(9-67)

CDP Form 01

P	T
V	R
	B

ADMISSION FORM

I.D. No.

Parts I and II of this form may be completed any time before or during Initial Visit 1 (I. V. 1). Parts III through VIII should be completed during Initial Visit 1 and Part IX during Initial Visit 2. If a check is made in any space on this form designated "STOP", the patient may be ineligible for the CDP. No further work should be done on the patient until the STOP condition is removed. Do not use red ink or pencil on this form. A completed copy of this form should be retained for your files.

Part I: Identifying Information

Complete this part before or during Initial Visit 1

1) Name: _____ 13-32
First Middle Last

2) Address: _____
Street and No.

_____
City State Zip code

3) Home telephone number: ..... _____

If NONE, check here: ..... ( )

4) Has the Orientation Session been held (see Manual of Operations for details) and has the patient signed the Patient Consent Form (CDP Form 07) or an equivalent consent form? ..... ( ) Yes (STOP) No

5) Does the patient have a private physician? ( ) Yes ( ) No

If *YES*, give his name and address:

Name: _____

Address: _____

6) Is the patient now employed? ..... ( ) Yes ( ) No

If *YES*, give the name and address of his employer:

Name: _____

Address: _____

_____ Phone: _____

7) Give the name, address and telephone number of two people (do not list other members of the patient's household) who are likely to know the patient's whereabouts at all times:

Name: _____

Address: _____

_____ Phone: _____

Name: _____

Address: _____

_____ Phone: _____

8) Does the patient own a car? ..... ( ) Yes ( ) No

If *YES*, in which state is it registered? ..... _____

9) Social Security No: _____

If *NONE* or unavailable, check here: ..... ( )

10) Veterans Administration Claim Number: ..... _____

If *NONE* or unavailable, check here: ..... ( )

11) Hospital Serial No.: ..... _____

If *NONE* or unavailable, check here: ..... ( )

12) Will the patient be at least 30 but less than 65 years of age at the time of Initial Visit 3? ..... ( ) Yes (STOP) No 33

13) Birthdate: _____ _____ _____ 34-39
Month Day Year

14) Sex: ..... ( ) Male (STOP) Female 40

15) Race (see Manual of Operations for definitions):

White ..... (1) 41
Negro ..... (2)
Other ..... (3)

16) Marital status (check one):

Never married ..... (1) 42
Married ..... (2)
Divorced ..... (3)
Widowed ..... (4)
Separated ..... (5)

If MARRIED, DIVORCED, or SEPARATED, give full name of wife (or ex-wife) and her address (if different from that given in item 2):

Name: _____

Address: _____

17) Number of living children: ..... _____ 43–44

Part II: Coronary Artery Disease History

Complete this part before or during Initial Visit 1.

18) Has the patient ever had surgery for coronary artery disease? ..... (STOP Yes) ( ) 45 No

19) Does the patient belong to Class III or IV of the New York Heart Association classification (see Manual of Operations for definitions)? ..... (STOP Yes) ( ) 46 No

20) Diagnostic criteria for a previous myocardial infarction.

In order for a patient to be eligible for this study he must have had a myocardial infarction at least three months prior to the date of Initial Visit 3, or at least one month prior to Initial Visit 1.

In order for the diagnosis of a previous myocardial infarction to be substantiated for this patient, he must *either* have an ECG which fulfills one of the QRS criteria listed in items A through Q below, *or else* have an ECG which shows ST-T wave or T wave changes *along with* a clinical history *and* SGOT changes indicative of a myocardial infarction (item R below).

The ECG which shows the diagnostic changes induced by an infarction is termed the *qualifying ECG.*

Start with item A and consider the criteria in order, one by one. If the ECG under consideration does not fulfill criterion A, proceed to consideration of B, and so forth, until you find a criterion that is unequivocally fulfilled. Place a check opposite that criterion item and proceed to item 21.

If the tracing for only a single cardiac cycle fulfills a particular criterion, consider this an artifact, or an expression of beat-to-beat variation, and do not report the ECG tracing as fulfilling that criterion.

The amplitude of a Q wave must be 0.1 mV or more, associated with an R wave of 0.1 mV or more in the same lead, in order to qualify, except for items F, G, N, and Q.

A) Q amplitude is equal to or greater than 1/3 of R amplitude, *and* Q duration is 0.03 seconds or more in *any* of leads I, II, V_2, V_3, V_4, V_5, V_6 ..... (1) 47–48

Item 20 continued:

B) Q duration is 0.04 seconds or more in *any* of leads I, II, V_1, V_2, V_3, V_4, V_5, V_6 ..... (2)

C) Q duration is 0.04 seconds or more *and* R amplitude is 0.3 mV or more in lead AVL ..... (3)

D) Q duration is 0.05 seconds or more in lead III *and* a Q wave is present in lead AVF .. (4)

E) Q duration is 0.05 seconds or more in lead AVF ..... (5)

F) QS pattern, when R wave is present in the adjacent precordial lead to the right, in *any* of leads V_2, V_3, V_4, V_5, V_6 ..... (6)

G) QS pattern in *all* of leads V_1 through V_4, or *all* of leads V_1 through V_5, or *all* of leads V_1 through V_6 ..... (7)

H) Q amplitude is 1/5 to 1/3 of the R amplitude, *and* Q duration is 0.03 seconds or more in *any* of leads I, II, V_2, V_3, V_4, V_5, V_6 ..... (8)

I) Q duration is 0.03 to 0.04 seconds in *any* of leads I, II, V_2, V_3, V_4, V_5, V_6 ..... (9)

J) Q duration is 0.03 to 0.04 seconds *and* R amplitude is 0.3 mV or more in lead AVL (10)

K) Q duration is 0.04 to 0.05 seconds in lead III *and* a Q wave is present in lead AVF .. (11)

L) Q duration is 0.04 to 0.05 seconds in lead AVF ..... (12)

M) Q amplitude is 0.5 mV or more in *any of* leads III, AVF ..... (13)

N) QS pattern *and* absence of left bundle branch block (defined below) in *all* of leads V_1, V_2, V_3 ..... (14)

Left bundle branch block: QRS duration is 0.12 seconds or more in *any* of leads I, II, III *and* R peak duration is 0.06 seconds or more in *any* of leads I, II, AVL, V_5, V_6.

P) Decreasing absolute R amplitude, *and* smallest R of 0.2 mV or less, *and* absence of patterns 1 and 2 (defined below) in *all* of leads V_1 through V_3 or in *all* of leads V_1 through V_4 ..... (15)

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Item 20 continued:

Pattern 1: Right high amplitude R waves: QRS duration less than 0.12 seconds *and* R amplitude of 0.5 mV or more *and* an R/S ratio of 1.0 or more *and* QRS transition zone or decreasing R/S to left of V_3 in the tracing for lead V_1. (Includes incomplete right bundle branch block which meets these criteria.)

Pattern 2: Complete right bundle branch block (QRS duration of 0.12 seconds or more in *any* of leads I, II, III *and* R prime greater than R in lead V_1) or incomplete right bundle branch block (R prime greater than R *and* QRS duration less than 0.12 seconds in V_1).

Q) Q duration is 0.04 seconds or more *or* a QS pattern is present in *any* ancillary lead (that is, any lead other than I, II, III, AVR, AVL, AVF, V_1, V_2, V_3, V_4, V_5, V_6 in their standard positions) ..... (17)

R) On the basis of clinical history, *and* SGOT changes, *and* ST-T wave or T wave changes, a diagnosis of myocardial infarction is substantiated (see Manual of Operations for details) ..... (18)

S) It is not possible to check any of the above items ..... (STOP)

21) Write the date of the qualifying ECG on the line below:

_____ Month _____ Day _____ Year 49–54

If a check mark was placed after item 20-R, answer items A through E below relative to the episode which resulted in a diagnosis of myocardial infarction:

A) Highest SGOT recorded (state units): .. _____ 55
If not done, check here: ..... (STOP)

B) Highest LDH recorded (state units): .... _____ 56
If not done, check here: ..... ( )

C) Highest sedimentation rate recorded (mm/hr): ..... _____ 57

If not done, check here: ..... ( )

D) Highest WBC recorded (cells per mm^3): _____ 58
If not done, check here: ..... ( )

E) Briefly indicate the clinical symptoms of myocardial infarction which were exhibited by the patient:

_____ 59

_____

_____

_____

Item 21 continued:

F) Date of M.I. (item deleted, please omit) 60–63

22) Is there evidence suggesting that the qualifying infarction was caused by a condition other than atherosclerotic coronary artery disease, such as dissecting aortic aneurysm or shock? ..... (STOP) Yes ( ) No 64

23) Give your estimate of the total number of myocardial infarctions the patient has had: ..... _____ 65–66

24) Was there evidence of any of the following during *any one* of the myocardial infarctions of the patient (answer each question):

	Yes	No	
A) Sustained arrhythmia (not merely premature contractions)?	( )	( )	67
B) Shock or cardiac arrest?	( )	( )	68
C) Acute congestive heart failure?	( )	( )	69
D) Extension of infarction?	( )	( )	70
E) Pericardial friction rub?	( )	( )	71
F) Thromboembolism?	( )	( )	72

25) Risk group (item deleted, please omit) 73

26) Give the month and year of the patient's *first* myocardial infarction (if the month is unknown give only the year; if the year is unknown put a check mark in the space indicated below):

_____ Month _____ Year (88) Year Unknown 74–77

27) Give the month and year of the patient's *last* myocardial infarction (if the month is unknown give only the year; if the year is unknown put a check mark in the space indicated below):

_____ Month _____ Year (88) Year Unknown 13–16

The date given in item 27 must be at least one month prior to the date of Initial Visit 1.

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INITIAL VISIT 1

Parts III through VIII of this form should be completed during Initial Visit 1.

This examination should not be performed if the patient has had a myocardial infarction within the past month.

The patient should arrive for this visit in a fasting state (described in the Manual of Operations and in the Dietary Instruction Sheet, Form 12-A). This visit, or at least the collection of the serum and plasma specimens, *must* be made in the *morning*.

A 70 ml. *fasting* blood sample should be obtained from the patient as soon as he arrives for this visit. He should then be given a solution containing 75 gm. of glucose to drink. A 10 ml. blood sample should be obtained one hour following the glucose challenge. Further details are given in Part V of this form.

Also required during this visit are the following: A P-A chest x-ray (if not done within the past six months); a urine specimen (for glucose and protein tests done locally); and an additional blood specimen (for hematocrit, white blood cell count, and differential done locally).

Part III: Medical History

28) Since the patient's *last* myocardial infarction, has he had any significant episodes of cardiac pain, aching, tightness, or pressure in the chest? ..... (Yes) (No) 17

If *NO*, proceed to item 29.

If *YES*, answer items A through E below:

A) Does the pain typically radiate (check only one)?

- Does not radiate ..... (1) 18
- Radiates to the left neck, jaw, shoulder, or arm ..... (2)
- Radiates to areas other than the left neck, jaw, shoulder, or arm ..... (3)
- Radiates to the left neck, jaw, shoulder, or arm *and* to other areas ..... (4)

B) How much exertion would it typically take to precipitate such an episode (check only one)?

- Walking at less than ordinary pace ..... (1) 19
- Walking at an ordinary pace ..... (2)
- Walking hurriedly or uphill, or climbing stairs ..... (3)
- Not related to exertion ..... (4)

C) Can excitement, emotion, or meals precipitate such an episode? ..... (Yes) (No) 20

D) Does rest typically relieve such an episode?

- Not at all ..... (1) 21
- After more than 10 minutes ..... (2)
- In less than 10 minutes ..... (3)
- Rest not used ..... (4)

E) Does nitroglycerin typically relieve such an episode?

- Not at all ..... (1) 22
- After more than 10 minutes ..... (2)
- In less than 10 minutes ..... (3)
- Nitroglycerin not used ..... (4)

29) Has the patient ever had any of the following (answer each question):

	Yes	No	
A) Cardiac asthma?	( )	( )	23
B) An obvious stroke?	( )	( )	24
C) Weakness or paralysis of any part of his body?	( )	( )	25
D) Spells of fainting or blacking out?	( )	( )	26
E) Spells of dizziness?	( )	( )	27
F) Sudden pain or coldness of a foot or leg?	( )	( )	28

30) Does the patient have pains or cramps in his legs when he walks? ..... (Yes) (No) 29

If *YES*, is the pain quickly relieved when he stops walking? ..... (Yes) (No) 30

31) Has the patient *EVER* had any episodes of gouty arthritis? ..... (Yes) (No) 31

If *YES*, how frequently does he have them now?

