TIM1 PHASE II FORMS*

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

October 11, 1988

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	Docunentaticn of Loss of RT-PA	Rev 0 08/13/86 (Not keyed)
5G	TA04	Dccunentation of Use of Back-up Mailer	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)

orm Number	Form Type	Title	Status
		A. FORMS CDMPLETED 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 Docunentaticn 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 Docwntation	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 Revieuer 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

TIM1 PHASE II

INSTRUCTIONS FOR COMPLETING
TIM1 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 symptans.

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 ECG taken in either the TIMI Clinical Center or referral center.

(OVER)

TIMI PHASE II

THROMBOLYSIS IN YYOCARDIAL INFARCTION
SCREENING FORM

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

Clinic No.												
ID No.												
Form Type	S	C	0	1								

PART I: Visit Identification

1. Patient's NAME CODE:

\- - - - -

2. Screening date:

Month ___ Day ___ Year ___

[*] 3. Time of qualifylng ECG: ERTIME (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

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

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

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

(A) Time of onset of pain: ONTIME (calc)

Data: ___ ONMO Month - ONDA Day - ONYR Year

Military time: ___ ONHR hours : ONMN minutes

TWOHRS (calc)

(B) Will the time be no greater than 4 hours from onset of pain to treatment? ___ (1)(STOP)
Yes No

[*]10. Does an ECC reveal ST segment elevation of at least 0.1mV? ___ (1)(STOP)
ves No

If YES, answer (A) through (E).
If NO, skip to item 11.

NSTE (calc)

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

STEII II (1)	STEV1 V1 (1)	STEV4 V4 (1)	STEI I (1)
STEIII III (1)	STEV2 V2 (1)	STEV5 V5 (1)	STEAVL aVL (1)
STEAVF aVF (1)	STEV3 V3 (1)	STEV6 V6 (1)	STEAVR aVR (1)

(B) Is ST segment elevation present in at least two of the three inferior leads (II, III, aVF)? ___ STEINF (1) (2)
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) Yes (2) No STEANT

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

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) Yes (2) No QWAVES

If YES, answer A.
If NO, skip to Item 12. NQ (calc.)

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

QII II (1)	V_1 (1) QV1	V_4 (1) QV4	I (1) QI
QIII III (1)	V_2 (1) QV2	V_5 (1) QV5	aVL (1) QAVL
QAVF aVF (1)	V_3 (1) QV3	V_6 (1) QV6	aVR (1) QAVR

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

If YES, answer A.
If NO, skip to item 13. NSTD (calc)

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

STDII II (1)	V_1 (1) STDV1	V_4 (1) STDV4	I (1) STDI
STDIII III (1)	V_2 (1) STDV2	V_5 (1) STDV5	aVL (1) STDAVL
STDAVF aVF (1)	V_3 (1) STDV3	V_6 (1) STDV6	aVR (1) STDAVR

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 **signif-icant** gastrointestinal bleeding? ———	(INEL)	(2)
G.	Current oral anticoagulant therapy? ———	(INEL)	(2)
H	Prosthetic heart valve? ———	(INEL)	(2)
I.	Uncontrolled hyper-tension 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 **throm-**bolytlc agent for myocardlal 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 VIII.

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

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 wfth 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) BBINELE

F. Implanted pacemaker? _____ (NOBB)(2) BBINELF

G. Asthma by history, wheezing by physical examination, or chronic obstructive pulmonary disease requiring chronic therapy with corticosterolds or 2 stimulants? _____ (NOBB)(2) BBINELG

[*]16. Are any Ineligible conditions for immediate Intravenous beta-blockers checked? _____ (NOBB)(2) BBINELI

Yes No

PART V: Risk Determination HIGHRISK Calc

17. History of previous MI? _____ (1) (2) BLMI

Yes No

18. Rales which do not clear on coughing: _____ (1) (2) BLRALES

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. Atria1 **fibrillation** or flutter? ——— (1) Yes (2) No BLAF

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) Yes (2) No BLPE

22. Cardlogenlc shock? **(Systolic** blood pressure **<85 mmHg** Interpreted as left ventricular dysfunction **with** evidence of **diminished** tissue **perfusion** on initial evaluation) ——— (1) Yes (2) No BLSHOCK

PART VI: Consent

COMPLETE ONLY **FOR** ELIGIBLE **PATIENTS**

23. Does the patient's physician consent to randomlxatfon of the patient Into the **TIMI** Study? ——— (1) **Yes** (REFUSE) No

If **YES, skip to item** 24.
If **NO,** answer (A) 0 .

(A) Explain ———

Skip to **item** 25.

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

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

(A) Explain ———

PART VII: Administrative **Matters**

[*] 25. Was this patient randomized? ——— (1) Yes (2) No

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

26 0 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 ———

Skip to item **29.**

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

27. Is the qualifying ECG being sent with this form? (1) Yes (2) No

28. Did the TIMI physician have a follow-up conference with this patient to review the nature and purpose, possible benefits, and possible risks of the study procedures and drugs? (1) Yes (2) No

29. Patient Hospital Chart Number:

30. Person assessing eligibility of patient:

Name:

TIMI Staff No: - - - - -

[*]31. Where was the qualifying ECG obtained? WHEREECG

TIMI Clinical Center (1)

Emergency room extension (2)

Specify

32. Research Nurse/Coordinator:

Signature:

TIMI Staff No: - - - - - -

33. FOR CC USE ONLY		
A. ECG	(1) Yes	(2) No

ID No.

Rev 0 03/14/86

TIMI PHASE II

INSTRUCTIONS FOR COMPLETING
TIM1 FORM 04
ADMISSION FORM

GENERAL INSTRUCTIONS

This form should be completed for all randomized patfents. 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 ldentlflcatlon 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 retalned 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 myocardlal 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

TIM1 PHASE II

THROMBOLYSIS IN MYOCARDIAL INFARCTION

ADMISSION FORM

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

Clinic No.			H								
ID No.			H							H	
Form Type	A	D	0	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) Yes (2) No SMOKE

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) Yes (2) No CURSMOKE

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.			H							H	

PART III: Present Illness

THE FOLLOWING QUESTIONS PERTAIN TO THIS QUALIFYING EPISODE.

6. What was the activity at onset of pain? ACTONSET

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

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

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): OTHERISD

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)

weeks g the three to the qualifying ANG3WK (calc.) PATT3WK (calc)

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

9. Has the patient experienced previous cheat pain or anglna? CHSTPAIN — (1) Yes (2) No

If YES, answer (A).

If NO, skip to Item 10.

(A) Angina classification: BLANGIN A (calc)

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

If DEFINITE or PROBABLE answer (B).

If PROBABLY NOT or MOT skip to Item 10.

(B) Date of onset of angina: ANGONSET

- ≤ 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)

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) Definite (2) No (3) Suspect (4) Unknown

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	Unknown
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: ____ - ____ - ____ (1)
Month Day Year Unknown

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

	Definitt	No	Suspect	Unknown	
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 claudlcatlon	(1)	(2)	(3)	(4)	BLIC

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

	Yes	No	Unknown	
A. Diabetes mellitus	(1)	(2)	(3)	BLDIAB
B. Hyptrttnslon	(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)	BLOCD
Specify ____				
F. Gastrointestinal disease	(1)	(2)	(3)	BLGI
G. Htmatologlcal disease	(1)	(2)	(3)	BLHMD
H. Renal disease	(1)	(2)	(3)	BLRENAL
I. Ntutologlcal disease	(1)	(2)	(3)	BLNEURO
J. Other significant disease	(1)	(2)	(3)	BLOTHDIS
Specify ____				

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

	Yes	No	Unknown
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-sating nitrates end oral vasodilators	(1)	(2)	(1) BLRXA	(2)	(3)
B. Short-acting nitrates	(1)	(2)	(1) BLRXB	(2)	(3)
C1. Metoprolol	(1)	(2)	(1) BLRXC1	(2)	(3)
C2. Other beta-blockers	(1)	(2)	(1) BLRXC2	(2)	(3)
(C3) Name(s)					
D. Calcium channel blockers	(1)	(2)	(1) BLRXD	(2)	(3)
(D) name(s)					
E. Antlarrhythmlcs (other than bate&lockers or calcium channel blockers)	(1)	(2)	(1) BLRXE	(2)	(3)
F. Intravenous inotropic agents or pressor agents	(1)	(2)	(1) BLRXF	(2)	(3)
G. Cardiac glycosldes and oral inotropic agents	(1)	(2)	(1) BLRXG	(2)	(3)
H. Diuretics	(1)	(2)	(1) BLRXH	(2)	(3)
I. Intravenous vasodilators	(1)	(2)	(1) BLRXI	(2)	(3)
J. Antihypertensives (other than diuretics and beta-blockers)	(1)	(2)	(1) BLRXJ	(2)	(3)
K. Aspirin	(1)	(2)	(1) BLRXK	(2)	(3)
L. Dipyridamole	(1)	(2)	(1) BLRXL	(2)	(3)
M. Platelet active agents (other than aspirin and dipyridamole)	(1)	(2)	(1) BLRXM	(2)	(3)
N. Methyl xanthines	(1)	(2)	(1) BLRXN	(2)	(3)
O. Heparin	(1)	(2)	(1) BLRXO	(2)	(3)
P. Anticoagulants (other than heparin)	(1)	(2)	(1) BLRXP	(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. Heert rate ——— BLHR beats/minute

19. Respiratory rate BLRESP ___ respirations/min.

20. Blood pressure: (First *recording* taken at the time of screening for eligibility)

A. Systolic ——— BLSBP ___ mm Hg

B. Diastolic ——— BLDBP ___ mm Hg

		Pre-sent	Ab-sent	Un-known	
21.	Abnormal neck vein distension	(1)	(2)	(3)	BLNKVEIN
22.	Heart sounds:				
A.	S_3	(1)	(2)	(3)	BLS3
B.	S_4	(1)	(2)	(3)	BLS4
C.	Pericardial friction rub	(1)	(2)	(3)	BLPFR
D.	Murmurs	(1)	(2)	(3)	BLMURMUR

If PRESENT, answer (D1).

If ABSENT or UNKNOWN, skip to item 23.

22. (Continued)

D. (Continued)

(D1) 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) BLOTHMUR

Specify ___

		Pre-sent	Ab-sent	
23.	Integument:			
A.	Ecchymosis ———	(1)	(2)	BLECCHY
B.	Hematoma ———	(1)	(2)	BLHEMA

24. Were other significant findings present? ——— (1) Yes (2) No

If YES. specify ___

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

PART VII: Local Laboratory Data

LABORATORY MEASUREMENTS At TIME OF SCREENING FOR ELIGIBILITY

		Not Available
25.	Creatinine ——— BLCREAT ___ . ___ mg/dl	(1)
26.	BUN ——— BLBUN ___ ___ ☐ Ifd1	(1)
27.	Tot81 bilirubin ——— BLBILI ___ . ___ s mg/dl	(1)
28.	SGOT ——— BLSGOT ___ ___ ___ IU/L	(1)
29.	LDH ——— BLLDH ___ ___ ___ run	(1)
30.	Alkaline phosphatase ——— BLALKPHS ___ ___ ___ IU/L	(1)
31.	Hematocrit ——— BLHCT ___ ___ %	(1)
32.	Hemoglobin ——— BLHGB ___ ___ gms/dl	(1)
33.	White blood cell count BLWBC ___ ___ . ___ thousands/mm3	(1)
34.	Potassium ——— BLK ___ . ___ ☐ Eq/L	(1)
35.	Plrtelet count	
	A. BLPLAT ___ ___ ___ ___ thousands/mm3	(1)
	Only • nauer B if A not available	
	B. Adequate on smear ———	(1) Yes (2) No (3) Unknown

		Present	Absent	Unknown
36.	Urine protein ——— BLUPROT	(1)	(2)	(3)
37.	Urine occult blood ——— BLOCCBLD	(1)	(2)	(3)
38.	Stool guiaic ——— BLGUIAIC	(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
TIM1 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 Coordlnat **ing** 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

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

THROMBOLYSIS IN MYOCARDIAL INFARCTION TREATMENT ASSIGNMENT FORM

ICL
ICL3

Clinic No.			H									CHECK
ID No.			H								H	
Form Type	T	A	0	1								

PART I: Identification

1. Patient's NAME CODE:

_ _ _ _ _

2. Screening dater

_ _ - _ _ - _ _
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): ASSIGN

A. PTCA timing study:

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

PTCAGRP(calc)
BBGRP(calc)

5. (Continued)

B. Beta-blocker study:

1. Beta-blocker eligible:

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

Immediate beta-blooker and no PTCA _____ (05)

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

Deferred beta-blooker and no PTCA _____ to7)

2. Beta-blocker ineligible:

18-48 hour PTCA _____ (08)
No PTCA _____ to9)

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.			H								H	

DOSEASGN (calc.)

7. **rt-PA treatment**

A. **Dose:** ——— ATPADOSE ___ ___ ___ mg

B. **If less than protocol specifieddose given, check primary reason:** ATPAREASN

- Urticaria ——— (01)
- Fever of chill8 ——— (02)
- Nausea or vomiting ——— (03)
- Bleeding at • rteri81 access ——— (04)
- Bleeding et central vein access ——— (05)
- Bleedingat other puncture sites ——— (06)

  Specify site:

  ———

- Other bleeding ——— (07)

  Specify sitar

  ———

- Convulsions ——— (08)
- Anaphylaxis ——— (09)
- Hypotension ——— (10)
- Bronchospasm ——— (11)
- Death ——— (12)
- Other (specify below) ——— (13)

  ———

8. **Was intravenous metoprolol therapy initiated?** ——— (1) Yes (2) No IVMET

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.

