08/12/87
2 Pages

NONFATAL MYOCARDIAL INFARCTION EVENT CLASSIFICATION FORM
FULL MYCC REVIEW

Clinic No.					
ID No.					
Form Type	R	C			

PART I: Reocclusion Identification

1. Patient's NAME CODE: _____

2. Date of reported event: MIDATE/MIDATEZ/MIDATE 3 (calc)

 Month Day Year

Military time -- _____ : _____ (1)
 Hours Minutes Unknown

PART II: Event Classification

3. Classification decision (check one):

Final _____ (1)
 Pending _____ (2)

If **FINAL**, continue with item 4.

If **PENDING**, skip to Item 10.

4. Timing of event since rt-PA initiation:

< 18 hours _____ (1)
 > 18 hours _____ (2) *F43TIME*

If < 18 hours answer item 5.

If > 18 hours answer item 6.

5. MMCC classification for event < 18 hours:

	Newly Occuring	Markedly Worse	No
A. Did the patient meet chest pain criteria? _____	(1)	(2)	(3)
B. Did the patient meet enzyme criteria? _____		(1)	(2)
C. Did the patient meet ECC criteria? _____		(1)	(2)
D. Classification of event:			4
Nonfatal myocardial infarction _____			(1)
Recurrent ischemic event _____			(2)
No recurrent ischemia _____			(3)

MMCCMI (calc)

Skip to item 7.

6. MMCC classification for event > 18 hours: *FATALMI I*
NONFATAL I'

A. Is this reported event a nonfatal myocardial infarction? (check one) _____ (1) (2)
 Yes No *MITYPE (calc)*

B. Nonfatal myocardial infarction classification criteria fulfilled:

	Yes	No
1. Enzyme _____	(1)	(2)
2. ECC _____	(1)	(2)

7. HMCC Chairman's brief descriptions:

A. Was this assignment decided by Committee vote? _____ (1) (2)
 Yes No

B. Reason(s) this event came to the full committee:

C. Reason(s) for final classification:

ID No.					
Form Type	R	C			

8. Were the contents of the narrative letter revealed to the committee? _____ (1) (2)
 Yes No

If YES, answer Item 9.
 If NO, skip to Item 11.

9. Did this letter reveal treatment assignment? _____ (1) (2)
 Yes No

Skip to item 11.

10. Specify information required for full committee to complete classification:

- | | Yes | No |
|---------------------------|-------|-------|
| A. Enzymes _____ | (1) | (2) |
| B. ECG(s) _____ | (1) | (2) |
| C. Narrative letter _____ | (1) | (2) |
| D. Other _____ | (1) | (2) |

State what additional information is required e.g., ECG dates and times; enzyme assay dates, times and upper limits of normal; etc.

PART III: Administrative Matters

11. MMCC Chairman's Signature:

12. Data form completed:

 Month Day Year

CC USE ONLY

13. Basis for Form 43 Status:
 Full MMCC _____ (1)
 Two Reviewers Congruent _____ (2)

ID No.							
Form Type	R	C					

THROMBOLYSIS IN MYOCARDIAL INFARCTION
HEMORRHAGIC EVENT CLASSIFICATION FORM

Clinic No.					
ID No.					
Form Type	H	C			

PART I: Event Identification

1. Patient's NAME CODE: _____

2. Date hemorrhagic event occurred:
HEMTIME (calc) HEMTIMEI - 9
Month Day Year

Military time: _____ : _____
Hours Minutes

5. (Continued)

0. Contributing (check all that apply):

- 1. Gastrointestinal _____ (1)
- 2. Intracranial _____ (1)
- 3. Catheterization site _____ (1)
- 4. Other puncture site(s) _____ (1)
- 5. Genitourinary _____ (1)
- 6. Retroperitoneal _____ (1)
- 7. Other, specify _____ (1)

PART II: Event Classification

3. Classification decision (check one):

- Final _____ (1)
- Pending _____ (2)

If **FINAL**, answer item 4.
If **PENDING**, skip to Part III.

4. Severity HEMSEVI HEMSEV9

A. Bleeding associated with TIMI procedures or therapy (check one):

- Major _____ (1)
- Minor _____ (2) HEMSEV (calc)
- None _____ (3) SEV TOT 1-4 (calc)
- Loss with no clinically detectable site _____ (4)

If MAJOR or MINOR, answer items 4B, 5 through 8.
If NONE or LOSS WITH NO CLINICALLY DETECTABLE SITE, skip to Part III.

B. Was total blood loss associated with surgical therapy for this event (e.g., coronary artery by-pass grafting, abdominal surgery, etc.)? Yes No
--- (,) (2)

5. Location

A. Primary (check one): HEMPRIMI - 9

- Coronary _____ (1) HEMPRIM (calc)
- Intracranial _____ (2)
- Catheterization site _____ (3)
- Other puncture site(s) _____ (4)
- Genitourinary _____ (5)
- Retroperitoneal _____ (6)
- Other, specify _____ (7)

Unknown _____ (8)

8. Unknown _____ (1)

6. Inducement to bleeding:

- Spontaneous _____ (1)
- Nonspontaneous _____ (2)

7. APTT results:

- A. Number of APTT measurements greater than 2 1/2 times normal prior to hemorrhagic event _____
- B. Number of APTT measurements made prior to hemorrhagic event _____

8. Timing:

Did this event start less than 24 hours after study therapy? LT24 1-9
- (1) (2)
Yea No

PART III: Administrative Matters

9. HERC Chairman:

Signature _____

10. Date form completed:

Month Day Year

11. Additional Information requested? - (1) (2)
Yea No

If YES, specify _____

CC USE ONLY

- 12. Basis for Form 44 Status: Full HERC _____ (1)
- Two Reviewers Congruent _____ (2)