- Not at all ..... (1) 32
- Less than once a year ..... (2)
- About once a year ..... (3)
- About twice a year ..... (4)
- More than twice a year, but not continuously (5)
- Continuously ..... (6)

32) How many *CIGARETTES* does the patient now smoke per day?

- None ..... (1) 33
- 1 to 10 ..... (2)
- 11 to 20 ..... (3)
- 21 to 30 ..... (4)
- 31 to 40 ..... (5)
- More than 40 ..... (6)

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33) Is the patient presently employed (see Manual of Operations)? ..... ( ) Yes ( ) No [34]

If *YES*, answer items A through D below:

A) How extensively? ..... ( ) Full Time ( ) Part Time [35]

B) Give job title or a brief (6 words or less) description of his work:

_____

_____

C) Which one of the following items best describes the physical nature of his work?

Sedentary ..... (1) [36]
Light physical work ..... (2)
Moderate physical work ..... (3)
Heavy physical work ..... (4)

D) To which of the occupation groups listed below does he belong (check only one; see Manual of Operations for definitions)?

Professional, technical worker ..... (1) [37-38]
Manager, official, proprietor ..... (2)
Craftsman, foreman ..... (3)
Clerical worker ..... (4)
Sales worker ..... (5)
Operative ..... (6)
Service worker ..... (7)
Laborer ..... (8)
Farmer ..... (9)

34) Has the patient ever been forced to change to less strenuous or stressful employment because of his coronary heart disease? ..... ( ) Yes ( ) No [39]

If *YES*, answer items A through C below concerning his employment just prior to that change:

A) How extensively employed? ..... ( ) Full Time ( ) Part Time [40]

B) Give job title or a brief (6 words or less) description of his work at that time:

_____

_____

Item 34 continued:

C) Which one of the following items best describes the physical nature of that work?

Sedentary ..... (1) [41]
Light physical work ..... (2)
Moderate physical work ..... (3)
Heavy physical work ..... (4)

35) Apart from employment, what degree of physical activity does the patient habitually engage in now?

Light ..... (1) [42]
Moderate ..... (2)
Vigorous ..... (3)

36) Apart from employment, what degree of physical activity did the patient habitually engage in just prior to any changes necessitated by coronary heart disease?

Light ..... (1) [43]
Moderate ..... (2)
Vigorous ..... (3)

Part IV: Physical Examination

37) Height (to nearest *INCH*, without shoes): _____ [44-45]

38) Weight (to nearest *POUND*, with all heavy outdoor garments and shoes removed): ..... _____ [46-48]

39) Casual blood pressure (with the patient lying down or, if sitting, with forearm at the level of the heart):

Systolic (in mm. Hg.): ..... _____ [49-51]

Diastolic (in mm. Hg.) at the disappearance of sound: ..... _____ [52-54]

40) Heart rate (per min.): ..... _____ [55-57]

41) Is the rhythm regular? ..... ( ) Yes ( ) No [58]

42) Are any of the following findings present:

A) Peripheral edema? ..... ( ) Yes ( ) No [59]

B) Ventricular diastolic gallop? ..... ( ) Yes ( ) No [60]

C) Rales? ..... (1) Dry (2) Moist (3) Not Present [61]

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43) Is the thyroid normal? ..... (3) Not Palpable (1) Yes (2) No 62

If *NO*, answer items A and B below:

A) Is it nodular (check one)?
Not nodular ..... (1) 63
Has one or two solitary nodules ..... (2)
Multinodular ..... (3)

B) Is it diffusely enlarged? ..... (Yes) (No) 64

44) Answer the following questions about the liver:

A) Enlarged? ..... (Yes) (No) 65

B) Firm? ..... (3) Not Palpable (1) Yes (2) No 66

C) Tender? ..... (3) Not Palpable (1) Yes (2) No 67

45) Is the spleen palpable? ..... (Yes) (No) 68

46) Any tenderness in the costovertebral angle? ..... (Yes) (No) 69

( ) Is the prostate normal? .... (4) Not Examined (3) Surgically Absent (1) Yes (2) No 70

If *NO*, answer items A through D below:

	Yes	No	
A) Is it enlarged?	( )	( )	71
B) Is it hard?	( )	( )	72
C) Is it tender?	( )	( )	73
D) Does it have one or two nodules? ..	( )	( )	74

48) Are the testes normal? ..... (Yes) (No) 75

If *NO*, specify: _____

_____

49) Peripheral pulses (answer each item):

(Nor. = Normal; Dim. = Diminished; Abs. = Absent or not palpable; L.M. = Limb missing.)

	Nor.	Dim.	Abs.	L.M.	
A) Right femoral	(1)	(2)	(3)	(4)	13
B) Left femoral	( )	( )	( )	( )	14
C) Right popliteal	( )	( )	( )	( )	15
D) Left popliteal	( )	( )	( )	( )	16
E) Right dorsal pedis ..	(1)	(2)	(3)	(4)	17
F) Left dorsal pedis	( )	( )	( )	( )	18
G) Right posterior tibial	( )	( )	( )	( )	19
H) Left posterior tibial ..	( )	( )	( )	( )	20

50) Are any of the following findings present:

	Yes	No	
A) Ichthyosis?	( )	( )	21
B) Acanthosis Nigricans?	( )	( )	22
C) Hyperpigmentation of the skin?	( )	( )	23
D) Gynecomastia?	( )	( )	24
E) Breast masses?	( )	( )	25
F) Exophthalmia?	( )	( )	26
G) Marked finger tremor?	( )	( )	27
H) Warmer and more moist skin than normal?	( )	( )	28
I) Icterus of sclera and/or skin?	( )	( )	29
J) Vascular spiders?	( )	( )	30
K) Visible collateral veins on abdomen or chest?	( )	( )	31

51) Any dermatologic ailment *not* already mentioned above? ..... (Yes) (No) 32

If *YES*, specify: _____

_____

52) Are any of the following gout indicators present:

	Not Known	Yes	No	
A) Hyperuricemia?	(3)	(1)	(2)	33
B) Bony erosions?	(3)	(1)	(2)	34
C) Podagra?		( )	( )	35
D) Tophi?		( )	( )	36
E) Urinary stones?		( )	( )	37

The findings reported in item 53 must relate to a P-A chest x-ray taken within six months of this visit.

53) Are the chest x-ray findings normal? .... (Yes) (No) 38

If *NO*, answer items A through D below concerning the findings:

A) Cardiomegaly?
No ..... (1) 39
Probable ..... (2)
Definite ..... (3)

B) Pleural effusion? ..... (Yes) (No) 40

C) Pulmonary congestion? ..... (Yes) (No) 41

D) Other findings (specify)? ..... (Yes) (No) 42

_____

_____

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54) On the basis of this physical examination and available laboratory data, is there indication of any noteworthy abnormality in the following systems:

	Yes	No	
A) Gastrointestinal?	( )	( )	43
B) Genitourinary?	( )	( )	44
C) Nervous?	( )	( )	45
D) Musculoskeletal?	( )	( )	46
E) Dermal?	( )	( )	47
F) Bronchopulmonary?	( )	( )	48

55) On the basis of the physical examination, medical history, and available laboratory data, are any of the following excluding conditions present:

	Yes	No	
A) Significant chronic renal disease?	(STOP)	( )	49
B) Significant chronic hepatic disease?	(STOP)	( )	50
C) Malignancy?	(STOP)	( )	51
D) Pulmonary insufficiency?	(STOP)	( )	52
E) Malignant hypertension?	(STOP)	( )	53
F) Hypothyroidism or hyperthyroidism?	(STOP)	( )	54
G) Hypogonadism?	(STOP)	( )	55
H) Present or past mammary malignancy?	(STOP)	( )	56
I) Active gastric or duodenal ulcer?	(STOP)	( )	57
J) Any other disease or condition which may be regarded as a contraindication for treating the patient with one or more of the drugs under study?	(STOP)	( )	58
K) Any other disease or condition other than coronary heart disease which makes his five year prognosis poor?	(STOP)	( )	59

Part V: Blood and Urine Specimens

A 70 ml. *fasting* blood sample should be obtained as soon as the patient arrives at the clinic for this visit. The patient is then given a solution containing 75 gm. of glucose to drink. A 10 ml. blood sample is obtained one hour following the glucose challenge.

At least 17.5 ml. of fasting serum should be obtained from 60 ml. of the fasting blood sample, and five vials (numbered 1, 2, 3, 4, and 6) should be filled with 3.5 ml. of serum each.

Three ml. of *fasting plasma* are obtained from the remaining 10 ml. of the fasting blood sample and placed in vial number 7. Also, 3 ml. of *1-hour post-challenge plasma* are obtained from the 10 ml. post-challenge blood sample and placed in vial number 8.

Each of the seven vials should be sealed and labeled with the following information:

Complete specimen identification number (consisting of patient identifying number, visit number, and vial number); patient's name; and month, day, and year of collection.

The vials should be immediately frozen and then shipped within a week to the CDP Central Laboratory in Atlanta.

See the Central Laboratory Manual for detailed instructions concerning collection, handling, and shipping of the serum and plasma specimens.

56) Date and time fasting blood specimen obtained:

Month	Day	Year	Hour	
_____	_____	_____	_____	60–67

The three laboratory test results listed below in items 57 through 59 may be based on blood drawn and analyzed in your laboratory either at this visit or within three months prior to this visit.

Recommended admissibility limits for these tests are the following:

Hematocrit	Above 38%
White blood cell count	Above 3500/mm³
Absolute neutrophil count	Above 2000/mm³

If the patient has one or more values outside the recommended limits, it is the investigator's responsibility to weigh these results with other existing information to determine whether this patient should be entered into the study.

57) Hematocrit (in %): ..... _____ 68–69

58) White blood cell count (cells per mm³): _____ 70–74

59) Absolute neutrophil count (cells per mm³): ..... _____ 13–17

A urine specimen should be obtained from the patient during this visit and the tests indicated in items 60 and 61 below performed locally.

60) Urine glucose (use Ames Clinistix): .... (+) (−) 18

61) Urine protein (use Ames Clinistix):
(1) Negative (2) Trace (3) 1+ (4) 2+ (5) 3+ (6) 4+ 19

Part VI: Medication History

62) During the month preceding Initial Visit I, has the patient been on, or is he currently on, any one of the following: A cholesterol lowering drug, a thyroid hormone preparation, a thyroid suppressant, an estrogen preparation, or an androgen preparation? .... (STOP) Yes ( ) No 20

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63) Are any of the following drugs or types of drugs currently being prescribed for the patient (answer each question):

	Yes	No	
A) Insulin?	(STOP)	( )	21
B) Oral hypoglycemic agents?	( )	( )	22
C) Digitalis?	( )	( )	23
D) Antiarrhythmic agents?	( )	( )	24
E) Diuretics?	( )	( )	25
F) Antihypertensives other than diuretics?	( )	( )	26
G) Nitroglycerin or other coronary dilators?	( )	( )	27
H) Gout medication?	( )	( )	28
I) Anticoagulants?	(STOP)	( )	29
J) Other (specify)?	( )	( )	30

Part VII: Clinical Summary

64) In your best judgment (based on the history, physical examination, and any available laboratory data) has the patient *EVER* had any of the following (answer each question):

	Suspect	Yes	No	
A) Congestive heart failure?	(3)	(1)	(2)	31
B) Angina pectoris?	(3)	(1)	(2)	32
C) Acute coronary insufficiency?	(3)	(1)	(2)	33
D) Intermittent cerebral ischemic attacks?	(3)	(1)	(2)	34
E) Stroke?	(3)	(1)	(2)	35
F) Intermittent claudication?	(3)	(1)	(2)	36
G) Peripheral arterial occlusion?	(3)	(1)	(2)	37
H) Gout?	(3)	(1)	(2)	38

Part VIII: Summary of Initial Visit 1

65) Do you feel that the patient is properly motivated for and capable of long term participation in the CDP? ..... ( ) Yes (STOP) No 39

66) On the basis of all the information obtained on the patient up to this point, do you consider the patient eligible for the CDP? ..... ( ) Yes (STOP) No 40

67) If no "STOP" conditions have been checked up to this point, the permanent identifying number (I.D. No.) should now be issued. The number, as obtained from the Permanent CDP Patient Identifying Number List furnished your clinic, is .. _____

This number should be written also in the box in the upper right hand corner of page 1 of this form, and in the box in the lower right hand corner of each of the other pages of this form.