9. **Metoprolol treatment**

A. **Intravenous dose** ——— IVDOSE ___ ___ mg

B. **If less than protocol specified** do88 given, cheek **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 bloak ——— (1)
5. 3° heart block ——— (1)
6. Worsening dyspnea ——— (1)
7. Cal4 sweats ——— (1)
8. Wheezing ——— (1)
9. Rales • xteedlng > 1/3 t h way t h e fields ——— (1)
10. Chestray f i n d i n g 8 of pulmonary edema ——— (1)
11. Death ——— (1)
12. Other(specify below) ——— (1)

    ———

C. Oral dose during first 24 hours ——— ORALDOSE ___ ___ ___ mg

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

9. (Continued)

D. It oral metoprolol less than protoool specified dosegiven, 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 ● xtmdlng >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: HEPBOL( ), DATE HEPBTIME (calc) MILITARY TIME : DOSE (USP)

[*]11. rt-PA treatment initiation: ——— SAME DATE (1) TIMO TIDA TIYR TIHR : TIMI

[*]12. Intravenous beta-blocker initiation: ——— NOT GIVEN (1) IVBB( ) IVBTIME(calc) : (1)

[*]13. Oral beta-blocker initiation: ——— (1) ORALBBOS( ) ORBOTIME(calc) : (1)

[*]14. Continuous heparin infusion (start): ——— (1) HEPINF( ) HEPITIME(calc) : RATE (USP/hr)

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

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

ID No.

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

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

18 **Cavllcstlonsr (cheek one for • seh item)**

	did not occur	occurred but did not Interrupt rt-PA trestmnt	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 st central vein access**	(1)	(2)	(3) CompE
F. **Bleeding st other puncture sltss**	(1)	(2)	(3) CompF
Specify site:			
G. **Other bleeding**	(1)	(2)	(3) CompG
Specify slter			
H. **Convulsions**	(1)	(2)	(3) CompH
I. Ansphylsrls	(1)	(2)	(3) CompI
J. **Hypotension**	(1)	(2)	(3) CompJ
K. **Bronchospasm**	(1)	(2)	(3) CompK
L. Desth	(1)	(2)	(3) CompL
M. **Other**	(1)	(2)	(3) CompM
Speolfy:			

19 **Was rt-PA treetment restsrted?** (1) Yes (2) (3) No Not Stopped

20. **Hemodynamic measurements :**

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

ID No.

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

	Ye3	No	Time from rt-PA treatment initiation 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 ● bnormalitira	RPEVD (1)	(2)	RPEVD MIN (Calc)
E. **Appearance of new a rrhythmias** or **conduction disturbances**	RPEVE (1)	(2)	RPEVE MIN (Calc)
F. **Resolution** of **arrhythmias** or condwtlon **distrubances**	RPEVF (1)	(2)	RPEVF MIN (calc)
G. **Decreased** blood **pressure** or **clinical signs** of **reduced perfusion**	RPEVG (I)	(2)	RPEVG MIN (calc)
H. **Increased** blood **pressure or clinical signs** of **increased** perfusion	RPEVH (1)	(2)	RPEVH MIN (calc)

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

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

(23) **Indicate type** and **appearance** of ● rrhythf4ies. ● xoluding **catheter-induced arrhythmias.** (**check** all that apply.)

	1 None	2 **Prior to thrombolytic** therapy	3 During thrombolytio therapy	4 **Number** of **minutes after onset of thrombolytic therapy**	5 After completion of **thrombolytic** therapy
A. Ventricular **tachycardia** (≥ 3 beat8 **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. Acoeleratad **idioventricular rhythm,** rate < 100	ARRG1 (1)	ARRG2 (1)	ARRG3 (1)	ARRG4	ARRG5 (1)
Ii. **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) Yes (2) No

PAINRE

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) Yes (2) No

PAININIT

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

PAINCONC

E. **Pain at conclusion Of therapy compared to pain at initiation Of therapy:**

PAINCOMP

- Increased — (1)
- Decreased but still present — (2)
- Same — (3)
- None — (4)

, 25. **Was than evidence of coronary thrombosis Or myocardial infarction within the first 24 hours after initiation of TIMI treatment?** — (1) Yes (2) 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 • lov8tod	(1)	(2)	(3)

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

PART III: Administrative Matters.

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

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

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		
	Ye8	NO
A. ECG	(1)	(2)

ID No. | | | | | | | |

TIHI PHASE II

INSTRUCTIONS FOR COMPLETING TIMI FORH 06 PTCA PROCEDURES FORM

GENERAL INSTRUCTIONS·

This form should be completed to document all PTCA procedures lnaludlng those rqulred by protocol, emergency or elective during the initial hospitalization or during the follow-up period. Balloon inflation must be doaumented angiographically at least once. *Either* 8 Form 06 or 8 Form 6B la rqulred for all patients assigned to PTCA. Complete Form 06 if the rqulred PTCA was performed *or* complete Form 6B if the rqulred 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, 88 well as in the lower right-hand corner of all pages. The cllnlo number should appear in the upper.right-hand corner of the first page.

Please use black ink to Complete this form. For item8 which cannot be answered by 8 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 filer.

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

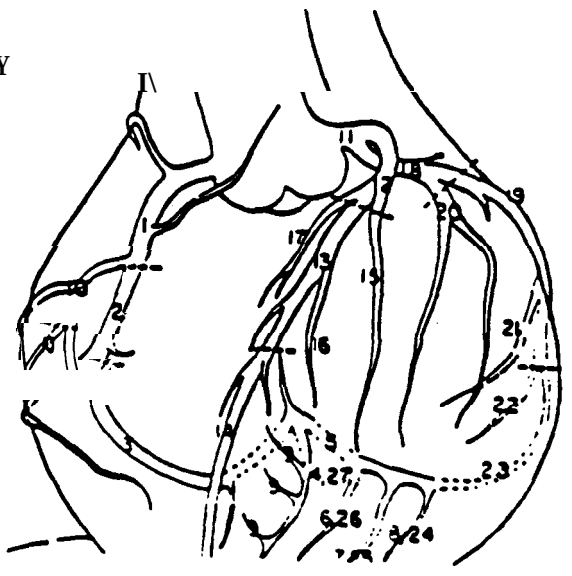
REFER TO ITEM 8B, PAGE 2

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. Dlst CX
20. 1st Ob Warg
21. 2nd Ob Harg
22. 3rd Ob Marg
23. L AV
24. 1st LPL
25. 2nd LPL
26. 3rd LPL
27. LPDA

(OVER)

TIM1 FORM 06 INSTRUCTION PAGE

Rev 1 10/08/86

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 perfuslon grade 2 Improves to 3
  or perfusion grade 3 remains 3
- b) . Post-PTCA ≥ 20% decrease In stenosis
  . and perfusion grade 2 remains 2

Ho Improvement - All Others, e.g.

- a) . Post PT'CA perfuslon 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 thrombolytlc 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 thrombolytlc agents other than rt-PA to treat TIM1 II patients is not permitted under Protocol.

TIMI PHASE II

THROMBOLYSIS IN MYOCARDIAL INFARCTION
PTCA PROCEDURES FORM

TIMI IS Form 06
Rev 1 05/28/86
5 Pages

Clinic No.											
ID No.											
Form Type	P	P									

F06P/F06NP
PTCASTAT (calc)

PART I: Identification

1. Patient's NAME CODE:

\- - - - -

2. Date and time of PTCA: F6TIMEP/F6TIMENP (calc.)

Month Day Year

Military time ____ hours : minutes

3. PTCA type:

Protocol PTCA ——— (1) F06P
Non Protocol PTCA ——— (2) F06NP

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? PTCAEENP

Emergency ——— (1)
Elective ——— (2)

(5) What was the indication for performing PTCA? REASONNP

Ischemia post infarction ——— (1)
Re-infarction post infarction — (2)
Other ——— (3)
Specify ———

PART 11: Procedure Notes

6. Was PTCA attempted at the site of the presumed occlusion or stenosis responsible For the infarction? SITE1P/SITE1N ——— (1) Yes (2) No

7. Was PTCA attempted at other lesion sites? SITE2P/SITE2NP ——— (1) Yes (2) No

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) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No
[*]B. Site Code	L18BP/L18BNP			
C. Branch vessel Involved	L18CP/L18CNP (1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No
D. Lesion discrete	L18DP/L18DNP (1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No
E. Lesion eccentric	L18EP/L18ENP (1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No
F. Lesion calcified	L18FP/L18FNP (1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No
[*]G. Perfusion grade pre-PTCA	L18GP/L18GNP			
H. Distal embolization during PTCA	L18HP/L18HNP (1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No
I. Dissection during PTCA	L18IP/L18INP (1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No
J. Intimal tear, flap or fissure post-PTCA	L18JP/L18JNP (1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No
K. Thrombosis past-PTCA	L18KP/L18KNP (1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) No	(1) Yes (2) 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 (1) Not Done	(1) Not Done	(1) Not Done	(1) Not Done
P. Gradient post-PICA (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) Full (2) Partial (3) None	(1) Full (2) Partial (3) None	(1) Full (2) Partial (3) None	(1) Full (2) Partial (3) None
T. Total inflation time	L18TP/L18TNP sec.	sec.	sec.	sec.
U. Number of different dilation catheters used:	L18UP/L18UNP			
V. Largest balloon size	L1MMP/L1MMNP mm	mm	mm	mm
W. Number of inflations	L1INP/L1INNP			
8. Maximum duration	L1SCP/L1SCNP sec.	sec.	sec.	sec.
b. Maximum pressure	L1ATP/L1ATNP atm.	atm.	atm.	atm.

9. Did PTCA result in any of the following acute complications: (answer a ach item)

	Yes	No
A. Emergency coronary artery bypass surgery	COMPAP/COMPANP[*] (1)	(2)
B. Development of total occlusion of infarct artery	COMPBP/COMPBNP (1)	(2)
C. Development of total occlusion of branch of infarct-related artery	COMPCP/COMPCNP (1)	(2)
D. Development of total occlusion of other major artery	COMPDP/COMPDNP (1)	(2)
E. Totally occluded embolization of branches or distal artery	COMPEP/COMPENP (1)	(2)
F. Re-infarction	COMPFP/COMPFNP (1)	(2)
G. Death	COMPGP/COMPGNP (1)	(2)
H. Other	COMPHP/COMPHNP (1)	(2)

Specify: _____

10. What was the total elapsed fluoroscopy time? FTIMEP/FTIMEN minutes

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

If YES OTHER PTCA, answer (A) through (E).
If YES 2 HR PTCA 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.)

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

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) Yea (2) No

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

(1) Medication: _____

(2) Total daily dose:

____ ____ ____ ____ mga

(3) Were undesirable side effects present at the maximum dose? ——(1) Yes (2) No

B. Calcium channel blockers ——— (1) Yea (2) No

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

(1) Medication: _____

(2) Total daily dose:

____ ____ ____ ____ mgs

(3) Were undesirable side effects present at the maximum dose? ——(1) Yes (2) No

13. (Continued)

C. Nitrates and vasodi-Latora ——— (1) Yea (2) No

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

(1) Medication: _____

(2) Total daily dose:

____ ____ ____ ____ mgs

(3) Were undesirable aide effects present at the maximum dose? -- (1) Yea (2) No

14. Angina status prior to PTCA:

A. Certainity of diagnosis (check one): ANGINAP

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? EPISODNP (1) Yes (2) 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)

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

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

(A) Maximum pulse: _ _ _ **beats/min**

0B **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) Yes (2) No

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

PART IV: Administrative Matters

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

18. **PICA Physician:**

Signature _____

TIMI Staff No: _ _ _ _ _ _ _

19. Research **Nurse/Coordinator:**

Signature _____

TIMI Staff No: _ _ _ _ _ _ _

20. FOR CC USE

Documents received:

PTCA Qeport (1) **Yes** (2) **No**

ID No.								
Form Type	P	P						

TIMI PHASE II

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

THROMBOLYSIS IN MYOCARDIAL INFARCTION
CARDIAC CATHETERIZATION PROCEDURES FORM

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:** CATHTIME/CTIMEHD/CTIMENP

__ __ - __ __ - __ __
Month Day Year

Military time ____ __ __ : __ __
hours minutes

3. **Sequence number:** _____ __

4. **Report for:** FTC/FTCHD/FTCNP

Protocol PTCA cath _____ (1)
Protocol predischarge 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 nonpotoool cardiac catheterization?** NPREASON

A. **Ischemia post infarction** ____ (1)

B. **Re-infarction poet infarction** _____ (2)

C. **Other** _____ (3)

Specify _____

PART II: Hemodynamics

[*] 6. **Left ventricular pressure:**

A. **Peak systolic** ___ LVPSBPP/LVPSBPHD/LVPSBPN ___ ___ ___ mm Hg

B. **End diastolic** ___ LVEDBPP/LVEDBPHD/LVEDBPN ___ ___ ___ mm Hg

Aortic pressure:

C. **Systolic** ____ ASBP/ASBPHD/ASBPNP ___ ___ ___ mm Hg

D. **Diastolic** ____ ADBP/ADBPHD/ADBPNP ___ ___ ___ mm Hg

ID No.									
Form Type	C	C							

PART III: Procedure Note8

7. **Sequence of ● gloq8m8:** (indicate the order of the following procedures enter 1,2, or 3: enter 0 if not don..)

   A. Ventriculography ——— ___
   8. 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) Yes (2) NO

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

[*]11. **When was sheath removed?**

A. **Date:**

___ ___ Month ___ ___ Day ___ ___ Year (1) Not Removed

B. **Time:** ——— ___ ___ hours : ___ ___ minutes

PART IV: Complications Of Angiography

12. **Were there any complications during ● giogrrPhY?** ——— (1) Yes (2) No F7CCOMP/F7CHDC/F7CNPC

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

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

		Yes	No	
A.	Arterial thrombosis?	(1)	(2)	F7CCOMPA/F7CHDCA/F7CNPCA
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/F7CNAC
E.	Was surgery performed for the vascular complication?	(1)	(2)	F7CCOMPE/F7CHDC F7CNPC

(14) **Was catheterization complicated by 8 new occlusion of 8 coronary artery or branch vessel?** ——— (1) Yes (2) No F7COCC/F7CHDOC F7CNPOC

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

ID No.	
Form Type	C C

14 (Continued)

Coronery occlusion vex due to thefollowing:

		Yes	No
A	Coronery thrombosis?	(1)	(2)
B	Coronary dissection?	(1)	(2)
C	Embolization of clot?	(1)	(2)

F7COCCA/F7CHDOCA/F7CNPOCA
F7COCCB/F7CHDOCB/F7CNPOCB
F7COCCC/F7CHDOCC/F7CNPOCC

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

Which artery?

		Yea	No
C1	Left main	(1)	(2)
C2	LAD	(1 X	2)
C3	Circumflex	(1)	(2)
C0	RCA	(1)	(2)

15 Were there catheter induced arrhythmias requiring
- leatrfcxl cardioversion
or defibrillation? (1) (2)
Yes No

F7CARR/F7CHDARR/F7CNPARR

16 Clinical complications of
- nglogrephy: (answer each item)

		Yes	No	
A.	Pulmonary edema	(1)	(2)	F7CPE/F7CHDPE/F7CNPPE
B.	Hypotenaion	(1)	(2)	F7CHPO/F7CHDPO/F7CNPPO
C.	Cardiac arrest	(1)	(2)	F7CCA/F7CHDCA/F7CNPCA
D.	Anaphylaxis due to oontrut	(1)	(2)	F7CANA/F7CHDANA/F7CNPANA

PART v: Administrative Hatters

17. Angiographer:

Signature _____

TIMI Staff No: — _ _ - _ _ _

18. Research Nurse/Coordinator:

Signature _____

TIMI Staff No: — _ _ - _ _ _

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.			H							
ID No.			H						H	
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 predischarge cath ____ (2)
Nonprotocol cath _____ (3)

If Protocol cath skip to item 6.

If Nonprotocol 08th answer item (5).

(5) What was th8 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

[8] 6. Left ventricular pressure:

A. Peak systolic ____ LVPSBP1/LVPSBP2/LVPSI mm Hg

B. End diastolic ____ LVEDBP1/LVEDBP2/LVED mm Hg

Aortic pressure:

C. Systolic _____ ASBP1/ASBP2/ASBP3 mm Hg

D. Diastolic _____ ADBP1/ADBP2/ADBP3 mm Hg

ID No.										H
Form Type	C	C								

PART III: Procedure Note.

7. Sequenoe of ● ngioqamar (indicate the order of the following procedure8 enter 1, 2, or 3; enter 0 if not don..)

A. Ventriculography ——— ___

B. Non-infarct artery ——— ___

C. Infarct artery ——— ___

8. Angiographers ● sreaament:

[*]A. Perfuaion 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. WasPTCA performed? ——— (1) Yea (2) No

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

[*]11. When was rheeth removed?

A. Date:

___ Month — ___ Day — ___ Year — (1) Not Removed

B. Time: ——— ___ hours : ___ minutes

PART IV: Complications of Angiography

12. Were there any complications during angiography? ——— (1) Ye. (2) No F7CCOMP1/F7CCOMP2/F7CCOMP

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

13. Vascularcoronarycom-plications: (answer item)

	Yes	No
A. Arterial thrombosis?	(1)	(2)
B. Arterial dissection?	(1)	(2)
C. Arterial embolus?	(1)	(2)

F7CCMPA1/F7CCMPA2/F7CCMPA3
F7CCMPB1/F7CCMPB2/F7CCMPB3
F7CCMPC1/F7CCMPC2/F7CCMPC3

D. Did arterial embolus rexult in stroke or central nervous system event? ——— (1) (2) F7CCMPD1/F7CCMPD2/F7CCMPD3

E. Was surgery performed for the vascular compli-cation? ——— (1) (2) F7CCMPE1/F7CCMPE2/F7CCMPE3

14. Was catheterization compli-cated by . new occlusion of a coronary artery or branch vessel? ——— (1) Yes (2) No F7CCCC1/F7CCCC2/F7CCCC3

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

ID No.								
Form Type	C	C						

14 (Continued)

Coronary occlusion was duo to thr following:

		Yes	No	
A	Coronary thrombosis?	(1)	(2)	F7C0CCA1/F7C0CCA2/F7C0CCA3
B	Coronary dissection?	(1)	(2)	F7C0CCB1/F7C0CCB2/F7C0CCB3
C	Embolization of clot?	(1)	(2)	F7C0CCC1/F7C0CCC2/F7C0CCC3

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

Which artery?

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

15 Were there catheter induced arrhythmias requiring electrical cardioversion or defibrillation? (1) Yes (2) No F7CARR1/F7CARR2/F7CARR3

16 Clinical complications of angiography: (answer each item)

		Yes	No	
A.	Pulmonary edema	(1)	(2)	F7CPE1/F7CPE2/F7CPE3
B.	Hypotension	(1)	(2)	F7CHP01/F7CHP02/F7CHP03
C.	Cardiac arrest	(1)	(2)	F7CCA1/F7CCA2/F7CCA3
D.	Anaphylaxis due to contrast	(1)	(2)	F7CANA1/F7CANA2/F7CANA3

PART v: Administrative Matters

17. Angiographer:

Signature _____

TIMI Staff No: -- _____ - - - -

18. Research Nurse/Coordinator:

Signature _____

TIMI Staff No: ___ ___ - ___ ___ ___

ID No.									
Form Type	C	C							

TIMI PHASE II
CORONARY ARTERIOGRAPHY VISUAL ASSESSMENT

TIMI II Form 7F
Rev 4 09/02/87

1. Patient's NAME CODE: _ _ _ _ _

Clinic No.											
ID No.											
Form Type	A	V	O								

F7F/F7FHD/F7FNP
F7F1/F7F2/F7F3

2. Date of arteriography: _ _ - _ _ - _ _ (Month - Day - Year)

3. Sequence: _ _

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

5. Quality: _

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

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

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

STENRCA (calc.)
STENLMCA
STENLAD (calc.)
STENCX (calc)

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

29. Anterior Infarct	_	Yes (1)
30. Inferior (or other) Inhrot	_	(1)

8.

	Lesion 1 Yes No	Lesion 2 Yes No	Lesion 3 Yes No	Lesion 4 Yes No
A. Suitable? _	(1) (2)	(1) (2)	(1) (2)	(1) (2)
If No why? Reason 1 _	_ _	_ _	_ _	_ _
If lb 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 _				
1. Pre Stenosis _	PREST/STENHD/STENNP	_ _ _	_ _ _	_ _ _
Pre grade _	PREGR/GRADEHD/GRADENP	_	_	_
2. Post Stenosis _	POSTST	_ _ _	_ _ _	_ _ _
Post grade _	POSTGR	_	_	_

F7FPRES1/F7FPRES2/F7FPRES3
F7FPREG1/F7FPREG2/F7FPREG3
F7FPST&1/F7FPST&2/F7FPST&3
F7FPSTG1/F7FPSTG2/F7FPSTG3

SUCCESS (calc

E. Complications of angioplasty:

	Lesion 1 Yes No	Lesion 2 Yes No	Lesion 3 Yes No	Lesion 4 Yes No
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)

	Lesion 1 Full Part No	Lesion 2 Full Part No	Lesion 3 Full Part No	Lesion 4 Full Part No
1. Initially successful?	(1) (2) (3)	(1) (2) (3)	(1) (2) (3)	(1) (2) (3)
	Yes No	Yes No	Yes No	Yes No
2. Reocclusion _	(1) (2)	(1) (2)	(1) (2)	(1) (2)

G. Observations:

	Lesion 1 Yes No	Lesion 2 Yes No	Lesion 3 Yes No	Lesion 4 Yes No
1. Hazey 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

RADIONUCLIDE SHIPPING RECORD
REST/EXERCISE RVG

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

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):

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

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

If NO, answer (A) and (B).

The rest portion should be performed even if the patient is not able to exorcise.

RESTHD/REST6W

	Not Done	Done
(A) Rest	(1)	(2)

If Rot Done, Reason Not Done

EXERHD/EXER6W

	Not Done	Done
(B) Exercise	(1)	(2)

If Not Done, Reason Not Done

5. Tim ot injection ot stannous pyrophosphate: _ _ : _ _
hours minutes

6. Time ot injection ot ^{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 end 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	___	___	___	___	___	___	___
EXERCISE (2min acquisitions)								
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. We8 there patient motion that interfered with the study? (1) Yea (2) No

If YES, answer (A).

(A) Which views? (cheek ● ll that apply) :

Rest

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

If XERCISE, • nswer (B).

(B) Stage number ___

29. Were there labeling difficulties? (1) Ye8 (2) No

If YES, answer (A).

(A) Specify

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

If YES, answer (A).

(A) Specify

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

If YES, answer (A).

(A) Specify

32. Exercise performed for - minutes ___ STAGEHD/ to stage ___ STAGE6W

33. Exercise ECG results: MUGAHD/MUGA6W

Positive (1)
Negetlve (2)
Indeterminate (3)

EXPAINHD/EXPAIN6W

34. Chest pain (1) Yes (2) 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

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

ID No.									
Form Type	R	S							

TIMI PHASE II

THROMBOLYSIS IN MYOCARDIAL INFARCTION

TIMI II Form 8C
Rev 1 08/08/86
2 Pages

RADIONUCLIDE DATA ANALYSIS REPORT
RESTING RVG

Clinic No.														
ID No.														
Form Type	R	D												

PART I: Visit Identification

1. Patient's NAME CODE:

_ _ _ _ _

2. Date of study:

__ __ Month __ __ Day __ __ Year

3. RV sequence:

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

4. Arterial blood pressure:
(check one)

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

B. Systolic -- _ _ _ mm Hg

C. Diastolic ------- _ _ _ mm Hg

5. Heart rate: _____ _ _ _ bpm

PART II: Quality Control

6. Number of views: (check one)

Complete :

4 view _____ (4)
3 views _____ (3)

Incomplete :

2 views - - - - _____ (2)
1 views - - - - _____ (1)

7. Technical quallty: (check one)

Fully satisfactory _____ (1)

Satisfactory for EF and limited RWM analysis (1 or 2 views) _____ (2)

Satisfactory for EF only -- ( )

Unsatisfactory _____ (4)

PART III: Results

8. Clobal LV function: RESTEF#D/RESTEF6

A. LVEF _____ __ __ %

B. PFR _____ __ __ . __ __ V/sec

9. Regional LV function-Visual analysis :

For each segment, score: Normal = 3, Mildly hypoklnetlc = 2, Severely hypoklnetlc = 1, Akinetlc = 0, Dysklnetlc = -1. Non-visualized = 9.

Segment Number and Name		Funct Ion Score Sign	Value	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.	Inferoaplcal	( )	__	__
H. 8.	Inferlor	( )	__	__
I. 9.	Posterobasal	( )	__	__
J. 10.	Inferolateral	( )	__	__
K. 11.	Posterolateral	( )	__	__

10. Regional LV function:

Total LV score (normal = 33) = ( ) Sign __ __ Value

11. RVMI _____ (1) Yes (2) No

If YES, answer (A).

(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. Sign	Mean	Regional LVEF (%)
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: (11-26), (27-42), (43-58), (59-74), (75-90), Inf

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

14. Hypokinesis

Number of Chords	1 All Chords	2 (Anterior) Chords 11-70	3 (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:

17. RNL investigator signature:

18. Date form completed:

Month - Day - Year

ID No.														
Form Type	R	D												

TIMI PHASE II

THROMBOLYSIS IN MYOCARDIAL INFARCTION

RADIONUCLIDE DATA ANALYSIS REPORT
EXERCISE RVG

TIMI II Form 8[illegible]
Rev 1 04/17/8[illegible]
2 Pages

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

BASEEFHD/
BASEEFBW

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

ID No.							
Form Type	X	D					

15. **Change in regional EF:**

	Sign	Value
A. Best zone (non-MI)	( )	_ _
B. Worst zone (MI)	( )	_ _

EFCHGHD/EFCHGGW

16. **LVEF change (check one):**

LVEF fall ≥ 5% (1)
LVEF increase ≥ 5% (2)
LVEF no change (3)

STAGEHD/STAGEGW

17. **Peek exercise stage** _____

EXEFHD/EXEFGW

18. **Peek 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 - ≤ 35% increase) (3)

RESULTHD/RESULTGW (calc)

PART III: Administrative matters

20. RNL technologist:

Signature: _____

21. **RNL Invtrtlgetor:**

Signature: _____

22. **Date form completed:**

__ __ - _ _ - _ _
Month Day Year

ID No.								
Form Type	X	D						

TIM1 PHASE II

INSTRUCTIONS FOR COMPLETING TIM1 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 myocardlal 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 TIM1 protocol and effects of TIM1 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	0	1							

PART I: Visit Identification

1. Patient's NAME CODE:

2. Date of hospital discharge or death: HDDAY
Month Day Year

3. Current statue of the patient: (Check one) HDSTAT
Alive ——— (1)
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.

4. Group assignment (check one):

A. PTCA timing study:

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

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 ——— (07)

2. Beta-blocker ineligible:

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

PART II: MI Diagnosis

5. Was myocardlal infarction confirmed? ——— (1) Yes (2) No MICONFIR

A. Wee CK-MBCK consistent with an MI? ——— (1) Yes (2) No (3) Not done MICK

B. Were serial ECGs conelatent with an MI? ——— (1) Yes (2) No (3) Not done MIECG

[*] 6. Myocardial salvage

A. Did this patient's course during rt-PA infusion (see Form 05 item 21) suggest reperfusion with myocardlal salvage? ——— (1) Yes (2) No

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

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

D. In the clinical judgment of the TIMI physician responsible for this patient was myocardlal infarction interrupted with salvage of jeopardized myocardium? ——— (1) Yes (2) No

ID No.											