If no "STOP" conditions have been checked up to this point, treatment with (placebo) capsules from bottle 99 should now be initiated. The patient should be given a sufficient supply to last until his return for Initial Visit 2 one month later. He should be instructed to take 3 capsules per day, one after each meal.

An appointment for Initial Visit 2, one month following Initial Visit 1, should be set prior to the conclusion of this visit.

The patient should be instructed to arrive for Initial Visit 2 in a fasting state and should be given the appropriate Dietary Instruction Sheet (Form 12-A). Initial Visit 2, or at least the collection of the serum and urine specimens, *must* be made in the *morning*.

The patient should be asked to return all his remaining capsules at the next visit. He should also be instructed not to take any capsules on the day of the next visit.

* * * * * * * * * * * * *

Part IX: Initial Visit 2

This part should be completed during Initial Visit 2. If this visit is not completed within three months following the date of Initial Visit 1, the patient must start anew with Initial Visit 1. If the patient has had a new myocardial infarction since Initial Visit 1, he should not complete Initial Visit 2 at this time, but rather should wait until at least one month passes since his latest episode and then start anew with Initial Visit 1.

During this visit a 40 ml. *fasting* blood sample should be obtained from the patient. At least 14 ml. of serum should be obtained from this specimen and four vials (numbered 1, 2, 5, and 6) should be filled with 3.5 ml. of serum each. Note that vial numbers 3 and 4 are not used.

Each of the four vials should be sealed and labeled with the following information:

Complete specimen identification number (consisting of patient identifying number, visit number, and vial number); patient's name; and month, day, and year of collection.

A urine specimen also should be obtained from the patient during this visit. A shipping vial (numbered 9) should be filled with about 6 ml. of urine. This vial should be sealed and labeled with the following information:

Complete specimen identification number; total volume of voided specimen; time of the collection and approximate time of last voiding; and approximate number of hours since the patient's last drug dose.

The serum and urine vials should be immediately frozen and then shipped within a week to the CDP Central Laboratory in Atlanta. See the Central Laboratory Manual for detailed instructions concerning collection, handling, and shipping of the serum and urine specimens.

68) Date and time blood specimen obtained:

Month	Day	Year	Hour
			41-48

I.D. No.

69) BSP (item deleted, please omit) 49-55

An assessment of the patient's adherence to the prescribed placebo medication since Initial Visit 1 is made by means of items 70 through 75.

70) How many capsules have been issued to the patient at and since Initial Visit 1? .. _____

71) How many capsules has the patient returned at this visit? ..... _____

72) Approximately how many capsules have been either left at home or lost or accidentally destroyed? ..... _____

73) Approximately how many capsules do you judge the patient has taken since Initial Visit 1 (obtain this number by subtracting items 71 and 72 from item 70 and tempering the result with any other information or impressions obtained from the patient)? ..... _____

74) How many capsules should the patient have taken since Initial Visit 1 (obtain this number by multiplying the number of days between this visit and Initial Visit 1 by three)? ..... _____

75) What is the patient's percent adherence to the prescribed medication (100 times item 73 divided by item 74)? ..... _____% 56-58

76) Considering the patient's adherence to the prescription made at Initial Visit 1 as well as any other new information which has come to your attention since Initial Visit 1, do you still consider the patient eligible for the CDP? ..... (Yes) (STOP) No 59

The determinations indicated in items 77 through 79 below should be obtained during this visit.

77) Weight (to nearest *POUND*, with all heavy outdoor garments and shoes removed): ..... _____ 60-62

78) Casual blood pressure (with the patient lying down or, if sitting, with forearm at the level of the heart):

Systolic (in mm. Hg.): ..... _____ 63-65

Diastolic (in mm. Hg.) at the disappearance of sound: ..... _____ 66-68

79) Heart rate (per min.): ..... _____ 69-71

Provided no "STOP" conditions have been checked, the patient should continue taking three capsules per day of the placebo medication (bottle 99).

An appointment for Initial Visit 3, one month following Initial Visit 2, should be set prior to the conclusion of this visit. The patient should be instructed to arrive for Initial Visit 3 in a fasting state and should be given the appropriate Dietary Instruction Sheet (Form 12-A). Initial Visit 3, or at least the collection of the serum and urine specimens, *must* be made in the *morning*.

The patient should be asked to return all his remaining capsules at the next visit. He should also be instructed not to take any capsules on the day of the next visit.

Part X: Review of Initial Visit 1 Central Laboratory Data

80) Has the report of the Initial Visit 1 Central Laboratory results (Form 06) been received and reviewed by a physician? ..... (Yes) (STOP) No 72

81) On the basis of the Initial Visit 1 Central Laboratory results, is the treatment of this patient with any of the drugs under study contraindicated? ..... (STOP) Yes (No) 73

82) On the basis of the Initial Visit 1 Central Laboratory results plus any new information, do you still consider the patient to be eligible for the CDP? .... (Yes) (STOP) No 74

Part XI: Treatment Allocation Request

This part of the form may be completed as soon as all of Parts I through X have been completed.

83) Are any "STOP" conditions checked on this form? ..... (STOP) Yes (No)

If *YES*, further CDP work on this patient should be terminated until the condition is removed.

84) This form has been checked for completeness by:

_____

85) The physician who is requesting that this patient be entered in the CDP is:

Dr. _____

86) The physician who evaluated the diagnostic criteria for a previous myocardial infarction (which provided a basis for answering item 20) was:

Dr. _____

A treatment allocation may now be requested for this patient. It is done by mailing the original copy of this form to:

CDP Coordinating Center
Institute of International Medicine
660 West Redwood Street
Baltimore, Maryland 21201

The allocation will be sent within a week of receipt of this form at the Coordinating Center. Do not open the envelope containing the treatment allocation until eligibility of the patient has been reassessed at Initial Visit 3.

87) The date on which this form is being mailed to the CDP Coordinating Center is:

_____ Month _____ Day _____ Year

I.D. No.

P	T
V	R

F.V.

I.D. No.

ANNUAL FOLLOW-UP EXAMINATION FORM

This form should be completed during each of Follow-up Visits 3, 6, 9, 12, and 15. The permissible time periods for completing these visits are given in each patient's CDP Appointment Schedule, Form 11. In the event that the time period for completing this visit elapses without the visit being completed, items 1 through 5 should be completed and page 1 of this form mailed immediately to the CDP Coordinating Center. (This last instruction does not apply if the patient has officially dropped out of the study or if he is no longer living.) Do not use red ink or pencil on this form. A completed copy of this form should be retained for your files.

The patient should arrive for this visit in a fasting state (described in the Manual of Operations and in the Dietary Instruction Sheet, Form 12-A). This visit, or at least the collection of the serum and plasma specimens, *must* be made in the *morning*.

A 70 ml. *fasting* blood sample should be obtained from the patient as soon as he arrives for this visit. He should then be given a solution containing 75 gm. of glucose to drink. A 10 ml. blood sample should be obtained one hour following the glucose challenge. Further details are given in Part IV of this form and in the Central Laboratory Manual.

Also required during this visit are the following: A standard 12 lead resting ECG; a P-A chest x-ray; a urine specimen (for glucose and protein tests done locally); and an additional blood specimen (for hematocrit, white blood cell count, and differential done locally).

Part I: Identifying Information

1) Name: _____
First Middle Last

2) Patient's current address:

_____
Street and Number

_____
City State Zip Code

3) Identifying Number: _____

The identifying number should appear also in the larger box in the upper right hand corner of this page and in the larger box in the right hand corner of each of the other pages of this form.

4) This is Follow-up Visit Number: _____ 13–14

The Follow-up Visit Number should appear also in the smaller box in the upper right hand corner of this page and in the smaller box in the lower right hand corner of each of the other pages of this form.

5) Was this follow-up visit completed within the time period specified in the patient's CDP Appointment Schedule? ..... (Yes) (No) 15

If *YES*, write the date on which the history and physical examination portions of this visit were completed and proceed to Part II of this form:

_____ _____ _____ 16–21
Month Day Year

If *NO*, write the reason the visit was missed on the lines below and send the first page of this form to the Coordinating Center:

_____

_____

If this is the third *consecutive* missed follow-up visit, or else if three consecutive follow-up visits have been missed since Form 08 (the Incomplete Follow-up Form) was last completed, you are required at this time to complete Form 08 and send it to the CDP Coordinating Center.

Part II: Medical History

Unless otherwise specified, the information in this part should cover the period since the patient's last *completed* follow-up visit. If the present visit happens to be the first completed follow-up visit, the information summarized here should cover the period since Initial Visit 3.

6) Since the patient's last completed follow-up visit has he had any significant episodes of cardiac pain, aching, tightness, or pressure in the chest? ..... (Yes) (No) 22

If *NO*, proceed to item 7.
If *YES*, answer items A through J below:

A) Approximately how many episodes *per week* has he had on the average during this period?

Less than 1 ..... (1) 23
1 to 2 ..... (2)
3 to 5 ..... (3)
6 to 10 ..... (4)
More than 10 ..... (5)

B) Does the pain typically radiate (check only one)?

Does not radiate ..... (1) 24
Radiates to the left neck, jaw, shoulder, or arm ..... (2)
Radiates to areas other than the left neck, jaw, shoulder, or arm ..... (3)
Radiates to the left neck, jaw, shoulder, or arm *and* to other areas ..... (4)

Item 6 continued:

C) How much exertion would it typically take to precipitate such an episode (check only one)?

Walking at less than ordinary pace ..... (1) 25
Walking at an ordinary pace ..... (2)
Walking hurriedly or up hill, or climbing stairs ..... (3)
Not related to exertion ..... (4)

D) Can excitement, emotion, or meals precipitate such an episode? ..... (Yes) (No) 26

E) Does rest typically relieve such an episode?

Not at all ..... (1) 27
After more than 10 minutes ..... (2)
In less than 10 minutes ..... (3)
Rest not used ..... (4)

F) Does nitroglycerin typically relieve such an episode?

Not at all ..... (1) 28
After more than 10 minutes ..... (2)
In less than 10 minutes ..... (3)
Nitroglycerin not used ..... (4)

G) What has been the longest duration of such an episode?

Less than 10 minutes ..... (1) 29
10 to 30 minutes ..... (2)
More than 30 minutes ..... (3)

H) Have any of the episodes been such that rest or nitroglycerin did *NOT* bring relief in the typical manner? (Yes) (No) 30

I) Did the patient get medical attention in connection with any episode of pain, aching, etc., during this period? ..... (Yes) (No) 31

If *NO*, proceed to item 6-J.

If *YES*, please give the place where such medical information may be found:

_____

Then avail yourself of this information and answer items i through viii below. (If medical attention was obtained on more than one occasion, answer the questions in connection with the most serious of the episodes.)

i) Did the patient have a pain suggestive of an episode of coronary insufficiency or a myocardial infarction?

No ..... (1) 32
Possibly ..... (2)
Definitely ..... (3)

Item 6-I continued:

ii) Any evidence of shock? ..... (Yes) (No) 33

iii) Arrhythmia? ..... (Yes) (No) 34

iv) Leucocytosis? ..... (3 Not Done) (1 Yes) (2 No) 35

If *YES*, what was the highest recorded value (cells/mm³)? ..... _____

v) Elevated sedimentation rate? ..... (3 Not Done) (1 Yes) (2 No) 36

If *YES*, what was the highest recorded value (mm/hr)? ..... _____

vi) Abnormal SGOT? .... (3 Not Done) (1 Yes) (2 No) 37

If *YES*, what was the highest recorded value (state units)? ..... _____

vii) Abnormal LDH? ..... (3 Not Done) (1 Yes) (2 No) 38

If *YES*, what was the highest recorded value (state units)? ..... _____

viii) ECG evidence of a new myocardial infarction?