PART III: Clinical Complications

7. Md any clinical complications occur? ——— (1) Yes (2) No CLNCOMH

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

		Yes	No	Date of first occurrence Month	Day	Year
(8)	Was there clinical or laboratory evidence of myocardlal Infarction or coronary thrombosis?	(1)	(2)	__ __	__ __ -	__ __

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

(9) Evidence:

1.	Anglographic 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 Fon (TIMI Form 23).

(10)	Congestive heart faflure?	CHF (1)	(2)	HDCHFT (calculated) __ __ - __ __ - __ __
(11)	Cardlogenlc shock?	SHOCK (1)	(2)	HDSHKT (calc.) __ __ - __ __ - __ __
(12)	Ventricular septal rupture?	VSRUP (1)	(2)	HDVSRUPT (calc.) __ __ - __ __ - __ __
(13)	Mitral regurgitation?	MITRAL (1)	(2)	HDMITT (calc.) __ __ - __ __ - __ __
(14)	Cardiac arrest?	ARREST (1)	(2)	HDARSTT (calc.) __ __ - __ __ - __ __
(15)	Recurrent ischemlc pain?	PAIN (1)	(2)	HDPNT (calc.) __ __ - __ __ - __ __

		Yes	No	Date of first occurrence: Month	Day	Year
16	Hemorrhagic complications?	(1)	(2)	HEMCOM		

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 bleedlng?	(1)	(2)	HEMCOMC	HDHEMCT (calc.)	
D	Significant decrease in hematocrit or hemoglobin?	(1)	(2)	HEMCOMD	HDHEMDT (calc.)	
E	Transfusion?	(1)	(2)	HEMCOME	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	Thrombocytopenfa?	(1)	(2)	HEMCOMJ	HDHEMJT (calc.)	
K	Hematurla?	(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 (TIMI Form 24). If (E) is answered YES complete a Transfusion Record Form (TIMI Form 26). For (K) and (L) a Hemorhagic Event Form may also be approprlate.

		Yea	No	Date of first occurrence: Month	Day	Year
17	Infectlon?	(1)	(2)	INFCOM		

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. | | | | | | | | | |

Date of first occurrence

		Yes	No	Month	Day	Year
18	Vascular complications?	(1)	(2)	VASCOM		

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)	VASCOME	HDVASET (calc)
F	Other?	(1)	(2)	VASCOMF	HDVASFT (calc)

Specify _____

19	Thoracic canplications?	(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	HDTHRCT (calc)
D	Hemomediastinum?	(1)	(2)	THRCOMD	HDTHRDT (calc)
E	Pulmonary embolism?	(1)	(2)	THRCOME	HDTHRET (calc)
F	Other?	(1)	(2)	THRCOMF	HDTHRFT (calc)

Specify _____

20	Other complications?	(1)	(2)	OTHCOM	

If YES, answer A through C.
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	HDOTHCT (calc)
D	Other?	(1)	(2)	OTHCOMD	HDOTHDT (calc)

Specify _____

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

PART IV: Special Procedures

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

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? ECARD	(1)	(2)	HDCRDT(calc)		
23	Right heart catheterization? RTCATH	(1)	(2)	HDRCTHT(calc)		
24	Protoool or non-protocol left heart cardiac catheterization? CARDCATH	(1)	(2)	HDCCTHT(calc)		

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

25	Intra-aortlc balloon counter pulsation? IABP	(1)	(2)	HDIABT(calc)		
26	Cardiac surgery? CARSUR	(1)	(2)			

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

A	Coronary artery bypass? CABG	(1)	(2)	HDCABGT(calc)		
B	Other? OTHSUR	(1)	(2)	HDOSURT(calc)		

Specify _____

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

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

28	Electrical pacing? EPACE	(1)	(2)	HDPACET(calc)		

If YES answer (A).

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

29	Electra-physiology studies? (IEPHY)(25)			HDEPHST(calc)		
30	Other special procedures? (OTHS(2)			HDOSPT(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. S_4	(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 ___

	Present	Absent
38. Integument:		
A. Ecchymosfs	(1)	(2)
B. Hematoma	(1)	(2)

	Yes	No
39. Were other significant findings present?	(1)	(2)

If Yes, specify: ___

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

PART VI: Medication History

If PATIENT DIED omit column prescribed at Hospital Discharge.

	1 Prescribed during hospitalization Yes / No	2 Prescribed at Hospital Discharge Yes / No
40. Have any of the following drugs or types of drugs been prescribed since onset of qualifying HI 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. Hetoprolol	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 lnotroplc agents or pressor agents	HDRXF (1) (2)	HDDRXF (1) (2)
G. Cardlac glycosides and oral lnotroplc agents	HDRXG (1) (2)	HDDRXG (1) (2)
H. Diuretics	HDRXH (1) (2)	HDDRXH (1) (2)
I. Intravenous vasodllators	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)	HDDRXK (1) (2)
L. Mpyridamole	HDRXL (1) (2)	HDDRXL (1) (2)
M. Platelet active agents (other than aspirin and dipyridamole)	HDRXM (1) (2)	HDDRXM (1) (2)
N. Methyl xanthlner	HDRXN (1) (2)	HDDRXN (1) (2)
O. Heparin	HDRXO (1) (2)	HDDRXO (1) (2)
P. Anticoagulants (other than heparin)	HDRXP (1) (2)	HDDRXP (1) (2)

41. Was the continuous infusion of heparin stopped prior to 5 days after treatment? (1) (2) HEPSTOP

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

(A) How many days of continuous heparfn infusion were administered before stopping heparin? HEPDAYS

(B) Reason for heparln discontinuation:

ID No.

42. Did the patient receive oral beta-blocker therapy in the **hospital?** ——— (1) Yes (2) No ORALBB10

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

(A) **Reason** ineligible for oral beta-blockers **(check all** that apply)

1. Ventrlculu 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** cheat X **ray** findings ——— (1)
5. **PR** Interval > 0.24 **seconds** ——— (1)
6. **Second degree heart** block (except **if** Permanent **paoernaker 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 corticsteroids 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

42. (Continued)

(C) **Was oral beta-blocker** therapy **Interrupted?** ——— (1) Yes (2) No

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

(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 reinstituted?** ——— (1) Yes (2) No

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

(G) **Date reinstituted:**

Month — Day — Year

ID No.

PART VII: Local Laboratory Data

RECORD LAST AVAILABLE RESULTS

		Not Available
43.	Creatinine ____ ___.___ m d d l	(1)
44.	BUN ____ _ _ _ mg/dl	(1)
45.	Total bilirubin ___ .____ gm/dl	(1)
46.	SGOT ____ ___ ___ ___ IU/L	(1)
47.	LDH ____ ___ ___ ___ IU/L	(1)
48.	Alkaline phoaphataae ____ _ _ _ IU/L	(1)
49.	Hematocrit ____ ___ ___.___ %	(1)
50.	Hemoglobin ___ .____ gms/dl	(1)
51.	White blood cell count ___ ___ . ___ thousands/mm3	(1)
52.	Potassium ____ ___ . ___ mEq/L	(1)
53.	Platelet count	
	A. ___ ___ ___ ___ thousands/mm3	(1)
	B. Adequate on smear -	(1) Yea (2) No (3) Unknown

		Pre-sent	Ab-sent	Un-known
54.	Urine protein ____	(1)	(2)	(3)
55.	Urine occult blood ___	(1)	(2)	(3)
56.	Stool gulalc ____	( )	( )	( )

PART VIII: Clinical Data Checklist

57. The following required items are being submitted withthis form:

		Yea	No
[*]A.	ECGs:		
1.	Day 2 ____	(1)	(2)
2.	Day 3 ____	(1)	(2)
3.	Day 4 ____	(1)	(2)
4.	Day 5 ____	(1)	(2)
5.	Predlacharge ____	(1)	(2)
[*]B.	Narrative summary ____	(1)	(2)

58. Was a radlonuclide rest/ exercise study performed? ___ (1) (2)

PART IX: Admlnlatratlve Matters

59. Phyalclan performing physical exam:

Name _____

TIMI Staff No. ___ - _____ ___ ___ ___

60. Research Nurse/Coordinator:

Signature _____

TIMI Staff No: ___ _ _ _ _ _

61. FOR CC USE ONLY

		Yes	No
A.	ECG:		
1.	Day 2 ____	(1)	(2)
2.	Day 3 ____	(1)	(2)
3.	Day 4 ____	(1)	(2)
4.	Day 5 ____	(1)	(2)
5:	Predlscharge ____	(1)	(2)
B.	Narrative summary ____	(1)	(2)

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 Fon 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 Hissed 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 wlth 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: DAYSFU (calc)
Month Day Year

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

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

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

PART II: Background Data

THE FOLLOWING QUESTIONS REFER TO THE TIME OF THIS TIMI VISIT UNLESS OTHERWISE NOTED. "THE LAST SCHEDULED TIMI CONTACT" REFERS TO THE HOST RECENT EVENT (e.g., THE HOSPITAL DISCHARGE OR THE 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) Yes (2) No
PHYACT6W
PHYACTYR

[*] 7. Current Canadian Heart Class: HRTCLS6W HRTCLSYR
- Class 0 (0)
- Class I (1)
- Class II (2)
- Class III (3)
- Class IV (4)

8. Is the patient a current cigarette smoker? (1) Yes (2) 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)
C. Congestive heart failure	(1)	(2)	(3)
D. Angina pectoris	(1)	(2)	(3)
E. Intermittent cerebral ischemic attack	(1)	(2)	(3)
F. Stroke	(1)	(2)	(3)
G. Intermittent clauaication	(1)	(2)	(3)

CAFV01/CAFV02
CHFV01/CHFV02
PAINFV01/PAINFV02

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?

	Yea	No
A. Cardiac catheterization	(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 TIHI 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?

	Never Yes	No	Started
A. Long-acting nitrates and oral vasodilators	(1)	(2)	FURXA6W/FURXAYR
B. Short-acting nitrates	(1)	(2)	FURXB6W/FURXBYR
C1. Metoprolol	(1)	(2)	FURXC16W/FURXC1YR (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) bate stopped _ _ __
Honth 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) Yes (2) No

If YES, answer (C6).

(C6) Names _____

D. Calcium channel blockers FURXD6W/FURXDYR (1) Yes (2) No

If YES, answer (D1).

(D1) Name(s) _____

E. Antiarrhythmics (other than beta-blockers or calcium channel blockers) FURXE6W/FURXEYR (1) (2)

F. Intravenous inotropic agents or pressor agents FURXF6W/FURXFYR (1) (2)

G. Cardiac glycosides and oral inotropic agents FURXG6W/FURXGYR (1) (2)

H. Diuretics FURXH6W/FURXHYR (1) (2)

I. Intravenous vasodilators FURXI6W/FURXIYR (1) (2)

J. Antihypertensives (other than diuretics and beta-blockers) FURXJ6W/FURXJYR (1) (2)

K. Aspirin FURXK6W/FURXKYR (1) (2) (3) Never Started

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

(K1) Date stopped _____ Month Year

(K2) Reason stopped _____

ID No.									
Form Type	F	V							

13. (Continued)

	Yes	No
L. Dipyridamole	(1)	(2)
M. Platelet active agents (other than aspirin and dipyridamole)	(1)	(2)
N. Methyl xanthlnes	(1)	(2)
0. Heparin	(1)	(2)
P. Antlcoagulants (other than heparin)	(1)	(2)

FURXL6W/FURXLYR
FURXM6W/FURXMYR
FURXN6W/FURXNYR
FURXO6W/FURXOYR
FURXP6W/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

	Present	Absent	Unknown
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:

	Present	Absent	Unknown
A. S_3	(1)	(2)	(3)
B. S_4	(1)	(2)	(3)
C. Perlcardlal friction rub	(1)	(2)	(3)
D. Murmurs	(1)	(2)	(3)

If PRESENT, answer (D1).

If ABSENT or UNKNOWN, skip to Item 21.

(D1) Murmur(s) characteristic of the following are present (check all that apply):

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

Specify _____

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

If YES, specify: _____

ID No.

Form Type F V

PART VI: Local Laboratory Data

		Not available
22. Creatinine ____ ___ . ___ mg/dl	(1)	
23. BUN ____ ___ mg/dl	(1)	
24. Total bilirubin ____ ___ . ___ mg/dl	(1)	
25. SCOT ____ ___ IU/L	(1)	
26. LDH ____ ___ IU/L	(1)	
27. Alkaline phosphastase ____ ___ IU/L	(1)	
28. Hematocrit ____ ___ . ___ %	(1)	
29. Hemoglobin ____ ___ . ___ gms	(1)	
30. White blood cell count ___ . ___ thousands/mm3	(1)	
31. Potassium ____ ___ . ___ mEq/L	(1)	
32. Platelet count		
A. ___ thousands/mm3	(1)	
B. Adequate on smear ____	(1) Yes	(2) No (3) Unknown

	Present	Absent	Unknown
33. Urine protein ____	(1)	(2)	(3)
34. Urine occult blood ____	(1)	(2)	(3)

PART VII: Clinical Data Checklist for 6 WEek Visit

ANSWER PART VII ONLY AT THE 6 WEEK VISIT

35. Is a 6 week ECC being submitted with this form? ____ (1) Yes (2) No

36. Was a rest/exercise radionuolide ventricular study performed? ____ (1) Yea (2) No

PART VIII: Clinical Date Checklist For 12 Months

ANSWER PART VIII ONLY AT THE 12 MONTH VISIT

37. Was a maximal treadmill exercise tolerance test performed? ____ (1) Yes (2) No

PART IX: Administrative Matters

38. Physician performing physical exam:

Name _____

TIMI Staff No: ____ _ _ _ _

39. Research Nurse/Coordinator:

Signature _____

TIMI Staff No: ____ _ _ _ _ _

40. CC USE ONLY		
ECG ____	(1) Yes	(2) No

ID No.									
Form Type	F	V							

Rev 0 03/03/86

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 B 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

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

Clinic No.			
ID No.			
Form Type	M	V	

TYPEFU
FUGW/FUYR
(calc.)

PART I: Visit Identffloation

1. Patient's NAME CODE

_ _ _ _ _

2. A. Date of contact:
DAYSFU (calc.)
Month - Day - Year

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

Month - Day - Year

3. Follow-up Visit Number: ____ - -

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

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

(A) Did you attapt to contact any oi 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	(1)	(2)	(3)

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

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

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

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

[*] 7. What is the main reason that the patient missed the visit? (Cheak only one.)
MISSGW/MISSYR

- Patient has been ill ____ (01)
- Moved (distance too far to continue at thls 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)

ID No.			
Form Type	M	V	

Part II: Medical History

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

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

	Definite	No	Suspect	Unknown
A. Myocardial infarction	(1)	(2)	(3)	(4)

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

CAFV01/CAFV02

B. Cardiac arrest	(1)	(2)	(3)	(4)

CHFV01/CHFV02

C. Congestive heart failure	(1)	(2)	(3)	(4)

PAINFV01/PAINFV02

D. Angina peotoris	(1)	(2)	(3)	(4)
E. Intermittent cerebral iscnemic attack	(1)	(2)	(3)	(4)
F. Stroke	(1)	(2)	(3)	(4)
C. Intermittent claudication	(1)	(2)	(3)	(4)

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

	Yes	No	Unknown
A. Diabetes mellitus	(1)	(2)	(3)
B. Hypertension	(1)	(2)	(3)
c. Peripneral vascular disease	(1)	(2)	(3)
D. Valvular heart disease	(1)	(2)	(3)
E. Other cardiac aisease	(1)	(2)	(3)
Speaify _____			
F. Gastrointestinal disease	(1)	(2)	(3)
G. Hematological disease	(1)	(2)	(3)
H. Renal disease	(1)	(2)	(3)
I. Neurological aisease	(1)	(2)	(3)
J. Other signif icant disease	(1)	(2)	(3)
Specify _____			

ID No.									
Form Type	M	V							

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

	Yes	No	Unknown
A. Cardiaa catheterizatlan	(1)	(2)	(3)

If YES, complete a Cardiac Catheterization Form (TIMI Form 7C) far eaah catheterlzatlon..

B. Percutaneous transluminal coronary angloplasty	(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.

0 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
A. Item 7 SOURCEGW/SOURCEYR	(1)	(2)	(3)	(4)	(5)	(6)	(7)
B. Item a	(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						

Rev 0 03/03/86

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 Caust 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 Appoint=ment 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 IL

THROMBOLYSIS IN MYOCARDIAL INFARCTION
TELEPHONE CONTACT FORM

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

Clinic No.	H
ID No.	H
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) Yes (2) No LOCATEFU

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

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

	Yes	No	Not Applicable
1. Patient	(1)	(2)	(3)
2. Patient's next ot 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 ● srist in locating the patient? — (1) Yes (2) No CCFU

5. Is the patient alive? — (1) Yes (2) No (3) 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) Yes (2) No (3) Not Applicable

ID No.	H
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) Yes (2) No (3) Unknown

If YES, answer A (A) complete a Subsequent Hoepiteliretlon Form (TIMI Form 14) for • eoh admission.

(A) Number of admissions to the hospital: ——— - -

8. Has the petient been seriously 111 (but not admitted to a hoepitrl for this illness) since the lest TIMI contact (do not include the qualifying TIMI episode)? ——— (1) Yes (2) No (3) Unknown

If YES, neuer@end@.

If NO or UNKNOWN, skip to item 9.

(A) How long was patient ill? ——— - - - days

0[8] Was this illness • myooerdiel infarction or other heart disease? ——— (1) Yes (2) Ho (3) Unknown

If YES, complete • 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							

Rev 03/03/86

TIM1 PHASE II

INSTRUCTIONS FOR COMPLETING

TIM1 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 Coordfnatlng 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 Fon 14
Rev 0 03/03/86
2 Pages

FORM14-1...5 (calc.)

Clinic No.								
ID No.								
Form Type	H	P						

PART I: Visit Idcntlflcation

1. **Patient's NAME** CODE:

2. **Dates of hospitollzatlon:**

A. **Admitted :** HOSCDAY CHFDAY ARRDAY - STKDAY HOSPDAY1...5 STAY1...5 } calc.

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** hospltallzatton 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) Yes (2) No

PART 11: Physician Assessment

7. Is the **cause for** this hospitalization **cardiovascular?** (1) Yes (2) 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) RHMI1...

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

B. **Angina pectoris** — (1) (2) (3) RHANG1

c. **Congestive** heart failure ——— (1) (2) (3) RHCHF1 CCHF (calc)

ID No.								
Form Type	H	P						

8 (Continued)

	Definite	No	Suspect	
D. Arrhythmia	(1)	(2)	(3)	RHARR1...5 CARR (calc)
E. Stroke	(1)	(2)	(3)	RHSTK1...5 CSTK (calc)
F. Cardiovaaoular procedure	(1)	(2)		

If DEFINITE answer (F1) to (F5).

(F1) Coronary angiography — (1) Yes (2) No — RHCATH1...5

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

(F2) PTCA — (1) Yes (2) No — RHPTCA1...5

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

(F3) CABG — (1) Yes (2) No — RHCABG1...5

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

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

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

Specify: _____

_____

	Definite	No	Suspect	
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. Hematopoetic	(1)	(2)
D. Hcprtobiliary	(1)	(2)
E. Ncurologic	(1)	(2)
F. Pulmonary	(1)	(2)
G. Musouloakclctal	(1)	(2)
H. Genito-urinary	(1)	(2)
I. Malignancy	(1)	(2)
J. Elcotivc 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) Yes (2) 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) Yes (2) No

ID No.									
Form Type	H	P							

Rev 0 03/03/86

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	0	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

[8] 4. I8 there any preliminary information available on the cause Of death? ——— (1) Yes (2) 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.)

FISCAUSE

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)

(5) (Continued)

B. Non-atherosclerotic Cardiovascular Disease

- Pulmonary embolism ——— (09)
- Non-atherosclerotic heart disease (cardiomyopathy, myocarditis, valvular disease, rheumatic heart disease, bacterial endocarditis, e 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.							

(6) Indicate the sources of information which were available and provided the basis for the diagnosis given in Item 5? (Answer each item.)

	Yea	No
A. Hospital narrative summary	(1)	(2)
B. Autopsy report	(1)	(2)
C. Ennt ECGs	(1)	(2)
D. Death certificate	(1)	(2)
E. Other (specify below)	(1)	(2)

_____

PART II: Administrative Matters

7. Researen Nurse/Coordinator:

Signature _____

TIMI Staff No: ___ _____ ___ ___ ___

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

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)

TIMI PHASE II

TIMI II Form 16
Rev 0 03/03/86
5 Pages

THROMBOLYSIS IN MYOCARDIAL INFARCTION
CAUSE OF DEATH FORM

Clinic No.									
ID No.									
Form Type	C	D	0	1					

PART I: Identifying Information

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

_ _ _ _ _

2. Date thisform completed:

Month _ _ Day _ _ Year _ _

3. Date of death:

Month _ _ Day _ _ Year _ _

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

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

PART II: Cause of Death

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

A. Atherosolerotlc Cardiovascular Disease (1)

If cheoked, skip to Item 6.

B. Non-atherosclerotic Cardiovascular Disease (2)

If cheoked, 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.									

[*] 6. Which atherosclerotic cardiovascular disease(s) was the underlying (basic) cause of death?

[*]A. Atherosclerotic coronary heart disease with recent or acute cardiac event (e.g., myooardlal infarction, acute coronary insufficiency, sudden unexpected or unobserved death) ——— (1)

If checked, answer (A1) and (A2).

(A1) Was this the qualifying myocardial infarction ——— (1) Yes (2) Ho

(A2) What was the chronology of death? (Check only one.)

a. Not a sudden unexpected or unobserved death ——— (1)

b. Sudden unexpected death within 60 minutes of onset of symptoms or unobserved death within 60 minutes of being seen alive without symptoms ——— (2)

c. Sudden unexpected death between one and 24 hours of onset of symtoms ——— (3)

d. Unobserved death between one and 24 hours of being seen alive without symptoms ——— (4)

e. Unobserved death more than 24 hours of being seen alive without symptoms - - (5)

[*] 6. (Continued)

B. Atherosclerotic coronary heart disease without recent or acute cardiac event (e.g., chronic congestive heart Failure) ——— (1)

C. Cardiac arrhythmia, without new infarct ——— (1)

D. Atherosclerotic coronary heart disease resulting in surgery for coronary heart disease (e.g., ——— (1)

E. Other (specify below) ——— (1)

ID No. | | | | | | | |

7. Underlying illness causing death and other significant diagnoses. Use conventional medical nomenclature and avoid abbrcvlattons.

Diagnoses:

	A. DIAGNOSES	B. ICD-9 CODES
(Primary) 1.	_____	1. ____.__
(Secondary) 2.	_____	2. ____.__
3.	_____	3. ____.__
4.	_____	4. ____.__
5	_____	5. ____.__
6.	_____	6. ____.__
7.	_____	7. ____.__
a.	_____	a. ____.__

---

[*] a. What was the immediate cause of death?

A. Cardiogenic shock _____ (1)

[*]B. Cardiac dysrhythmia _____ (1)

If checked, answer (B1).

(B1) How was it diagnosed?

Documented by ECG or cardiac monitor _____ (1)

Presumptive other cause found at autopsy _____ (2)

Presumptive autopsy not done _____ (3)

C. Congestive heart failure _____ (1)

[*] a. (Continued)

D. Pulmonary edema _____ (1)

E. Ruptured myocardlum with tanponade _____ (1)

[*]F. Stroke (thromboembolic or hemorrhagic _____ (1)

G. Acute pulmonary thrombo-embolism _____ (1)

H. Hemorrhage _____ (1)

I. Respiratory failure _____ (1)

J. Other _____ (1)

Specify: _____

K. Unknown _____ (1)

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

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) Yes (2) 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) Yes (2) No

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

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

		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. | | H | | | | H |

TIMI PHASE II
THROHBOLYSIS IN HYOCARDIAL INFARCTION

MORBIDITY AND MORTALITY CLASSIFICATION COMMITTEE DEATH CLASSIFICATION FORM
FULL HHCC REVIEW

DEATH(calc)

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

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. Yas 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) DHEMORR
Yes No HEMDEATH

If YES, continue with item 6B1-6B5.

If NO, skip to item 6C.

Is this hemorrhagic death atttibutable 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

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 thow of PTCA, CABG surgery, or hemorrhage?	(1)	(2)	DOTHER

Specify compllcattons (e.g., catheter induced aortlc dissection, drug reaction, etc.)

7. Did this patient die of cardiovascular disease7 (1) Yes (2) No DCVD

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) Yea (2) No DCARDIAC

Skip to item 11.

If YES, continue with item 8B.

If NO, skip to item 9.

B. Did thls patient die of acute myocardlal infarction? (1) Yes (2) No

If YES, continue with items 8B1 and 8B2.

If NO, skip to Item 8C.

8. (Continued)

B. (Continued)

1. The fatal acute myocardlal Infarction was:

The TIM1 Qualifylng myocardial lnfarctlon	(1)	FITMI
A recurrent myocardlal infarction	(2)	
Unknown	(3)	

2. When did the myocardlal infarction occur? FITTIME

Before any procedures	(1)
After any procedures	(2)
No procedures performed	(3)

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

Pump failure	(1)	DPMP FAIL
Ventricular rupture	(1)	DVENTRUP
Arrhythmia	(1)	DARRTH
Other	(1)	DOTHCAR

Specify, _____

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.

10. Other causes.

Did this patient die of a cause other than cardiovascular disease or treatment complications? ——— (1) Yes (2) No

11. Summary.

A. Immediate Cause of Death (e.g., anoxlc brain in jury, asystole, ventricular fibrillation, cardiogenic shock, . ..):

B. Due to. or as a consequence of (e.g., acute myocardlal infarct ion, chronic coronary artery disease, gastrointestinal hemorrhage, pulmonary embolism, . ..):

C. Due to, or as a consequence of (e.g., peptic ulcer disease. bronchogenic carcinoma, mitral stenosis, . . .):

D. Other significant conditions (e.g., chronic obstructive pulmonary disease, Parkinson's dlsease, polycystic kidney disease, . ..) :

E. Rationale for death classification:

F. Did the Information provided to classify this case unbllnd treatment assignment? ——— (1) Yes (2) No

G. Reason(s) this event came to the full committee:

Skip to item 13.

12. Additional information required to complete classification:

	Yes	No	
A. Death certificate ----	(1)	(2)	
B. Discharge summary --	(1)	(2)	
C. Full autopsy report ---	(1)	(2)	(3) Not Available
D. Narrative letter --	(1)	(2)	
E. Other ——	(1)	(2)	

Specify other information required (e.g., TIMI forms, operation reports, microscopic pathology)

PART III: Administrative Matters

13. MMCC Chairman's signature:

14. Date form completed:

Month Day Year

CC USE ONLY

15. ICD Code: DICDCODE

16. Basis for Form 17 Status:

Full MMCC —— (1)
Two reviewers congruent -- (2)

ID No.

Rev 0 03/14/86

TIM1 PHASE II

INSTRUCTIONS FOR COMPLETING
TIM1 FORM 19
LABORATORY DATA FORM

GENERAL INSTRUCTIONS

Tiiis 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 snould be submitted to the Coordinating Center in conjunction with the Hospital Discharge Form.