ECG not done ..... (1) 39
Negative ..... (2)
Suggestive ..... (3)
Definite ..... (4)

J) Did any of the episodes since the last completed follow-up visit result in a diagnosis of:

	Suspect	Yes	No	
i) Myocardial infarction?	(3)	(1)	(2)	40
ii) Acute coronary insufficiency?	(3)	(1)	(2)	41
iii) Angina pectoris?	(3)	(1)	(2)	42

7) Has the patient required nitroglycerin since his last completed follow-up visit? (Yes) (No) 43

If *YES*, how did his requirement since the last completed follow-up visit compare with his requirement during the four months just prior to the last completed follow-up visit (check one)?

Requirement increased since last visit ..... (1) 44
Requirement decreased since last visit ..... (2)
Requirement remained unchanged since last visit ..... (3)
Nitroglycerin not taken during the four months prior to last visit ..... (4)

F.V.	I.D. No.

8) Since the patient's last completed follow-up visit, has he had any of the following (answer each question):

	Yes	No	
A) Cardiac asthma?	( )	( )	45
B) An obvious stroke?	( )	( )	46
C) Weakness or paralysis of any part of his body?	( )	( )	47
D) Spells of fainting or blacking out?	( )	( )	48
E) Spells of dizziness?	( )	( )	49
F) Sudden pain or coldness of a foot or a leg?	( )	( )	50

9) Does the patient have pains or cramps in his legs when he walks? (Yes) (No) 51

If *YES*, is the pain quickly relieved when he stops walking? (Yes) (No) 52

10) Has the patient ever been hospitalized since his last completed follow-up visit? (Yes) (No) 53

If *YES*, answer items A through C below:

A) Where?_____

B) For what reason?

Heart disease (1) 54
Other circulatory disease (2)
Some other reason (specify) (3)

_____

C) For how many days? _____ 55-56

11) Has the patient had any problems in connection with his CDP medication since his last completed follow-up visit (or since Initial Visit 3 if this is his first completed follow-up visit)?

Yes (1) 57
No (2)
No capsules of any CDP medication (including codes 1-30 and 99) were prescribed since the last completed follow-up visit (3)

If *YES*, what sorts of problems has he had? (Summarize the *patient's SPONTANEOUS* remarks to this question by checking the appropriate item or items below.)

A) Forgetfulness or some other non-medical matter which interfered with taking the medication properly ( ) 58

Item 11 continued:

B) Unwillingness to take the prescribed medication ( )
C) Difficulty swallowing the capsules ( )

D) Too many capsules ( ) 61
E) Decrease in appetite ( )
F) Increase in appetite ( )

G) Recent decreased muscle strength ( ) 64
H) Rapid or irregular heartbeat ( )
I) Unexpected loss of weight ( )

J) Quivering or trembling of fingers ( ) 67
K) Sleeplessness ( )
L) Shortness of breath at night ( )

M) Other shortness of breath ( ) 70
N) Excessive sweating or inability to stand heat ( )
O) Diarrhea ( )

P) Nausea without vomiting ( ) 73
Q) Vomiting ( )
R) Black tarry stools ( ) 75

S) Stomach pain ( ) 15
T) Blurring of vision ( )
U) Unusual loss of hair ( )

V) Decreased sexual desire or ability ( ) 18
W) Breast tenderness or enlargement ( )
X) Development or worsening of angina ( )

Y) Flushing ( ) 21
Z) Burning sensation or pain when urinating ( )
AA) Frequent urination ( )

BB) Reduced or delayed flow of urine ( ) 24
CC) Swelling of the ankles ( )
DD) Itching of the skin ( )

EE) Urticaria ( ) 27
FF) Other types of rash which, in the patient's opinion, might be related to the drug (specify) ( ) 28

_____

_____

GG) Other symptoms which, in the patient's opinion, might be related to the drug (specify) ( ) 29

_____

_____

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Item 11 continued:

If you have reason to believe that one or more of the problems checked in item 11 above are *not* related to the CDP medication, circle the check marks for those problems and write *NDR* (meaning Not Drug Related) after the check marks.

12) Which one of the New York Heart Association functional classes does the patient belong to (see Manual of Operations for definitions)?

Class I (no limitation) ..... (1) 30
Class II (slight limitation) ..... (2)
Class III (marked limitation) ..... (3)
Class IV (discomfort in any activity) ..... (4)

13) During the past *year* has the patient had any episodes of gouty arthritis? ..... ( ) Yes ( ) No 31

If *YES* how many episodes has he had during the past year?

One ..... (1) 32
Two ..... (2)
Three or more but not continuously ..... (3)
Continuously ..... (4)

14) How many *CIGARETTES* does the patient now smoke per day?

None ..... (1) 33
1 to 10 ..... (2)
11 to 20 ..... (3)
21 to 30 ..... (4)
31 to 40 ..... (5)
More than 40 ..... (6)

15) Is the patient presently employed (see Manual of Operations)? ..... ( ) Yes ( ) No 34

If *YES*, answer items A through D below:

A) How extensively? ..... ( ) Full Time ( ) Part Time 35

B) Give job title or a brief (6 words or less) description of his work: _____

_____

C) Which *one* of the following terms best describes the physical nature of his work?

Sedentary ..... (1) 36
Light physical work ..... (2)
Moderate physical work ..... (3)
Heavy physical work ..... (4)

Item 15 continued:

D) Since the patient's last completed ANNUAL follow-up visit (or since I. V. 3 if this is his first completed annual follow-up visit), has there been a change in his ability to work, as defined by items 15, 15-A, and 15-C above?

It has increased ..... (1) 37
It has decreased ..... (2)
It has remained about the same ..... (3)

16) Apart from employment, what degree of physical activity does the patient habitually engage in now?

Light ..... (1) 38
Moderate ..... (2)
Vigorous ..... (3)

17) Is the degree of physical activity in which the patient presently engages different from that reported at his last completed ANNUAL follow-up visit (or at I. V. 3 if this is his first completed annual follow-up visit)?

It has increased ..... (1) 39
It has decreased ..... (2)
It has remained about the same ..... (3)

Part III: Physical Examination

18) Height (to nearest *INCH*, without shoes) ..... _____ 40-41

19) Weight (to nearest *POUND*, with all heavy outdoor garments and shoes removed): ..... _____ 42-44

20) Casual blood pressure (with the patient lying down or, if sitting, with forearm at the level of the heart):

Systolic (in mm. Hg.): ..... _____ 45-47
Diastolic (in mm. Hg.) at the disappearance of sound: ..... _____ 48-50

21) Heart rate (per min.): ..... _____ 51-53

22) Is the rhythm regular? ..... ( ) Yes ( ) No 54

23) Are any of the following findings present:

A) Peripheral edema? ..... ( ) Yes ( ) No 55

B) Ventricular diastolic gallop? ..... ( ) Yes ( ) No 56

C) Rales? ..... (1) Dry (2) Moist (3) Not Present 57

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24) Is the thyroid normal? ..... (3) Not Palpable (1) Yes (2) No 58

If *NO*, answer items A and B below:

A) Is it nodular (check one)?

Not nodular ..... (1) 59
Has one or two solitary nodules ..... (2)
Multinodular ..... (3)

B) Is it diffusely enlarged? ..... ( ) Yes ( ) No 60

25) Answer the following questions about the liver:

A) Enlarged? ..... ( ) ( ) 61

	Not Palpable	Yes	No	
B) Firm?	(3)	(1)	(2)	62
C) Tender?	(3)	(1)	(2)	63

26) Is the spleen palpable? ..... ( ) Yes ( ) No 64

27) Any tenderness in the costovertebral angle? ..... ( ) Yes, ( ) No 65

28) Is the prostate normal? .. (4) Not Examined (3) Surgically Absent (1) Yes (2) No 66

If *NO*, answer items A through D below:

	Yes	No	
A) Is it enlarged?	( )	( )	67
B) Is it hard?	( )	( )	68
C) Is it tender?	( )	( )	69
D) Does it have one or two nodules? ..	( )	( )	70

29) Are the testes normal? ..... ( ) Yes ( ) No 71

If *NO*, specify: _____

_____

30) Peripheral pulses (answer each item):

Nor. = Normal
Dim. = Diminished
Abs. = Absent or not palpable
L.M. = Limb missing

	Nor.	Dim.	Abs.	L.M.	
A) Right femoral	(1)	(2)	(3)	(4)	15
B) Left femoral	( )	( )	( )	( )	16
C) Right popliteal	( )	( )	( )	( )	17

Item 30 continued:

D) Left popliteal	( )	( )	( )	( )	18
E) Right dorsal pedis ..	(1)	(2)	(3)	(4)	19
F) Left dorsal pedis	( )	( )	( )	( )	20
G) Right posterior tibial	( )	( )	( )	( )	21
H) Left posterior tibial	( )	( )	( )	( )	22

31) Are any of the following findings present:

	Yes	No	
A) Ichthyosis?	( )	( )	23
B) Acanthosis Nigricans?	( )	( )	24
C) Hyperpigmentation of the skin?	( )	( )	25
D) Gynecomastia?	( )	( )	26
E) Breast masses?	( )	( )	27
F) Exophthalmia?	( )	( )	28
G) Marked finger tremor?	( )	( )	29
H) Warmer and more moist skin than normal?	( )	( )	30
I) Icterus of sclera and/or skin?	( )	( )	31
J) Vascular spiders?	( )	( )	32
K) Visible collateral veins on abdomen or chest?	( )	( )	33

32) Any dermatologic ailment *not* already mentioned above? ..... ( ) Yes ( ) No 34

If *YES*, specify: _____

_____

33) Has the patient had a pathologic loss of hair during the past year? ..... ( ) Yes ( ) No 35

34) Base your answers to the following questions on your best clinical judgment and any tests or procedures which may be of practical value in your assessment of lens opacities.

A) Is there evidence of any opacities in the lens of the patient's *LEFT* eye?

Yes ..... (1) 36
No ..... (2)
Lens has been removed ..... (3)
Not examined ..... (4)

B) Is there evidence of any opacities in the lens of the patient's *RIGHT* eye?

Yes ..... (1) 37
No ..... (2)
Lens has been removed ..... (3)
Not examined ..... (4)

F.V.	I.D. No.

Item 34 continued:

C) If either one or both of the lenses have been removed, give dates and reasons on the lines below:

_____

_____

D) If opacities are present in one or both lenses, is there evidence of any definite cause (injury, for example) for the opacities? Indicate on the line below:

_____

E) If opacities are present in one or both lenses, check one of the following statements:

The opacities first developed during the past year ..... (1) 38
The opacities were present a year ago and have increased since then ..... (2)
The opacities were present a year ago, but have not increased since then ..... (3)
The status of the lenses a year ago is unknown ..... (4)

35) Are any of the following gout indicators present:

	Not Known	Yes	No
A) Hyperuricemia?	(3)	(1)	(2) 39
B) Bony erosions?	(3)	(1)	(2) 40
C) Podagra?	( )	( )	( ) 41
D) Tophi?	( )	( )	( ) 42
E) Urinary stones?	( )	( )	( ) 43

36) Are the findings of the P-A chest x-ray taken at this visit normal? ..... (Yes) (No) 44

If *NO*, answer items A through D below concerning the x-ray findings:

A) Cardiomegaly?
No ..... (1) 45
Probable ..... (2)
Definite ..... (3)

B) Pleural effusion? ..... (Yes) (No) 46

C) Pulmonary congestion? ..... (Yes) (No) 47

D) Other findings? ..... (Yes) (No) 48

If *YES*, specify: _____

_____

37) Please review the ECG taken at this visit and answer the following questions using the criteria given in the Manual of Operations:

Item 37 continued:

A) Compared with the ECG taken at the patient's last completed annual follow-up visit (or at I. V. 3 if this is the first completed annual follow-up visit), does the present ECG indicate the development of a *new* myocardial infarction (check one)?

No ..... (1) 49
Yes - QRS changes ..... (2)
Yes - ST-T wave changes (in conjunction with history and enzyme changes) (3)
Yes - Other ECG criteria ..... (4)

B) Compared with the ECG taken at the patient's last completed annual follow-up visit (or at I. V. 3 if this is the first completed annual follow-up visit), does the present ECG demonstrate evidence of ischemia or injury not previously present (check one)?