The patient's identification number snould 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 snould 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 THROJJGH 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 willusually 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

Clinic No.				H								
ID No.				H								H
Form Type	L	D	0	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

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

ID No.				H								H

PART III: Hematologic **Measurements** and Medication

4. Hospital limits.

A. **APTT** (seconds): Upper Limit Normal ___

a. **APTT (seconds):** Hospital's Highest ___

5. Pretreatment.

			Not Done
A.	Hemoglobin:	___ . ___ gms/dl	(1)
a.	Hematocrit:	___ . ___ %	(1)
C.	Platelet Count:	_ _ _ _ thousands/mm3	(1)

6. First day, **Date:** ___ ___ ___ (Month Day Year) IVD01

A. Total Daily Heparin Dose (UUSP): HEP19D01 IV (1) Subcu (1)

a. Total daily aspirin dose: ASA19D01 mg

C. Total daily **coumadin** dose: COU19D01 mg

D. Total daily metoprolol dose (oral) MET19D01 mg

E. Other beta-blocker (oral) (1) Yes (2) No OBBD01

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

(E1) Name ___

(E2) Total daily dose: ___

	1 Military Time Hours	Minutes	APTT (seconds)	Not Done	2 PT/control (seconds)	Not Done	3 Hemoglobin (gms/dl)	Not Done	4 Hematocrit %	Not Done	5 Platelet Count thousands/mm3	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)

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

7. Second day. Date: ___ ___ - ___ ___ - ___ ___ (Month - Day - Year)

A. Total Daily Heparin Dose (U USP): HEP19D02 IVD02 IV (1) Subcu (1)

B. Total daily aspirin dose: ASA19D02 mg

C. Total dally coumadin dose: COU19D02 mg

D. Total daily metoprolol dose (oral) MET19D02 mg

E. Other beta-blocker (oral) ___ (1) Yes (2) No OBBD02

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

(E1) Name ___

(E2) Total daily dose: ___

	1 Military Time Hours : Minutes	APTT (seconds) Not Done	2 PT/control (seconds) Not Done	3 Hemoglobin (gms/dl) Not Done	4 Hematocrlt % Not Done	5 Platelet Count thousands/mm3 Not Done
F.	___ ___ : ___ ___	___ ___ ___ (1)	___ ___/___ ___ (1)	___ ___.___ (1)	___ ___.___ (1)	___ ___ ___ ___ (1)
G.	___ ___ : ___ ___	___ ___ ___ (1)	___ ___/___ ___ (1)	___ ___.___ (1)	___ ___.___ (1)	___ ___ ___ ___ (1)
H.	_ _ : ___ ___	___ ___ ___ (1)	___ ___/___ ___ (1)	___ ___.___ (1)	___ ___.___ (1)	___ ___ ___ ___ (1)
1.	_ _ : ___ ___	___ ___ ___ (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)

A. Total Daily Heparin Dose (UUSP): HEP19D03 IVD03 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) Yes (2) No OBBD03

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

(E1) Name ___

(E2) Total dally dose: ___

	1 Military Time Hours : Minutes	APTT (seconds) Not Done	2 PT/control (seconds) Not Done	3 Hemoglobin (gms/dl) Not Done	4 Hematocrlt % Not Done	5 Platelet Count thousands/mm3 Not tone
F.	___ ___ : ___ ___	___ ___ ___ (1)	___ ___/___ ___ (1)	___ ___.___ (1)	___ ___.___ (1)	___ ___ ___ ___ (1)
c.	___ ___ : ___ ___	___ ___ ___ (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 dally **coumadin** dose: COU19D04 mg

D. Total daily metoprolol dose (oral) MET19D04 mg

E. Other beta-blocker (oral) (1) Yes (2) No OBBD04

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

(E1) Name

(E2) Total daily dose:

	Military Time Hours	Minutes	1 APTT (seconds)	Not Done	2 PT/control (seconds)	Not Done	3 Hemoglobin (gms/dl)	Not Done	4 Hematocrit %	Not Done	5 Platelet Count thousands/&	Not Done
F.	__ __	__ __	__ __ __	(1)	__ __/__ __	(1)	__ __.__	(1)	__ __.__	(1)		(1)
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 dally coumadin dose: COU19D05 mg

D. Total daily metoprolol dose (oral) MET19D05 mg

E. Other beta-blocker (oral) (1) Yes (2) No OBBD05

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

(E1) Name

(E2) Total daily dose:

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

ID No.

11. Sixth day. Date: ___ - ___ - ___ (Month - Day - Year) IVD06

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) Yes (2) No OBBD06

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

(E1) Name _____

(E2) Total daily dose: _____

	1 Military Time Hours	Minutes	APTT (seconds)	Not Done	2 PT/control (seconds)	Not Done	3 Hemoglobin (gms/dl)	Not Done	4 Hematocrit %	Not Done	5 Platelet Count thousands/mm3	Not Done
F.	__ __	__ __	__ __ . __	(1)	__ __ / __ __	(1)	__ __ . __	(1)	__ __ . __	(1)	__ __ __ __	(1)
G.	__ __	__ __	__ __ . __	(1)	__ __ / __ __	(1)	__ __ . __	(1)	__ __ . __	(1)	__ __ __ __	(1)
H.	__ __	__ __	__ __ __	(1)	__ __ / __ __	(1)	__ __ . __	(1)	__ __ . __	(1)	__ __ __ __	(1)

---

12. Seventh day. Date: - B - - B - - (Month - Day - Year) IVD07

A. Total Daily **Heparin** Dose (U USP): HEP19D07 IV (1) Subou (1)

B. Total dally aspirin dose: ASA19D07 mg

C. **Total daily** coumadln dose: COU19D07 mg

D. Total daily metoprolol dose (oral) MET19D07 mg

E. **Other** beta-blocker (oral) (1) Yes (2) No OBBD07

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

(E1) Name _____

(E2) Total daily dose: _____

	1 Military Time Hours	Minutes	APTT (seconds)	Not Done	2 PT/control (seconds)	Not Done	3 Hemoglobin (gms/dl)	Not Done	4 Hematocrit %	Not Cone	5 Platelet Count thousands/ma3	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) IVD08

A. Total Daily Heparin Dose (UUSP): HEP19D08 IV (1) Subcu (1)

B. Total daily aspirin dose: ASA19D08 mg

C. Total daily coumadin dose: COU19D08 mg

D. Total daily metoprolol dose (oral) MET19D08 mg

E. Other beta-blocker (oral) ____ (1) Yes (2) No OBBD08

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

(E1) Name ____

(E2) Total daily dose: ____

	Military Time Hours	Minutes	1 APTT (seconds)	Not Done	2 PT/control (seconds)	Not Done	3 Hemoglobin (gms/dl)	Not Done	4 Hematocrit %	Not Done	5 Platelet Count thousands/mm3	Not 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) IVD09

A. Total Dally Heparin Dose (UUSP): HEP19D09 IV (1) Subcu (1)

B. Total dally aspirin dose: ASA19D09 mg

C. Total daily coumadin dose: COU19D09 mg

D. Total daily metoprolol dose (oral) MET19D09 mg

E. Other beta-blocker (oral) ____ (1) Yes (2) No OBBD09

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

(E1) Name ____

(E2) Total daily dose: ____

	Military Time Hours	Minutes	1 APTT (seconds)	Not Done	2 PT/control (seconds)	Not Cone	3 Hemoglobin (gms/dl)	Not Done	4 Hematocrit %	Not Done	5 Platelet Count thousands/mm3	Not 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)

IVD10

A. Total Daily Heparin Dose (U USP): HEP19D10 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) Yes (2) No OBBD10

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

(E1) Name _____

(E2) Total daily dose: _____

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

PART IV: Administrative Matters

16. Additional pages are included for the following measurements:

	Yes	No
A. CK	(1)	(2)
B. Hematologlc and medication	(1)	(2)

17. Research Nurse/Coordinator:

Signature _____

TIMI Staff No: ____ - - - - - -

ID No. _____

Rev 2 12/08/87

TIM1 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 thronbolytic therapy for TIM1 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.

TIMI PHASE II

THROMBOLYSIS IN MYOCARDIAL INFARCTION
MYOCARDIAL INFARCTION EVENT FORM

TIMI II Form 23
Rev 2 12/08/87
2 Pages

Clinic No.			
ID No.			
Form Type	R	O	

CLINICMI (calc.)

PART I: Identifying Information

1. Patient's **NAME** CODE: ____ ____ ____ ____ ____

2. Date **event** *occurred:* MIDAT2 / MIDAT21 (calc.) / MIDAT23
   Month ___ Day ___ Year ___

   Military time: ___ ___ : ___ ___

PART II: Pain

4. **Duration** of **pain:** ___ ___ hours ___ ___ minutes

3. Evidence of myocardial infarction **and/or coronary thrombosis:**

		Yes	No
A.	**Angiographic**	(1)	(2)

If YES, complete Cardiac Cath Forms (TIMI Forms 7B and 7C) and send films to RGL.

F23PAIN

B.	**Reappearance** of pain	(1)	(2)
C.	**ECG evidence**	(1)	(2)
D.	CK evidence	(1)	(2)
E.	Other enzymes **elevated**	(1)	(2)

PART III: Enzyme Results

5. **CK**

	1 Date Month	Day	Year	Military Time	2 Total CK	Not Done	3 MB Band	Not Done	Total MB	Not Done
(a)	__	__	__	__ : __	_____	(1)	__	(1)	___	(1)
(b)	__	__	__	__ : __	_____	(1)	__	(1)	___	(1)
(c)	__	__	__	__ : __	_____	(1)	__	(1)	___	(1)
(d)	__	__	__	__ : __	_____	(1)	__	(1)	___	(1)
(e)	__	__	__	__ : __	_____	(1)	__	(1)	___	(1)
(f)	__	__	__	__ : __	_____	(1)	__	(1)	___	(1)
(g)	__	__	__	__ : __	_____	(1)	__	(1)	___	(1)
(h)	__	__	__	__ : __	_____	(1)	__	(1)	___	(1)
(i)	__	__	__	__ : __	_____	(1)	__	(1)	___	(1)
(j)	__	__	__	__ : __	_____	(1)	__	(1)	___	(1)

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

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

7. Was nonprotocol **thrombolytic** therapy administered? (1) Yes (2) 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. Anglography 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 _____

9. Research Nurse/Coordinator:

Signature _____

TIMI Staff No: - - - - -

FOR **COORDINATING** CENTER **USE ONLY**

10. Documents received:

	Yes	No
A. **Narratlve summary**	(1)	(2)
B. **Angiography report**	(1)	(2)
C. **ECG(s)**	(1)	(2)
D. **Mher**	(1)	(2)

Rev 1 11/10/86

TIM1 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 TIM1 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 YYOCARDIAL 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

Hllltary time: Hours : Minutes

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

4. Weight: kg.

5. Height: cm.

6. Age: years

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

9. Were any of there sites Instrumented (e.g.. Foley catheter, cystoscopy, bronchoscopy, N-G tube, eto.)? (1) Yes (2) 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		

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

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 then heparln)	(1)	(2)
Platelet active agents (other than aspirin and dipyridamole)	(1)	(2)

Explain fully in narrative.

12. **Medications used to** treat this **event (check** all that apply):

A. **None** (1)
B. **Protamine** (1)
C. Epsilon **amino caproic acid** (1)
D. **Other, specify** (1)

13. **Were** blood **products transfused to** the patient **in** the treat ment of **this** event? HEMTRNS1-9 (1) (2) Yea No

If YES, answer (14).
If NO, skip to Part III.

14. **Products,** If YES. specify **number** of Units **(answer each** item)

	Yea	No
A. Whole blood	(1) (2)	U
B. **Packed** cells	(1) (2)	U
C. Platelets	(1) (2)	U
D. Fresh frozen plasma	(1) (2)	U
E. **Cryoprecipitate**	(1) (2)	U
F. Other	(1) (2)	U

Specify

If YES is answered for WHOLE BLOOD or PACKED CELLS, complete a Transfusion Report **Form (TIMI** Form **26).**

PART III: **Administrative** Matters

[*]15. **Is** the required Narrative Summary attached? (1) (2) Yea No

16. **Research** Nurse/Coordinator:

Signature

TM Staff No:

FOR CC USE ONLY		
17. Narrative Summary	(1) Yes	(2) No

ID No.

Rev 1 11/10/86

TIMI PHASE II

INSTRUCTIONS FOR COMPLETING
TIM1 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

Angina1 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 ordfnary 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 -- angina1 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

FORM25 (calc.)

PART I: Event Identification

1. Patient's NAME CODE: ___ ___ ___ ___ ___

2. Date and time of surgery: SURGTIME, SURGTIM2 (calc.)

Month ___ Day ___ Year ___

Military time: ___ : ___ Hours Minutes

PART II: Procedure Notes

3. Medical therapy prior to surgery:

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

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

(1) Medication: ______

(2) Total daily dose: ____ mgs

(3) Were undesirable side effects present at the maximum dose? — (1) Yes (2) No

3. (Continued)

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

C. Nitrates and vasodilators: ______ (1) Yes (2) 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) Yes (2) No

ID No.	

4. Was surgery an emergency or an elective procedure? SURGREAS

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 ≥ .1mV, T wave inversion, pseudonormalization of T waves or transient nw St elevation ≥ .1mV ——— (2)

Persistent chest pain and new sustained ST elevation ≥ .1mV suggestive of reinfarction —— (3)

Other (specify) ——— (4)

5. Angina status prior to surgery: ANGSTAT

A. Certainity of diagnosis (cheek 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) Yes (2) No ANGPAIN

(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) Yes (2) No F25EXER

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 blcyole ——— (3)
Other, specify ——— (4)

ID No.