No ..... (1) 50
Yes - ST wave changes ..... (2)
Yes - T wave changes ..... (3)
Yes - Both ST *and* T wave changes .... (4)

C) Compared with the ECG taken at the patient's last completed annual follow-up visit (or at I. V. 3 if this is the first completed annual follow-up visit), does the present ECG demonstrate evidence of a ventricular conduction defect not previously present (check one)?

No ..... (1) 51
Yes - Left Bundle Branch Block ..... (2)
Yes - Right Bundle Branch Block (complete or incomplete) ..... (3)
Yes - Both LBBB and RBBB ..... (4)
Yes - Intraventricular Block ..... (5)

D) Compared with the ECG taken at the patient's last completed annual follow-up visit (or at I. V. 3 if this is the first completed annual follow-up visit), does the present ECG indicate the development of an arrhythmia not previously present (check one)?

No ..... (1) 52
Yes - Atrial fibrillation or flutter ..... (2)
Yes - Other arrhythmias ..... (3)
Yes - Both atrial fibrillation or flutter *and* other arrhythmias ..... (4)

38) On the basis of this physical examination and available laboratory data, is there indication of any noteworthy abnormality in the following systems:

	Yes	No
A) Gastrointestinal?	( )	( ) 15
B) Genitourinary?	( )	( ) 16
C) Nervous?	( )	( ) 17
D) Musculoskeletal?	( )	( ) 18
E) Dermal?	( )	( ) 19
F) Bronchopulmonary?	( )	( ) 20

Part IV: Blood and Urine Specimens

A 70 ml. *fasting* blood sample should be obtained as soon as the patient arrives at the clinic for this visit. The patient is then given a solution containing 75 gm. of glucose to drink. A 10 ml. blood sample is obtained one hour following the glucose challenge.

At least 17.5 ml. of fasting serum should be obtained from 60 ml. of the fasting blood sample, and five vials (numbered 1, 2, 3, 4 and 6) are filled with 3.5 ml. of serum each.

Three ml. of *fasting plasma* are obtained from the remaining 10 ml. of the fasting blood sample and placed in vial number 7. Also, 3 ml. of *1-hour post-challenge plasma* are obtained from the 10 ml. post-challenge blood sample and placed in vial number 8.

Each of the seven vials should be sealed and labeled with the following information:

Complete specimen identification number (consisting of patient identifying number, visit number, and vial number); patient's name; and month, day, and year of collection.

The vials should be immediately frozen and then shipped within a week to the CDP Central Laboratory in Atlanta.

See the Central Laboratory Manual for detailed instructions concerning collection, handling, and shipping of the serum and plasma specimens.

39) Date and time fasting blood specimen obtained:

Month _____ Day _____ Year _____ Hour _____ 21–28

An additional blood sample and a urine specimen should be obtained during this visit and the determinations indicated in items 40 through 44 below performed locally.

40) Hematocrit (in %) ..... _____ 29–30

41) White blood cell count (cells per mm³): _____ 31–35

42) Absolute neutrophil count (cells per mm³): ..... _____ 36–40

43) Urine glucose (use Ames Clinistix): .... ( ) + ( ) − 41

44) Urine protein (use Ames Clinistix):
(1) Negative (2) Trace (3) 1+ (4) 2+ (5) 3+ (6) 4+ 42

Part V: Other Drug Prescription

The information in item 45 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 Initial Visit 3.

45) Are any of the following drugs or types of drugs being prescribed now or have any of them been prescribed in the period defined in the box above (answer each question):

	Yes	No	
A) Insulin?	( )	( )	43
B) Oral hypoglycemic agents?	( )	( )	44
C) Digitalis?	( )	( )	45
D) Antiarrhythmic agents?	( )	( )	46
E) Diuretics?	( )	( )	47
F) Antihypertensives other than diuretics?	( )	( )	48
G) Nitroglycerin or other coronary dilators?	( )	( )	49
H) Gout medication?	( )	( )	50
I) Anticoagulants?	( )	( )	51

If *YES*, answer items i and ii below:

i) For how many weeks during the period defined in the box above were anticoagulants prescribed? ..... _____ 52–53

ii) What was the predominant type of anticoagulant used (check one)?

Heparin ..... (1) 54
Prothrombin-depressing agent ..... (2)

J) Cholesterol lowering drugs other than study medication?	( ) Yes	( ) No	55
K) Other drugs (specify)?	( ) Yes	( ) No	56

46) During the month preceding the collection of the serum specimen for this visit, has the patient been on thiazide diuretics? ..... ( ) Yes ( ) No 57

47) Is the present visit the patient's first completed ANNUAL follow-up visit? .... ( ) Yes ( ) No 58

If *YES*, please answer the following retrospective question:

Was the patient on thiazide diuretics during the month preceding the collection of the serum for his baseline laboratory profile (collected at I. V. 2 for most patients entered before Fall 1966, and at I. V. 1 for patients entered more recently)? ..... (3) Unknown (1) Yes (2) No 59

Part VI: Clinical Summary

The information in item 48 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 Initial Visit 3.

48) Based on the history, physical examination, and any available laboratory data, has the patient had any of the following events in the period defined in the box above (answer each question; see the Manual of Operations for definitions of criteria for making the following diagnoses):

F.V.	I.D. No.

Item 48 continued:

	Suspect	Yes	No	
A) Congestive heart failure?	(3)	(1)	(2)	60
B) Angina pectoris?	(3)	(1)	(2)	61
C) Acute coronary insufficiency?	(3)	(1)	(2)	62
If *YES*, how many episodes		_____		63
D) Myocardial infarction?	(3)	(1)	(2)	64
If *YES*, how many?		_____		65
E) Intermittent cerebral ischemic attacks with neurological deficit lasting less than 24 hours?	(3)	(1)	(2)	66
F) Stroke with neurological deficit lasting more than 24 hours?	(3)	(1)	(2)	67
If *YES*, how many?		_____		68
G) Intermittent claudication? ..	(3)	(1)	(2)	69
H) Peripheral arterial occlusion?	(3)	(1)	(2)	70
I) Gout?	(3)	(1)	(2)	71
J) Venous pulmonary embolism?	(3)	(1)	(2)	72
K) Thrombophlebitis?	(3)	(1)	(2)	73
L) Atrial fibrillation?	(3)	(1)	(2)	74
M) Arrhythmias other than atrial fibrillation?	(3)	(1)	(2)	75

49) Since the patient's last completed ANNUAL follow-up visit (or since I. V. 3 if this is his first completed annual follow-up visit), has he developed any of the following:

	Suspect	Yes	No	
A) Peripheral arterial emboli?	(3)	(1)	(2)	15
If *YES*, how many and where?		_____		
B) Arterial aneurysm?	(3) Suspect	(1) Yes	(2) No	16
If *YES*, how many and where?		_____		
C) Hypertension?	(3) Suspect	(1) Yes	(2) No	17
If *YES*, is it treated?		( ) Yes	( ) No	18
D) An increase in heart size? ..	(3) Suspect	(1) Yes	(2) No	19

50) Was the patient seen by a consultant in connection with any of the events listed in items 48 or 49? ..... ( ) Yes ( ) No 20

If *YES*, give the names of all such consultants and the diagnoses they made on the lines below:

_____

_____

_____

_____

51) Is the patient a known diabetic? ..... ( ) Yes ( ) No 21

If *YES*, answer items A and B below:

A) Has the patient developed diabetes mellitus since his last completed ANNUAL follow-up visit (or since I. V. 3 if this is his first completed annual follow-up visit)? ..... ( ) Yes ( ) No 22

B) Did the patient have a diagnosis of diabetes mellitus at the time of his entry into the study? ..... ( ) Yes ( ) No 23

Part VII: CDP Medication

In item 52 a record of every change in prescription of the assigned CDP medication from the time of the patient's last *completed* follow-up visit through the present date is required.

NOTE: If no capsules per day were prescribed for any interval during this period, or IF THE PATIENT WAS SWITCHED FROM HIS STUDY DRUG TO THE KNOWN PLACEBO for any interval, a *ZERO* should be written on the line indicating "No. of capsules per day."

52) Patient's Prescription Record:

A) Write the date and prescription given in part B of the prescription record of the patient's last completed follow-up visit form (Form 04 or 05) on the lines below. (If this is the first completed follow-up visit, give THE DATE THE TREATMENT ALLOCATION ENVELOPE WAS OPENED and the prescription given at that time.)

Month	Day	Year	No. of capsules per day	
_____	_____	_____	_____	24-30

F.V.	I.D. No.

Item 52 continued:

B) Write the present date and the prescription from this time forward:

Month	Day	Year	No. of capsules per day
_____	_____	_____	_____ [31–37]

C) Have any changes been made in the prescription between the two dates given in parts A and B above? ( ) Yes ( ) No [38]

If *YES*, give the date of each change and the prescription made on that date on the lines below:

	Date of prescription (month, day, year)	No. of capsules per day
a.	_____	_____
b.	_____	_____
c.	_____	_____
d.	_____	_____
e.	_____	_____
f.	_____	_____

53) Using the prescription record in item 52, calculate the total number of capsules prescribed during the period covered by that record (see Manual of Operations for instructions). Write the total number of capsules here: ..... _____ [39–42]

54) In your best judgment (based on a capsule count and/or any other information or impressions obtained from the patient at this visit), what percentage of the total prescribed number of capsules (the number given in item 53) has the patient actually taken?

At least 80% ..... (1) [43]
At least 60% but less than 80% ..... (2)
At least 40% but less than 60% ..... (3)
At least 20% but less than 40% ..... (4)
Less than 20% ..... (5)

If no capsules of ALLOCATED medication were prescribed, check here: ..... (6)

55) If the percent adherence checked in item 54 is less than 80%, what is the *main* reason for the reduced level of adherence? (If more than one reason is given, please indicate which *ONE* you judge to be the *most important* reason by circling the appropriate letter or reason given below.)

If it is impossible to determine the reason, check here: ..... ( ) [44–53]

If the main reason is one the problems listed in item 11, write the letter designation of that problem here: .... _____

Item 55 continued:

If some other reason, specify:

_____

_____

56) During the period covered by the prescription record in item 52, has the prescription of ALLOCATED medication ever been less than nine capsules per day? (If this is the patient's *first completed* follow-up visit, check *YES either* if the prescription has ever been decreased since Initial Visit 3 *or* if the prescription has never yet reached 9 capsules per day.) ..... ( ) Yes ( ) No [54]

If *YES*, what is the *main* reason for this? (If more than one reason is checked, please indicate by circling the appropriate check mark the *ONE* reason you judge to be the *most important*.)

A) Hepatic signs and/or symptoms ..... (1) [55–64]
B) Renal signs and/or symptoms ..... (2)
C) Abnormality in the hematopoietic system .. (3)
D) Development or worsening of a peptic ulcer (4)
E) Gastrointestinal irritation ..... (5)
F) Gout signs and/or symptoms ..... (6)
G) Development or suspicion of toxic amblyopia ..... (7)
H) Development or worsening of diabetes mellitus ..... (8)
I) Development or worsening of angina pectoris ..... (9)
J) Congestive heart failure ..... (10)
K) Arrhythmia ..... (11)
L) Def. ACI, or def. or susp. MI, stroke, pulmonary embolism, pulmonary infarction, arterial embolism ..... (12)
M) Clinical hyperthyroidism ..... (13)
N) Decreased libido or potentia ..... (14)
O) Feminization ..... (15)
P) Flushing ..... (16)
Q) Itching ..... (17)
R) Rash or other dermatologic problems ..... (18)

Item 56 continued:

S) Serious complaints of the patient possibly related to side effects of the drug ..... (19)

T) Unwillingness of the patient or his personal physician to accept the prescribed dosage (20)

U) Other (specify) ..... (21)

_____

_____

V) ESG2 ..... (22)
W) Baseline VPBs, D-T4 group ..... (23)
X) D-T4 ..... (24)

INTERNAL USE ONLY

Y) Non-medical reasons (missed visits, re-instated dropouts, etc.) ..... (25)

Z) Patient taking other cholesterol-lowering medication ..... (26)

(AA) ESG and D-T4 patients not enrolled in the CDPA ..... (27)

57) What is the bottled code number of the medication being dispensed to the patient at this time?

No capsules of any medication ..... (00) 65–66
Codes 65, 86, or 99 ..... (99)
Codes 1 to 60 (specify code): ..... ——

58) Has the patient's sealed medication code ever been broken? ..... (Yes) (No) 67

If *YES*, you should inform the Coordinating Center of the reasons for this if you have not done so already.

Unless contraindicated, the patient should be instructed to continue taking nine capsules per day of the assigned medication.

At this time an appointment for the next follow-up visit should be made for a date as close as possible to the date indicated in the patient's Appointment Schedule, Form 11.

The patient should be instructed to arrive for his next visit in a "fat-free" state and should be given the appropriate Dietary Instruction Sheet (Form 12-B). It is strongly preferred that this next visit, or at least the collection of the serum and urine specimens, be made in the morning.

The patient should be reminded to return all his remaining capsules at the next visit. He should also be instructed not to take any capsules on the day of the next visit until after the visit is completed.

Part VIII: Administrative Matters

59) The name of the physician responsible for the medical information recorded on this form is:

Dr._____

60) This form has been checked for completeness by:

_____

The original copy of this form and a copy of the ECG obtained at this visit should be mailed now to:

CDP Coordinating Center
Division of Clinical Investigation
610 W. Lombard Street
Baltimore, Maryland 21201

The carbon copy of this form and the chest x-ray obtained at this examination should be filed in your clinic.

61) The date on which this form is being mailed to the CDP Coordinating Center is:

_____ Month _____ Day _____ Year

Part IX: Addendum

62) Is this visit Follow-up Visit 3? ..... (Yes) (No) 68

If *YES*, please answer items A and B below concerning the results of the baseline examination for lens opacities:

A) Was there evidence of any opacities in the lens of the patient's *LEFT* eye at baseline?

Yes ..... (1) 69
No ..... (2)
Lens was absent ..... (3)
Examination for lens opacities not done (4)

B) Was there evidence of any opacities in the lens of the patient's *RIGHT* eye at baseline?

Yes ..... (1) 70
No ..... (2)
Lens was absent ..... (3)
Examination for lens opacities not done (4)

63) Measure the patient's visual acuity for each eye (with his glasses and without dilation of the pupils) using the standard distant Snellen.

Left Eye

20/20 and better ..... (1) 71
20/21 to 20/40 ..... (2)
20/41 to 20/200 ..... (3)
Worse than 20/200 or blind ..... (4)
Acuity test not done ..... (5)

Right Eye

20/20 and better ..... (1) 72
20/21 to 20/40 ..... (2)
20/41 to 20/200 ..... (3)
Worse than 20/200 or blind ..... (4)
Acuity test not done ..... (5)

64) Has the patient had cardiac, aortic, peripheral arterial or other cardiovascular surgery since his entry into the study which has not yet been reported to the Coordinating Center on Form 22? ..... ( ) Yes ( ) No 73

If *YES*, complete the Cardiovascular Surgery Form (CDP Form 22) and mail it to the Coordinating Center.

65) Since the patient's last completed follow-up visit has he taken aspirin or other drugs containing aspirin (for example, Anacin, Alka-Seltzer, A.P.C., Bufferin, Darvon-compound, Empirin-compound and Excedrin)? ..... ( ) Uncertain ( ) Yes ( ) No 74

If YES, give the patient's best estimate of frequency of taking such drugs since the last completed follow-up visit:

Less than one day a week ..... (1) 75
One day a week ..... (2)
Two to three days a week ..... (3)
Four or more days a week ..... (4)

F.V. _____ | I.D. No. _____

ADDITIONAL ITEMS TO BE COMPLETED AT CV 2

66) Did the patient have any problems in connection with his CDP medication immediately prior to discontinuation of his medication at CV1?

Yes ---------- (1)[15]
No ---------- (2)
Patient on zero capsules prior to CV 1 ---------- (3)

If YES, answer Item 67. Otherwise proceed to Item 68.

67) Have any of the problems abated or been relieved since the discontinuation of the medication? ---------- ( ) ( )[16]
Yes No

If YES, what sort of problems have abated or been relieved? (Summarize the patient's SPONTANEOUS remarks to this question by checking the appropriate item or items below.)

A) Decrease in appetite ---------- ( )[17]
B) Increase in appetite ---------- ( )
C) Recent decreased muscle strength ---------- ( )

D) Rapid or irregular heartbeat -- ( )[20]
E) Unexpected change in weight
i) Loss of weight ---------- ( )
ii) Gain of weight ---------- ( )

F) Quivering or trembling of fingers ---------- ( )[23]
G) Sleeplessness ---------- ( )
H) Shortness of breath at night -- ( )

I) Other shortness of breath ----- ( )[26]
J) Excessive sweating or inability to stand heat ---------- ( )
K) Diarrhea ---------- ( )

L) Nausea without vomiting ------- ( )[29]
M) Vomiting ---------- ( )
N) Black tarry stools ---------- ( )

O) Stomach pain ---------- ( )[32]
P) Blurring of vision ---------- ( )
Q) Unusual loss of hair ---------- ( )

R) Decreased sexual desire or ability ---------- ( )[35]
S) Breast tenderness or enlargement ---------- ( )
T) Development or worsening of angina ---------- ( )

U) Flushing ---------- ( )[38]
V) Burning sensation or pain when urinating ---------- ( )
W) Frequent urination ---------- ( )

67) (Continued)

X) Reduced or delayed flow of urine ---------- ( )[41]
Y) Swelling of the ankles ------- ( )
Z) Itching of the skin ---------- ( )

AA) Urticaria ---------- ( )[44]
BB) Other types of rash which, in the patient's opinion, might be related to the drug (specify)- ( )

_____

_____

CC) Other (specify) ---------- ( )

_____

_____

68) Has the patient had any problems in connection with the discontinuation of his CDP medication at CV1?

Yes ---------- (1)[47]
No ---------- (2)
Patient was on zero capsules immediately prior to CV1 --- (3)

If YES, what sort of problems has he had? (Summarize the patient's SPONTANEOUS remarks to this question by checking the appropriate item or items below.)

A) Decrease in appetite --------- ( )[48]
B) Increase in appetite --------- ( )
C) Recent decreased muscle strength ---------- ( )

D) Rapid or irregular heartbeat - ( )[51]
E) Unexpected change in weight
i) Loss of weight ---------- ( )
ii) Gain of weight ---------- ( )

F) Quivering or trembling of fingers ---------- ( )[54]
G) Sleeplessness ---------- ( )
H) Shortness of breath at night - ( )

I) Other shortness of breath ---- ( )[57]
J) Excessive sweating or inability to stand heat ---------- ( )
K) Diarrhea ---------- ( )

L) Nausea without vomiting ------ ( )[60]
M) Vomiting ---------- ( )
N) Black tarry stools ---------- ( )

O) Stomach pain ---------- ( )[63]
P) Blurring of vision ---------- ( )
Q) Unusual loss of hair --------- ( )

F.V.	I.D. No.

ADDITIONAL ITEMS TO BE COMPLETED AT CV 2

68) (Continued)

R) Decreased sexual desire or ability ---------- ( )[66]
S) Breast tenderness or enlargement ---------- ( )
T) Development or worsening of angina ---------- ( )

U) Flushing ---------- ( )[69]
V) Burning sensation or pain when urinating ---------- ( )
W) Frequent urination ---------- ( )

X) Reduced or delayed flow of urine ---------- ( )[72]
Y) Swelling of the ankles ---------- ( )
Z) Itching of the skin ---------- ( )

AA) Urticaria ---------- ( )[75]
BB) Other types of rash which, in the patient's opinion, might be related to discontinuation of the drug (specify) --------- ( )

_____

_____

CC) Other symptoms which, in the patient's opinion, might be related to discontinuation of the drug (specify) ---------- ( )[77]

_____

_____

69) Has the patient returned all of his unused study medication? ---------- ( ) Yes ( )[78] No

If NO, the patient should be asked to return all unused study medication to the clinic as soon as possible.

70) Since CV1, has the patient been prescribed:

	Yes	No
A) CPIB ----------	( )	( )[79]
B) Nicotinic acid ---------	( )	( )[80]

If a Form 76 was requested for this patient on the Form 76 checklist, please forward the completed CDP Form 76 including the name and address of the patient's private physician to the Coordinating Center. If the patient does not have a private physician, the study physician should assist the patient in establishing a continuing source of personal medical care.

(6-72)

CDP Form 22

I.D. No.

CARDIOVASCULAR SURGERY FORM

This form should be completed and forwarded to the Coordinating Center each time cardiovascular surgery is performed on a CDP patient since entry into the study.

1) Name: _____ (First) _____ (Middle) _____ (Last)

2) Identifying Number: _____

3) Date of surgery: _____ (Month) _____ (Day) _____ (Year)

4) Date form completed: _____ (Month) _____ (Day) _____ (Year)

5) Type of surgery (check the appropriate item(s) below):

A) Valvular repair or replacement ..... ( )

B) Septal repair ..... ( )

C) Papillary muscle repair ..... ( )

D) Infarctectomy ..... ( )

E) Ventricular wall aneurysmectomy ..... ( )

F) Saphenous vein by-pass of coronary arteries ..... ( )

G) Coronary endarterectomy ..... ( )

H) Vineberg--mammary artery implants ..... ( )

I) Internal mammary artery anastomosis into coronary artery ..... ( )

J) Cardiac transplantation ..... ( )

K) Permanent pacemaker implantation ..... ( )

L) Arterial surgery other than coronary (please specify) ..... ( )

_____

M) Other (please specify) ..... ( )

_____

_____

6) Name of physician completing this form:

_____

After completion, this form should be mailed to:

CDP Coordinating Center
Institute of International Medicine
610 West Lombard Street
Baltimore, Maryland 21201

A carbon copy of this form should be filed in your clinic.

(1/73)

CDP Form 09A

C
P

I.D. No.

CAUSE OF DEATH CODING FORM

This form should be completed and forwarded to the Coordinating Center within 60 days after notification of a patient's death. 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 form asks for both the underlying (or basic disease process) and the immediate (or final step in the disease process) cause of death. Copies of the death certificate and autopsy report (if available) should be forwarded along with this form to the Coordinating Center.

Name: _____ Identifying Number: _____
First Middle Last

Date of Death: _____
Month Day Year

Part I: Underlying (Basic) Cause of Death

Check appropriate item(s). More than one item may be checked, but should be explained in the Physicians Summary, Part IV.

A) Atherosclerotic Cardiovascular Disease

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

If item A-1 is checked, please check one of the following statements pertaining to chronology of death:

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

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

3) Sudden unexpected death between 1 and 24 hours of onset of symptoms .....( )

4) Unobserved death between 1 and 24 hours of being seen alive without symptoms .....( )

5) Unobserved death greater than 24 hours of being seen alive without symptoms.....( )

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

Item A Continued:

2) Atherosclerotic coronary heart disease without recent or acute cardiac event (e.g., chronic congestive heart failure) .....( )

3) Atherosclerotic coronary heart disease resulting in surgery for coronary heart disease (e.g., vein by-pass, transplant, resected ventricular infarction or aneurysm, cardiac catheterization, etc.) .....( )

4) Item deleted

5) Atherosclerotic cerebrovascular disease with thrombosis and infarction .....( )

6) Atherosclerosis of carotid and/or vertebral arteries with obstruction or thromboembolism .....( )

7) Atherosclerotic arterial aneurysm with rupture:

a) Aortic .....( )

b) Coronary artery .....( )

c) Other (Specify name of artery on line below) .....( )

_____

8) Atherosclerotic renovascular disease:

a) With hypertension .....( )

b) Without hypertension .....( )

9) Mesenteric atherosclerosis with intestional infarction .....( )

10) Atherosclerosis of peripheral arteries distal to aortic bifurcation with gangrene of lower extremities .....( )

11) Other (specify on line below) .....( )

_____

B. Nonatherosclerotic Cardiovascular Disease

1) Myocardiopathy unrelated to atherosclerotic coronary heart disease (e.g., toxin, neoplasm) .....( )

I.D. No.