7. Was coronary angiography performed for this surgery? F25CATH (1) Yes (2) 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)	LADGRAFT
C. Circumflex	(1)	(2)	CXGRAFT
D. Obtuse marginal	(1)	(2)	CXGRAFT
E. RCA or RPDA	(1)	(2)	RCAGRAFT
F. LMCA	(1)	(2)	LMCGRAFT

9. Conduits used (cheek all that apply):

A. Saphenous vein(s) (1) CONDSAP

B. Left internal mammary artery (1) CONDLIM

C. Right internal mammary artery (1) CONDRIM

D. Other (1) CONDOTH

Specify

10. Did my of the following complications occur within 21 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) Yes (2) No F25TRANS

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

PART III: Administrative Matters

[*]12. Is the required operation report enclosed? (1) Yes (2) 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.

Rev 0 11/10/86

TIM1 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 HYOCARDIAL INFARCTION
TRANSFUSION REPORT FORM

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

Clinic No.								
ID No.								
Form Type	T	F	0	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

   Speaify ______________

4. Products, If YES, spealfy number of Units: (answer eaah item)

	Yes	No	UNITS
A. Whole blood	(1)	(2)	F26WBU __ __ . __
B. Paaked cells	(1)	(2)	F26PCU __ __ . __

TFUNIT (calc.)

[*] 5. Blood transfusion record

	Date Month	Dey	Year	Military Time Hours	Minutes	Units Whole Blood	Units Packed Cells
a)	__ __	__ __ -	__ __	__ __ :	__ __	__ __ . __	__ __ . __
b)	__ __ -	__ __ -	__ __	__ __ :	__ __	__ __ . __	__ __ . __
c)	__ __ -	__ __	__ __	__ __ :	__ __	__ __ . __	__ __ * __
d)	__ __ -	__ __ -	__ __	__ __ :	__ __	__ __ a __	__ __ * __
e)	__ __	__ __	__ __	__ __ :	__ __	__ __ * __	__ __ * __
f)	__ __ -	__ __	__ __	__ __ :	__ __	__ __ . __	__ __ * __
g)	__ __ -	__ __ -	__ __	__ __ :	__ __	__ __ . __	__ __ . __
h)	__ __ -	__ __	__ __	__ __ :	__ __	__ __ . __	__ __ . __
i)	__ __ -	__ __	__ __	__ __ :	__ __	__ __ . __	__ __ . __
j)	__ __	__ __ -	__ __	__ __ :	__ __	__ __ . __	__ __ * __
k)	__ __ -	__ __ -	__ __	__ __ :	__ __	__ __ . __	__ __ * __
l)	__ __ -	__ __ -	__ __	__ __ :	__ __	__ __ . __	__ __ a __
m)	__ __	__ __ -	__ __	__ __ :	__ __	__ __ . __	__ __ * __
n)	__ __	__ __	__ __	__ __ :	__ __	__ __ . __	__ __ . __
o)	__ __ -	__ __	__ __	__ __ :	__ __	__ __ . __	__ __ . __

PART III: Administrative Matters

6. Researoh Nurse/Coordinator:

   Signature ______________

   TIMI Staff No: -- _ _ _ _

ID No.							

Rev 0 08/01/88

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 if 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 3 7 . P A G E 1 4

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

1. Patient's NAME CODE: ---------- _ _ _ _ _

2. Date of event: ---------- __ __ Month __ __ Day __ __ Year

PART 11: Prior Conditions

3. Handedness:

Right ---------- (1)
Left ---------- (2)
Ambidextrous or switched ---------- (3)
Unknown ---------- (4)

4. Has this patient ever been treated for or diagnosed to have cancer? ---------- (1) Yes (2) No (3) Unknown

If NO or UNKNOWN, skip to item 5.

A. If YES, specify type of cancer: _____

5. 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) Yes (2) No

If YES, specify: _____

ID No.								

6. What was this patient's average daily alcohol consumption prior to entry into TIMI? ALCOH

≤ 1 oz ---------- (1)
2-3 oz ---------- (2)
4-5 oz ---------- (3)
≥ 6 oz ---------- (4)
Unknown ---------- (5)

7. Past history of migraines? ---------- (1) Yes (2) No (3) Unknown

a. Past history of seizures? ---------- (1) Yes (2) No (3) Unknown

* 9. A. Has the patient ever had a TIA? ---------- (1) Yes (2) No (3) 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) Yes (2) No (3) **Unknown**

10. A. Has the patient ever had a stroke before this event? ---------- (1) Yes (2) No (3) **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.

10. (Continued)

E. Vascular territory; (check all that apply)

1. Right carotid ---------- (1)
2. left carotid ---------- (1)
3. Vertebral-basilar ---------- (1)
4. Multiple territories ---------- (1)
5. Subarachnoid hemorrhage ---------- (1)
6. unknown ---------- (1)

PART III: Onset

11. Date and time of onset of **neurologic** signs or symptoms in **TIMI?**

*A. Earliest possible:

1. Date ---------- EPMO - EPDA - EPYR
   Month Day Year
2. Time ---------- EPHR __ . __ EPMN (1)
   Unknown

***B.** Latest possible:

1. Date ---------- LPMO - LPDA - LPYR
   Month Day Year
2. Time ---------- LPHR __ : LPMN __ (1)
   unknown

C. Was this deficit first noticed upon the patient's regaining consciousness (waking up or coming out of coma)? ---------- (1) Yes (2) No (3) Unknown

ID No.			H			H	

12. At the time of earliest possible onset, was there:

		Yes	No	Unknown	
A.	Severe headache	(1)	(2)	(3)	ITEM12A
B.	Vomiting	(1)	(2)	(3)	ITEM12B
C.	Seizures	(1)	(2)	(3)	ITEM12C
D.	Focal deficit	(1)	(2)	(3)	ITEM12D
E.	Altered mental state (e.g., decreased consciousness)	(1)	(2)	(3)	ITEM12E
F.	Coma	(1)	(2)	(3)	ITEM12F

***13.** Onset was: (check one only)

Sudden (maximum deficit within 10 minutes) ---------- (1) ITEM13
Steplike worsening ---------- (2)
Gradual worsening ---------- (3)
unknown ---------- (4)

***14.** How long after the earliest possible onset was maximum stable deficit achieved?

≤ 6 hours ---------- (1) ITEM14
> 6 but ≤ 12 hours ---------- (2)
> 12 but ≤ 24 **hours** ---------- (3)
> 24 but ≤ 48 **hours** ---------- (4)
> 48 but ≤ 72 hours ---------- (5)
> 72 hours ---------- (6)
unknown ---------- (7)

15. Did improvement occur (even temporarily) within the first 24 hours after onset? ---------- (1) Yes (2) No (3) Unknown ITEM15

ID No.

16. Was documented change in blood pressure a possible precipitator of this event? ---------- (1) Yes (2) No (3) Unknown ITEM16

If **YES**, answer items A and B.

If **NO** or **UNKNOWN**, skip to item 17.

		Yes	No	Unknown	
A.	Hypotension ----------	(1)	(2)	(3)	ITEM16A
B.	Hypertension ----------	(1)	(2)	(3)	ITEM16B

17. Medications

A. Had this patient taken antiplatelet agents within 48 hours of the event? --------- (1) Yes (2) No (3) Unknown ITEM17A

If **YES**, answer items Al 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) Yes (2) No (3) Unknown ITEM17B

If **YES**, answer items **B1** and **B2.**

If **NO** or **UNKNOWN**, skip to item 17C.

B1. Agent: _____

B2. Total daily dose: ---------- _ _ _ mg

17. (Continued)

C. Had this patient taken ergotamines within 24 hours of the event? ---------- (1) Yes (2) No (3) Unknown ITEM17C

If YES, answer items C1 and C2.

If NO or UNKNOWN, skip to item 17D.

C1. Agent: _____

C2. Total daily dose: ---------- ___ ___ ___ mg

D. Had this patient been administered intravenous nitroglycerin within four hours prior to the event? ---------- (1) Yes (2) No (3) Unknown ITEM17D

If YES, answer items D1.

If NO or UNKNOWN, skip to item 18.

D1. Maximum continuous infusion: --------- _ _ _ _ µg/min

18. Cardiovascular stability:

A. Within four hours prior to the event did the patient experience profound hypotension (systolic BP < 80 mm Hg)? -------- (1) Yes (2) No (3) Unknown ITEM18A

B. Within four hours prior to the event did the patient experience fluctuations (positive or negative) in systolic blood pressure ≥ 60 mm Hg? ---------- (1) Yes (2) No (3) Unknown ITEM18B

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) Yes (2) No (3) Unknown ITEM18C

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) ITEM19
Disoriented and/or confused ---------- (2)
Inappropriate words ---------- (3)
Incomprehensible sounds ---------- (4)
None ---------- (5)
Untested ---------- (6)

20. Eye opening:

Spontaneous ---------- (1) ITEM20
To speech ---------- (2)
To pain ---------- (3)
None ---------- (4)
Untested ---------- (5)

"21. Motor response:

Obeys ---------- (1) TRM2
Localizes ---------- (2)
Withdraws ---------- (3)
Abnormal flexion ---------- (4)
Abnormal extension ---------- (5)
None ---------- (6)
Untested ---------- (7)

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) Yes (2) No (3) 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) Yes (2) No (5) Unknown

25. Is one muscle group weaker than the others? ------- (1) Yes (2) No (3) 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) Yes (2) No (3) 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) Yes (2) No (3) Unknown

ID No.

28. Sensory deficits (pin test):

None ---------- (1)
Left sided ---------- (2)
Right sided ---------- (3)
Crossed deficit ---------- (4)
Both sides ---------- (5)
Untested ---------- (6)

If NONE or UNTESTED, skip to 30.

*A. Related to present event? ---------- (1) Yes (2) No (3) Unknown

29. Is one sensory area more severely affected than all others? ---------- (1) Yes (2) No (3) Unknown

If **YES,** answer A and B.

If **NO** or UNKNOWN, skip to item 30.

A. Most affected area: _____

*B. Severity:

Mild ---------- (1)
Partial, **dense** ---------- (2)
Total, dense ---------- (3)

*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) Yes (2) No (3) Unknown

*31. A. Language:

Normal ---------- (1)
Broca ---------- (2)
Wernicke ---------- (3)
Global ---------- (4)
Anomic ---------- (5)
Other ---------- (6)
unknown ---------- (7)

*B. Related to present event? ---------- (1) **Yes** (2) No (3) Unknown

32. Dysarthria:

Absent ---------- (1)
Present ---------- (2)
Unknown ---------- (3)

If **ABSENT** or **UNKNOWN**, skip to 33.

*A. Related to present event? ---------- (1) Yes (2) No (3) Unknown

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

33. Nuchal rigidity?

Absent ---------- (1)
Slight ---------- (2)
Severe ---------- (3)
Unknown ---------- (4)

34. Cervical bruit:

Absent ---------- (1)
Present ---------- (2)
Unknown ---------- (3)

If PRESENT, answer A.

If ABSENT or **UNKNOWN,** skip to 35.

A. Side ---------- (1) Right (2) Left (3) Both

35. Peripheral pulses in the foot and ankle:

Present ---------- (1)
Diminished or absent ---------- (2)
Unknown ---------- (3)

36. Other hemispheral signs (apraxia, neglect, etc.) related to present deficit?

Absent ---------- (1)
Present ---------- (2)
Untested ---------- (3)

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	Study: 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) Yes (2) No

If YES, answer 40.

If NO, skip to 41.

ID No. | | | N | | | | H

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.

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?	(1)	(2)	(3)
C. Hemichorea?	(1)	(2)	(3)
D. Aphasia only?	(1)	(2)	(3)
E. Visual field defect only?	(1)	(2)	(3)
F. Other hemisphere deficit, specify	(1)	(2)	(3)
G. Bilateral brainstem-cerebellar?	(1)	(2)	(3)
H. Unilateral brainstem-cerebellar (not lacunar)?	(1)	(2)	(3)
I. Other, specify	(1)	(2)	(3)

45. Lumbar puncture evidence of hemorrhage? ---- (1) (2) (3) (4)

Yes	No	Unknown	Not Done

ID No. [ ][ ][ ][ ][ ][ ][ ]

	Yes	No	Unknown	Not Done	
46. CT scan evidence of a lesion compatible with this event?	(1)	(2)	(3)	(4)	ITEM46

If NO, UNKNOWN, or NOT DONE, skip to 47.

A. Deep lacunar infarction < 2 cm	(1)	(2)	(3)	ITEM46A
B. Cortical infarction < 1/2 lobe	(1)	(2)	(3)	ITEM46B
C. Larger infarction	(1)	(2)	(3)	ITEM46C
D. Mottled hemorrhagic infarction	(1)	(2)	(3)	ITEM46D
E. Subarachnoid hemorrhage	(1)	(2)	(3)	ITEM46E
F. Intraparenchymal hemorrhage	(1)	(2)	(3)	ITEM46F
G. Watershed area infarction	(1)	(2)	(3)	ITEM46G
H. More than 1 infarction, old or new	(1)	(2)	(3)	ITEM46H

	Yes	No	Unknown	Not Done
47. EEG normal?	(1)	(2)	(3)	(4)

If NO, UNKNOWN, or NOT DONE, skip to 48.

A. EEG shows focal slowing compatible with stroke?	(1)	(2)	(3)

*48. Noninvasive testing shows evidence of severe stenosis or occlusion of relevant carotid?	(1)	(2)	(3)	(4)

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

	Yes	No	Unknown	Not Done
*49. Angiographic (including DSA) evidence of a cause or source of event?	(1)	(2)	(3)	(4)

If NO, UNKNOWN, or NOT DONE, skip to 50.

A.	Arteriovenous malformation	(1)	(2)	(3)
B.	**Aneurysm**	(1)	(2)	(3)
C.	Mass effect	(1)	(2)	(3)
D.	Source for embolus (e.g., ulcerated plaque, diseased valve, free clot, etc.)	(1)	(2)	(3)
E.	Stenosis ≥ 70% or occlusion:			
	(1) Relevant extra cranial artery	(1)	(2)	(3)
	(2) Relevant major cerebral stem or basilar	(1)	(2)	(3)
	(3) Relevant branch occlusion	(1)	(2)	(3)
F.	Arteritis	(1)	(2)	(3)
G.	Dissection of the arterial wall	(1)	(2)	(3)
H.	**Other**	(1)	(2)	(3)

If **YES**, answer **H1.**

If **NO** or **UNKNOWN**, skip to 50.