Item B Continued:

2) Cardiovascular surgery unrelated to coronary heart disease (e.g., valvular surgery, arterial aneurysm, embolectomy) .....( )

3) Bacterial endocarditis .....( )

4) Recurrent pulmonary thromboembolism .....( )

5) Hyper- or auto-immune cardiovascular disease .....( )

6) Congenital heart disease .....( )

7) Hypertensive disease:

a) With cerebral hemorrhage .....( )

b) Other hypertensive disease (e.g., hypertensive heart disease ....( )

8) Rheumatic heart disease .....( )

9) Idiopathic calcific aortic valvular stenosis .....( )

10) Other (specify on line below) .....( )

_____

C) Noncardiovascular Disease

Specify diagnosis, site, and etiology where appropriate.

1) Neoplasia .....( )

2) Infection .....( )

3) Peptic ulcer disease .....( )

4) Liver disease .....( )

5) Renal disease .....( )

6) Pulmonary disease .....( )

7) Blood dyscrasia .....( )

8) Hyper- or auto-immune disease .....( )

9) Suicide .....( )

10) Homicide .....( )

11) Accident (specify type of accident on line below) .....( )

_____

I.D. No.

Item C Continued:

12) Other (specify on line below) .....( )

_____

D) Unknown Cause of Death .....( )

Part II: Immediate Cause of Death

Check appropriate item(s). If more than one item is checked, please explain in the Physician Summary, Part IV. This list includes only the most frequent immediate causes of death relating to coronary heart disease.

A) Cardiogenic shock .....( )

B) Cardiac dysrhythmia:

1) Documented by ECG or cardiac monitor .....( )

2) Presumptive--no other immediate cause found at autopsy .....( )

3) Presumptive--autopsy not done .....( )

C) Congestive heart failure .....( )

D) Pulmonary edema .....( )

E) Ruptured myocardium with tamponade .....( )

F) Stroke (thromboembolic or hemorrhagic).....( )

G) Acute pulmonary thromboembolism .....( )

H) Other (specify on line below) .....( )

_____

I.D. No.

Part III: Source of Information

Please indicate which items below were used to help you arrive at the conclusions stated in Parts I and II above. Number those items used in order of importance (1=most important) in arriving at your conclusions.

A) History .....____

B) Physical exam .....____

C) ECG .....____

D) Blood tests (specify on line below) .....____

_____

E) Chest x-ray .....____

F) Pulmonary scan .....____

G) Pulmonary angiography .....____

H) Autopsy .....____

I) Other (specify on line below) .....____

_____

J) Lack of evidence of any other cause of death .....____

I.D. No.

Part IV: Physician Summary

Please give a summary and sequence of events and/or circumstances surrounding the final illness which led to the patient's death. Please comment on each of the sources of information checked in part III.

Name of physician completing this form: _____

Date form completed ..... _____
Month Day Year

I.D. No.

J) Adjudicated .....( ) ( ) [69]
Yes No

K) Number of Times Coded

One .....(1) [70]
Two .....(2)
Three .....(3)
Four .....(4)
Five .....(5)
Six .....(6)

L) Repeat Coding .....(1) [80]

I.D. No.

P	T
V	R
F.V.	

I.D. No.

DEATH FORM

This form should be completed and forwarded to the Coordinating Center within 48 hours after notification of a patient's death. When the death certificate and autopsy report become available, the information originally supplied on this form should be reviewed and, if necessary, corrected, and a revised copy of this form should be forwarded to the Coordinating Center along with copies of the death certificate, autopsy report (if available), and the Cause of Death Coding Form (CDP Form 09A).

1) Name: _____
First Middle Last

2) Identifying Number: _____

The identifying number should appear also in the box in the upper right hand corner of this page and in the lower right hand corner of the next page.

3) Date of death: _____ _____ _____
Month Day Year

4) Did the patient die in a hospital?.....( ) ( )
Yes No

5) Was an autopsy done on this patient?.....( ) ( )
Yes No

6) Did the patient die suddenly, that is, within 60 minutes of the onset of symptoms?...( ) ( ) ( )
Un- Yes No
known

7) In your best judgment was the underlying cause of death atherosclerotic coronary heart disease with recent or acute cardiac event (e.g., myocardial infarction, acute coronary insufficiency, sudden unexpected or unobserved death)? (Check one of the below)

Yes--MI or ACI.....( )
Yes--No or Unknown MI or ACI.....( )
No or Unknown.....( )

If Item 7 is checked YES--MI or ACI, either Item 10A or 10B must be checked SUSPECT or YES.

8) If Item 7 is checked YES, that is, if the patient died of atherosclerotic coronary heart disease with recent or acute event, is your judgment supported by (answer each question):

	YES	NO
A) ECG findings?.....	( )	( )
B) Enzyme studies?.....	( )	( )
C) Other laboratory data symptoms or signs?.....	( )	( )
D) Lack of evidence of any other cause of death?.....	( )	( )

9) If Item 7 is checked NO or UNKNOWN, what in your best judgment, was the underlying cause of death (check only one)?

A) Unknown.....( )
B) Cerebrovascular accident.....( )
C) Pulmonary embolism.....( )
D) Chronic congestive heart failure.....( )
E) Other cardiovascular disease (specify).....( )

_____

_____

F) Noncardiovascular disease or condition (specify).....( )

_____

_____

The answers to Items 10 and 11 below should be based on your best clinical judgment after review of all available pertinent records and information. The patient's terminal event as well as previous events should be considered when answering these two items. If Item 10A and/or 10B are checked SUSPECT or YES, an interim ECG or Missing ECG Form (CDP Form 17) should be forwarded to the Coordinating Center.

10) Since the patient's last completed follow-up visit or since Item 8 on Form 08 (9-68 revision) was last completed has the patient experienced any of the events listed below?

A) Myocardial Infarction ..... ( ) Unknown ( ) Suspect ( ) Yes ( ) No

If YES, how many episodes? . _____

Date(s): _____

B) Acute Coronary Insufficiency... ( ) Unknown ( ) Suspect ( ) Yes ( ) No

If YES, how many episodes? . _____

Date(s): _____

C) Stroke with neurological deficit lasting more than 24 hours? ..... ( ) Unknown ( ) Suspect ( ) Yes ( ) No

If YES, how many episodes? . _____

Date(s): _____

11) Has the patient ever been hospitalized since his last completed follow-up visit or since Item 9 on Form 08 (9-68 revision) was last completed? ..... ( ) Unknown ( ) Yes ( ) No

If YES, answer A through D below:

A) Where? _____

_____

B) For what reason?

Heart disease .....( )
Other circulatory disease .....( )
Some other reason (specify) .. ( )

_____

_____

C) For how many days? ..... _____

D) Date(s): _____

12) Name of physician completing this form?

Dr._____

After completion, this form and copies of the death certificate, autopsy report (if available) and Cause of Death Coding Form (CDP Form 09A) should be mailed to:

CDP Coordinating Center
Institute of International Medicine
610 West Lombard Street
Baltimore, Maryland 21201

A carbon copy of this form should be filed in your clinic.

DO NOT WRITE BELOW THIS LINE

		YES	NO	
13)	Death Certificate Received	( )	( )	
14)	Autopsy Report Received	( )	( )	(3)
15)	Cause of Death Coding Form Received	( )	( )	
16)	International Death Code	( )	( )	
17)	Underlying Cause Code	( )	( )	
18)	Immediate Cause Code	( )	( )	

I.D. No.

(9-68)

CDP Form 08

P	T
V	R

I.D. NO.

DROPOUT FORM

This form should be completed as soon after a patient is known to have dropped out of the study as possible and after each period of three consecutive missed follow-up visits thereafter until his death or until a follow-up examination (CDP Form 04 and 05) in your CDP clinic or some other participating CDP clinic has been completed.

1) Name: _____
First Middle Last

2) Identifying Number: _____

The identifying number should appear also in the box in the upper right hand corner of this page and in the lower right hand corner of the next page.

3) The last missed visit was Follow-up Visit Number..... _____

4) Today's date: _____ _____ _____
Month Day Year

5) In your best judgment, what is the main reason for the lack of participation on the part of the patient (check only one)?

Moved to a less convenient location.....( )

Unable to participate because of death or ill health.....( )

Frustration due to side-reactions.....( )

General decrease of motivation...( )

Other reason (specify).....( )

_____

_____

6) Is the patient NOW living?.....( ) ( ) ( )
Uncer- Yes No
tain

If NO, you need not complete this Form 08. Rather, complete the Death Form (CDP Form 09) and forward it to the Coordinating Center.

7) If item 6 is checked UNCERTAIN, are steps being taken to locate this patient?.....( ) ( )
Yes No

Consult the Manual of Operations for suggested procedures to be used in locating and maintaining contact with patients in this project.

The answers to items 8 and 9 should be based on your best clinical judgment after review of all available pertinent records and information.

8) Since the patient's last completed follow-up visit or since this item was last completed on a Form 08, has he experienced any of the events listed below?

	Un-known	Sus-pect	Yes	No
A) Myocardial Infarction....	( )	( )	( )	( )
If YES, how many?..... _____				
B) Acute Coronary Insufficiency.	( )	( )	( )	( )
If YES, how many episodes?..... _____				
C) Stroke with neurological deficit lasting more than 24 hours.....	( )	( )	( )	( )
If YES, how many?..... _____				

9) Has the patient ever been hospitalized since his last completed follow-up visit or since this item was last completed on a Form 08?.....( ) ( )
Yes No

If YES, answer items A through C below:

A) Where?_____

_____

B) For what reason?

Heart disease.....( )

Other circulatory disease....( )

Some other reason (specify)..( )

_____

C) For how many days?....._____

10) Give the patient's current address, if available, on the lines below:

_____
Street Number

_____
City State Zip Code

After completion, this form should be mailed to:

CDP Coordinating Center
Institute of International Medicine
660 West Redwood Street
Baltimore, Maryland 21201

I.D. NO.

I.D. No.

GALLBLADDER DISEASE QUESTIONNAIRE

This form is to be completed for CDP patients having a history of gallbladder disease prior to entry and/or a diagnosis of gallbladder disease since entry and/or evidence of gallbladder disease at autopsy. Note that Items 4 through 9 relate to gallbladder disease manifested at or prior to entry into the study, Items 10 through 15 relate to gallbladder disease manifested since entry, and Items 16 and 17 relate to gallbladder disease detected at autopsy only.

1. Patient's Name: _____ (First / Middle / Last)

2. Identifying Number: _____

3. Follow-up Visit Number (if this form is not being completed in conjunction with a follow-up visit, give the number of the last completed follow-up visit): ---------- _____

GALLBLADDER DISEASE AT OR PRIOR TO ENTRY

4. Did the patient have a history of gallbladder disease at or prior to entry? ---------- ( ) Yes ( ) No

If NO, SKIP TO ITEM 10.

5. Approximate date of first manifestation of gallbladder disease prior to entry: ---------- _____ Month _____ Year

6. Type of disease prior to entry (check as many as applicable):

Acute cholecystitis ---------- ( )
Chronic cholecystitis ---------- ( )
Cholelithiasis ---------- ( )
Gallbladder cancer ---------- ( )

Common duct stone ---------- ( )
Nonfunctioning gallbladder (by x-ray) ---------- ( )
Other (specify) ---------- ( )

_____

7. How was the diagnosis in Item 6 made? (Check one or more of the items below.)

Unknown ---------- ( )
History ---------- ( )
Physical examination ---------- ( )

Cholecystography and/or cholangiography ---------- ( )
Surgical findings ---------- ( )
Other (specify) ---------- ( )

_____

8. Did the patient have a cholecystectomy prior to entry? ---------- ( ) Yes ( ) No

9. Were stones available for analysis prior to entry? ---------- ( ) Unknown ( ) Yes ( ) No

If YES, what were the chemical composition and mode of analysis of the gallstones (check only one)?

Cholesterol -- chemical analysis ---------- ( )
Cholesterol -- gross appearance only ---------- ( )
Other (please specify) ----------

_____ ( )

Unknown ---------- ( )

GALLBLADDER DISEASE SINCE ENTRY

10. Has the patient manifested symptoms of gallbladder disease since entry? ---------- ( ) Yes ( ) No

If NO, SKIP TO ITEM 16.