H1. Specify

_____

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

	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)
Partial, minor residual (2)
Partial, major residual (3)
Comatose (4)
Deceased (5)

ITEM53

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

PART VII: Diagnosis

54. Diagnosis (check one and only one primary, and as many secondary as apply):

		Primary	Secondary
A.	Not a stroke	(1)	(2)
B.	Subarachnoid hemorrhage	(1)	(2)
C.	Intraparenchymal hemorrhage	(1)	(2)
D.	Lacunar.infarction	(1)	(2)
E.	Embolic infarction	(1)	(2)
F.	Atherosclerotic infarction	(1)	(2)
G.	Other, unknown infarction	(1)	(2)
H.	Unknown type of stroke	(1)	(2)

PART VIII: Administration

55. Date form completed: _ _ - _ _ - _ _ _ _
Month Day Year

56. Signature of neurologist or physician completing this form:

_____

CC USE ONLY	
CAT SCAN	(1)
CAT SCAN Report	(2)
Other	(3)

ID No.

SEVERE NEUROLOGIC EVENT CLASSIFICATION FORM

Clinic No.	111-1
I.D. No.	111-
Form Type	

STHCAT (case)

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) Yes (2) No	ITEM4F

5. Vascular Territory Codes:

A. **Primary** ---------- __ __ ITEM5A

B. **Other** ---------- __ __ ITEM5B

C. **Other** ---------- __ __ ITEM5C

D. **Other** ---------- __ __ ITEM5D

E. **Other** ---------- __ __ ITEM5E

F. Are more than five vascular territories involved? ----- (1) Yes (2) No. ITEM5F

6. Hours from study entry to possible onset of event: ITEM6

< 12 hours ---------- (1)
12 - 23 hours ---------- (2)
24 - 71 hours ---------- (3)
≥ 72 hours ---------- (4)

7. Classes of infarct:

		Yes	No	
A.	**Lacune** ----------	(1)	(2)	ITEM7A
B.	Embolism ----------	(1)	(2)	ITEM7B
C.	Thrombosis/Atherosclerosis ----------	(1)	(2)	ITEM7C
D.	None ----------	(1)	(2)	ITEM7D
E.	unlcnown ----------	(1)	(2)	ITEM7E

8. Classes of hemorrhage:

		Yes	No	
A.	Subdural ----------	(1)	(2)	ITEM8A
B.	Parenchymatous ----------	(1)	(2)	ITEM8B
C.	Subarachnoid ----------	(1)	(2)	ITEM8C
D.	Epidural ----------	(1)	(2)	ITEM8D
E.	None ----------	(1)	(2)	ITEM8E

I.D. No.								

9. Extension(s) of hemorrhage:

		Yes	No	
A.	Subdural	(1	)(2)	ITEM9A
B.	Parenchymatous	(1)	(2)	ITEM9B
C.	Subarachnoid space	(1)	(2)	ITEM9C
D.	Epidural space	(1)	(2)	ITEM9D
E.	**None**	(1)	(2)	ITEM9E

10. Did hemorrhage occur in an infarct? (1) (2) ITEM10

11. Casual factors:

		Primary	Secondary	Not at all	
A.	**t-PA**	(1)	(2)	(3)	ITEM11A
B.	Heparin controlled according to **PTT**	(1)	(2)	(3)	ITEM11B
C.	Heparin not documented to be controlled according to PTT	(1)	(2)	(3)	ITEM11C
D.	Coumadin controlled according to PT	(1)	(2)	(3)	ITEM11D
E.	Coumadin not documented to be controlled according to PT	(1)	(2)	(3)	ITEM11E
F.	Embolism	(1)	(2)	(3)	ITEM11F
G.	Hypotension	(1)	(2)	(3)	ITEM11G
H.	Hypertension	(1)	(2)	(3)	ITEM11H
I.	Trauma	(1)	(2)	(3)	ITEM11I
J.	Aortic balloon pump	(1)	(2)	(3)	ITEM11J

11. (Continued)

	Primary	Secondary	Not at all	
K. PTCA ----------	(1)	(2)	(3)	ITEM11K
L. Surgery ----------	(1)	(2)	(3)	ITEM11L
L1. Specify _____				
M. Vascular malformation ----------	(1)	(2)	(3)	ITEM11M
M1. Specify _____				
N. Other ----------	(1)	(2)	(3)	ITEM11N
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.									

Rev 1 11/10/88

TIM1 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	MAX HR	ECG Changes	Angina	Exercise Response
≤ 2	Yes	Marked	Yes	Severe
≤ 2	Yes	Moderate	Yes	Severe
≤ 2	Ye5	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	Ischemlc
≤ 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 ≥ 1 mm horizontal or down sloping
2. STD ≥ 1.5 upsloping
3. STE ≥ 1 in non Q only if Bruce Stage ≥ 3

B. Marked ECG changes (any one of 3 criteria)

1. STD ≥ 1.5 horizontal or down sloping
2. STD ≥ 2.0 upsloping
3. STE ≥ 1 in non Q If Bruce Stage ≤ 2

(OVER)

TIMI PHASE II
THROMBOLYSIS IN MYOCARDIAL INFARCYION

ONE YEAR TREADMILL EXERCISE TEST FORH

Clinic No.												
ID No.												
Form Type	E	T	0	1								

1. Patient's NAME CODE:

\- - - - -

2. Date of study: F40DAYS (calc)

Month Day Year

3. Protocol **followed** (check one) :

Modified Bruce - initial stage 0 ——— (1)

Modified Bruce - initial stage 1/2 ——— (2)

Standard Bruce - initial stage 1 ——— (3)

4. Complications (within two hours of ETT)? ——— (1) Yes (2) No

If YES, answer item (A).

If NO, skip to item 5.

(A) Check all that apply

1. Unstable angina ——— (1)
2. MI ——— (1)
3. CHF ——— (1)
4. VT ——— (1)
5. VF ——— (1)
6. Death ——— (1)

5. Reasons for stopping (check one **Primary and,** if necessary, one **Secondary)** REASYR

		Primary	Secondary
A.	Cheat pain ———	(1)	(1)
B.	ST-segment change --	(1)	(1)
C.	**Arrhythmia-** supraventricular ———	(1)	(1)
D.	Arrhythmia- ventricular ———	(1)	(1)
E.	Hypertension ———	(1)	(1)
F.	Hypotension ———	(1)	(1)
G.	**Fatique/exhaustion** ——	(1)	(1)
H.	Dyspnea ———	(1)	(1)
I.	Dizziness ———	(1)	(1)
J.	Poor motivation ———	(1)	(1)
K.	Physician's request -	(1)	(1)
L.	Patient completed protocol ———	(1)	(1)
M.	Adequate HR achieved ———	(1)	(1)
N.	Claudication ———	(1)	(1)

ID No.												

6. **Is the patient taking any o f the following cardiovaaoular 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:** TTIMEYR
____ secs.

8. **Final stage entered (check one):** FSTAGEYR

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:** PMAXHRYR ___ %

10. Vital signs at:

A. **Rest:** RSTHRYR RSTSBPYR/RSTDBPYR
Heart Rate Systolic BP Diastolic BP

B. **Peak exercise:** EXHRYR EXSBPYR, EXDBPYR
Heart Rate Systolic BP Diastolic BP

C. **Three minutes reoovery:** RECHRYR RECSBPYR, RECDBPY R
Heart Rate Systolic BP Diastolic BP

11. **Did chest pain occur during ETT?** EXPAINYR (1) Yes (2) No

If YES, answer item (12).
If NO, skip to item 13.

(12) Type of chest pain: PAINTYR
Angina (1)
Atypical chest pain (2)

13. **Did a fall in the systolic blood pressure occur during exercise?** SBPDECYR (1) Yes (2) No

If YES, answer item (14).
If NO, skip to item 15.

(14) **By how much?** SBPMCHYR ___ mmHg

15. **Did the resting ECC show any** of the following:

	Yes	No
A. LBBB	(1)	(2) LBBBYR
B. RBBB	(1)	(2) RBBBYR
C. LVH	(1)	(2) LVHYR
D. ST-segment elevation (≥ 1 mm)	(1)	(2) STEVR

16. **Was there abnormal ST-segment depression at rest?** (1) Yes (2) No RSTSTDY

If YES, answer item (17).
If NO, skip to item 18.

(17) **How much?** __.__ mm STDMCHYR

ID No.

18. Did **ischemic** ST-segment depression (≥ 1 mm below baseline) occur during or following exercise? (1) Yes (2) No EXSTDYR

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 (mm)	Configuration (1, 2, or 3)
A. During exercise	EXSTDPYR .	EXCFYR
B. During recovery	RCSTDYR .	RECCFYR

(20) Exercise stage at the onset of ischemic (≥ 1 mm) ST-segment depression (O-7): ONSTGYR

(21) Number of leads with **ischemic** (≥ 1 mm) ST-segment depression: STDLDYR

22. Did ST-segment elevation (≥ 1 mm above baseline) occur during or following exercise? (1) Yes (2) No EXSTEYR

If YES, answer item (23). If NO, skip to item 24.

(23) If YES, what was the maximum ST-segment elevation acoordlng to **the following?**

	(mm)
A. **Q-wave lead**	STEQYR .
B. **Non Q-wave** lead	STENQYR .

24. **Did any** of **the following** arrhythmias occur during the study? (Check all that apply)

	None	Rest	Exercise	Recovery
A. Isolated (< 10/min) PVCs	(1)	(1)	(1)	(1)
B. Frequent (≥ 10/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) Yes (2) No

ID No. _____

[*] **27.** Did the **patient** experience en ischemic response? ——— (1) (2)
Yes No

[*] **28.** **Did** the patient experience a **severe ischemic** response? — (1) (2)
Yes No

29. Wee 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 __ __ Dey ____ **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 Catheteri-**zrtlon **Procedures** Form **(TIMI** Form **7C).**

(A) Dete 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)

RESULTYR (calc.)

ID No.

TIMI PHASE II
THROMBOLYSIS IN MYOCARDIAL INFARCTION

TIMI II Form 41
Rev 1 12/07/88

TREADMILL EXERCISE TEST NON-PERFORHANCE FORM

Clinic No.				U										
ID No.				H								H		
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.** F41REAS

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 HYOCARDIAL 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/MIDATE2/MIDATE3(calc)

Month Day Year

Military time — Hours Minutes (1) Unknown

PART II: Event Classification

3. Classlficatfon 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)

	Yea	No
B. Did the patient meet enzyme criteria?	(1)	(2)
C. Did the patient meet ECC criteria?	(1)	(2)

4

D. Classification of event: MMCCMI(calc)

Nonfatal myocardial infarction ——— (1)
Recurrent ischemic event ——— (2)
No recurrent ischemia ——— (3)

Skip to item 7.

6. MMCC classification for event_> 18 hours: FATALMI / NONFATAL I'

A. Is this reported event a nonfatal myocardial infarction? (check one) MITYPE(calc)

(1) Yes (2) No

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) Yes (2) No

B. Reason(s) this event came to the full committee:

_____

_____

C. Reason(s) for final classification:

_____

_____

ID No.														
Form Type	R	C												

a. Ware the contents of the narrative letter revealed to the committee? ——— (1) Yes (2) No

If YES, answer Item 9.

If NO, skip to Item 11.

9. Dfd this letter reveal treatment assignment? ——— (1) Yes (2) No

Skip to item 11.

10. Specify information required for full committee to completa 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 rquirad e.g., ECG dates and times: enzyme assay dates, times and upper limits of normal; etc.

PART III: Administrative Hatters

11. MMCC Chairman's Signature:

12. Data form cwplatad:

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						

TIMI PHASE II

THROMBOLYSIS IN HYOCARDIAL INFARCTION
HEMORRHAGIC EVENT CLASSIFICATION FORM

TIMI II Form 44
Rev 1 04/28/87
1 Page

Clinic No.													
ID No.													
Form Type	H	C											

PART I: Event Identification

1. Patient's NAME CODE:

2. Date hemorrnagic event occurred: HEMTIME (calc) HEMTIMEI-9

Month ___ Day ___ Year ___

Military time: ___ ___ : ___ ___
Hours Minutes

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):

tlajor (1)
Minor (2) HEMSEV (calc)
None (3) SEVTOT1-4 (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 tnla blood loss associated witn surgical therapy for this &lent (e.g., coronary artery by-pass grafting, abdominal surgery, etc.)? Yes (,) No (2)

5. Locatlon

A. Primary (check one): HEMPRIM1-9

Caatrolnteatlnal (1)
Intracranial (2)
Catheterization site (3)
Other puncture site(s) (4)
Genitourinary (5)
Retroperitoneal (6)
Other, specify (7)

Unknown (8)

HEMPRIM (calc)

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. Retroperltoneal (1)
7. Other, specify (1)

8. Unknown (1)

6. Inducement to bleeding:

Spontaneous (1)
Nonapontaneoua (2)

7. APTT results:

A. Number of APTT measurements greater than 2 1/2 times normal prior to hemorrnagic event ___

B. Number of APTT measurements made prior to hemorrnagic event ___

8. Timing:

Did this event start leas than 24 hours after study therapy? (1) Yea (2) No LT24_1-9

PART III: Administrative Matters

9. HERC Chairman:

Signature ___

10. Date form completed:

Month ___ Day ___ Year ___

11. Aadltlonal Information requested? (1) Yea (2) No

If YES, speolfy ___

CC USE ONLY

12. Basis for Form 44 Status:
Full HERC (1)
Two Reviewers Congruent (2)