11. Approximate date of first symptoms of gallbladder disease since entry: ---------- _____ Month _____ Year

12. Type of disease since entry (check as many as applicable):

Acute cholecystitis ---------- ( )
Chronic cholecystitis ---------- ( )
Cholelithiasis ---------- ( )
Gallbladder cancer ---------- ( )

Common duct stone ---------- ( )
Nonfunctioning gallbladder (by x-ray) ---------- ( )
Other (specify) ----------

_____

13. How was the diagnosis in Item 12 made? (Check one or more of the items below.)

History ---------- ( )
Physical examination ---------- ( )
Cholecystography and/or cholangiography ---------- ( )

Surgical findings ---------- ( )
Autopsy ---------- ( )
Other (specify) ----------

_____

I.D. No.

14. Has the patient had a cholecystectomy since entry? ---------- ( ) Yes ( ) No

If YES, give approximate date: ---------- _____ Month _____ Year

15. Have stones been available for analysis since entry? --------- ( ) Unknown ( ) Yes ( ) No

If YES, what were the chemical composition and mode of analysis of the gallstones (check only one)?

Cholesterol -- chemical analysis ---------- ( )
Cholesterol -- gross appearance only ---------- ( )
Other (please specify) ---------- ( )

_____

Unknown ---------- ( )

GALLBLADDER DISEASE DETECTED AT AUTOPSY

16. Was evidence of gallbladder disease found at autopsy in the absence of any clinical history of gallbladder disease? ---------- ( ) Yes ( ) No ( ) No Autopsy ( ) Living

If YES, please indicate on the line below the type of gallbladder disease that was found:

_____

17. If Item 16 was checked YES, were gallstones found at autopsy? ------ ( ) Yes ( ) No

If YES, what were the chemical composition and mode of analysis of the gallstones (check only one)?

Cholesterol -- chemical analysis ---------- ( )
Cholesterol -- gross appearance only ---------- ( )
Other (please specify) ---------- ( )

_____

Unknown ---------- ( )

18. Name of physician completing this form: _____ M.D.

19. Date this form is completed: ---------- _____ Month _____ Day _____ Year

The original copy of this form should be mailed to

CDP Coordinating Center
Division of Clinical Investigation
610 West Lombard Street
Baltimore, Maryland 21201

A copy of this form should be filed in your clinic.

I.D. No.

P	T
V	R

INITIAL VISIT 3 BASELINE FORM

I.D. No.

This form should be completed during Initial Visit 3. If this visit is not completed within four months following the date of Initial Visit 1, the patient must start anew with Initial Visit 1. If the patient has had a new myocardial infarction since Initial Visit 1, he should not complete Initial Visit 3 at this time, but rather should wait until at least one month passes since his latest episode and then start anew with Initial Visit 1. If a check is made in any space on this form designated "STOP", the patient may be ineligible for the CDP. No further work should be done on the patient until the "STOP" condition is removed. Do not use red ink or pencil on this form. A completed copy of this form should be retained for your files.

The patient should arrive for this visit in a fasting state (described in the Manual of Operations and in the Dietary Instruction Sheet, Form 12-A). This visit, or at least the collection of the serum and urine specimens, *must* be made in the *morning*.

At some time during this visit the following are required for this patient: A standard 12 lead resting ECG; a 40 ml. fasting blood sample (for Central Laboratory analysis); and a urine specimen (for Central Laboratory adherence tests).

Part I: Identifying Information

1) Name: ..... (First / Middle / Last)

2) Identifying Number: .....

The identifying number should appear also in the box in the upper right hand corner of this page and in the box in the lower right hand corner of each of the other pages of this form.

Part II: Medical History

3) Since Initial Visit 1 has the patient had any significant episodes of cardiac pain, aching, tightness, or pressure in the chest? ( ) Yes ( ) No [13]

If *NO*, proceed to item 4.

If *YES*, answer items A through J below:

A) Approximately how many episodes *per week* has he had on the average during this period?

- Less than 1 ..... (1) [14]
- 1 to 2 ..... (2)
- 3 to 5 ..... (3)
- 6 to 10 ..... (4)
- More than 10 ..... (5)

B) Does the pain typically radiate (check only one)?

- Does not radiate ..... (1) [15]
- Radiates to the left neck, jaw, shoulder or arm ..... (2)
- Radiates to areas other than the left neck, jaw, shoulder or arm ..... (3)
- Radiates to the left neck, jaw, shoulder, or arm *and* to other areas ..... (4)

C) How much exertion would it typically take to precipitate such an episode (check only one)?

- Walking at less than ordinary pace ..... (1) [16]
- Walking at an ordinary pace ..... (2)
- Walking hurriedly or up hill, or climbing stairs ..... (3)
- Not related to exertion ..... (4)

Item 3 continued:

D) Can excitement, emotion or meals precipitate such an episode? ..... ( ) Yes ( ) No [17]

E) Does rest typically relieve such an episode?

- Not at all ..... (1) [18]
- After more than 10 minutes ..... (2)
- In less than 10 minutes ..... (3)
- Rest not used ..... (4)

F) Does nitroglycerin typically relieve such an episode?

- Not at all ..... (1) [19]
- After more than 10 minutes ..... (2)
- In less than 10 minutes ..... (3)
- Nitroglycerin not used ..... (4)

G) What has been the longest duration of such an episode since Initial Visit 1?

- Less than 10 minutes ..... (1) [20]
- 10 to 30 minutes ..... (2)
- More than 30 minutes ..... (3)

H) Have any of the episodes since Initial Visit 1 been such that rest or nitroglycerin did *NOT* bring relief in the typical manner? ..... ( ) Yes ( ) No [21]

I) Did the patient get medical attention in connection with any episode of pain, aching, etc., since Initial Visit 1? ( ) Yes ( ) No [22]

If *NO*, proceed to item 3-J.

If *YES*, please give the place where such medical information may be found: _____

_____

Then avail yourself of this information and answer items i through viii below (if medical attention was obtained on more than one occasion, answer the questions in connection with the most serious of the episodes):

Item 3-I continued:

i) Did the patient have a pain suggestive of an episode of coronary insufficiency or a myocardial infarction?

No ..... (1)[23]
Possibly ..... (2)
Definitely ..... (3)

ii) Any evidence of shock? ..... (Yes) (No)[24]

iii) Arrhythmia? ..... (Yes) (No)[25]

iv) Leucocytosis? ..... (3) Not Done (1) Yes (2) No[26]

If *YES*, what was the highest recorded value (cells per mm³)? _____

v) Elevated sedimentation rate? ..... (3) Not Done (1) Yes (2) No[27]

If *YES*, what was the highest recorded value (mm/hr)? ..... _____

vi) Abnormal SGOT? ..... (3) Not Done (1) Yes (2) No[28]

If *YES*, what was the highest recorded value (state units)? .... _____

vii) Abnormal LDH? ..... (3) Not Done (1) Yes (2) No[29]

If *YES*, what was the highest recorded value (state units)? .... _____

viii) ECG evidence of a new myocardial infarction?

ECG not done ..... (1)[30]
Negative ..... (2)
Suggestive ..... (3)
Definite ..... (4)

J) Did any of the episodes since Initial Visit 1 result in a diagnosis of (answer each question):

	Suspect	Yes	No	
i) Myocardial infarction?	(3)	(STOP)	(2)	[31]
ii) Acute coronary insufficiency?	(3)	(STOP)	(2)	[32]
iii) Angina pectoris?	(3)	(1)	(2)	[33]

If the "STOP" condition in either of items 3-J-i or 3-J-ii has been checked, that is, if the patient has had acute coronary insufficiency or a myocardial infarction since Initial Visit 1, do not continue with this examination. See the box following item 17 in this form for further details.

4) Since Initial Visit 1 has the patient required nitroglycerin? ..... (Yes) (No)[34]

If *YES*, how did his requirement since Initial Visit 1 compare with his requirement during the two months just prior to Initial Visit 1 (check one)?

Requirement increased since Initial Visit I ..... (1)[35]
Requirement decreased since Initial Visit I ..... (2)
Requirement remained unchanged since Initial Visit I ..... (3)
Nitroglycerin not taken during the two months prior to Initial Visit I ..... (4)

If *NO*, check the statement below which is correct:

Patient has NEVER required nitroglycerin ..... (1)[36]
Patient has previously required nitroglycerin but has not required it since Initial Visit I .. (2)

5) Since Initial Visit 1 has the patient had any of the following (answer each question):

	Yes	No	
A) Cardiac asthma?	( )	( )	[37]
B) An obvious stroke?	( )	( )	[38]
C) Weakness or paralysis of any part of his body?	( )	( )	[39]
D) Spells of fainting or blacking out?	( )	( )	[40]
E) Spells of dizziness?	( )	( )	[41]
F) Sudden pain or coldness of a foot or leg?	( )	( )	[42]

6) Has the patient ever been hospitalized since Initial Visit 1? ..... (Yes) (No)[43]

If *YES*, answer items A through C below:

A) Where? _____

_____

B) For what reason?

Heart disease ..... (1)[44]
Other circulatory disease ..... (2)
Some other reason (specify) ..... (3)

_____

C) For how many days? ..... ____[45–46]

7) Which one of the New York Heart Association functional classes does the patient belong to (see Manual of Operations for definitions)?

Class I (no limitation) ..... (1)[47]
Class II (slight limitation) ..... (2)
Class III (marked limitation) ..... (STOP)
Class IV (discomfort even at rest) ..... (STOP)

I.D. No.

8) Since Initial Visit 1 has the patient had any of the following problems (answer each question):

	Yes	No	
A) Decrease in appetite?	( )	( )	48
B) Increase in appetite?	( )	( )	
C) Recent decreased muscle strength?	( )	( )	
D) Rapid or irregular heartbeat?	( )	( )	51
E) Unexpected loss of weight?	( )	( )	
F) Quivering or trembling of fingers?	( )	( )	
G) Sleeplessness?	( )	( )	54
H) Shortness of breath at night?	( )	( )	
I) Other shortness of breath?	( )	( )	
J) Excessive sweating or inability to stand heat?	( )	( )	57
K) Diarrhea?	( )	( )	
L) Nausea without vomiting?	( )	( )	
M) Vomiting?	( )	( )	60
N) Black tarry stools?	( )	( )	
O) Stomach pain?	( )	( )	
P) Blurring of vision?	( )	( )	63
Q) Unusual loss of hair?	( )	( )	
R) Decreased sexual desire or ability?	( )	( )	
S) Breast tenderness or enlargement?	( )	( )	66
T) Development or worsening of angina?	( )	( )	
U) Flushing?	( )	( )	
V) Burning sensation or pain when urinating?	( )	( )	69
W) Frequent urination?	( )	( )	
X) Reduced or delayed flow of urine?	( )	( )	
Y) Swelling of the ankles?	( )	( )	72
Z) Itching of the skin?	( )	( )	73
AA) Urticaria?	( )	( )	13
BB) Other types of rash which, in the patient's opinion, might be related to the drug (specify)?	( )	( )	14

_____

_____

CC) Other symptoms which, in the patient's opinion, might be related to the drug (specify)? ..... ( ) ( ) 15

_____

_____

Part III: Physical Examination

9) Weight (to nearest *POUND*, with all heavy outdoor garments and shoes removed): ..... _____ 16-18

10) Casual blood pressure (with the patient lying down or, if sitting, with forearm at the level of the heart):

Systolic (in mm. Hg.): ..... _____ 19-21

Diastolic (in mm. Hg.) at the disappearance of sound: ..... _____ 22-24

11) Heart rate (per min.): ..... _____ 25-27

12) Is the rhythm regular? ..... ( ) Yes ( ) No 28

13) Are any of the following findings present:

A) Peripheral edema? ..... ( ) Yes ( ) No 29

B) Ventricular diastolic gallop? ..... ( ) Yes ( ) No 30

C) Rales? ..... (1) Dry (2) Moist (3) Not Present 31

14) Have there been any *obvious* changes in the patient's physical condition since Initial Visit 1 which alter any of the historical and physical findings reported in Form 01 and which have not already been reported in this form? ..... ( ) Yes ( ) No 32

If *YES*, what findings given in Form 01 have changed (please mention specific item numbers)?

_____

_____

_____

_____

_____

I.D. No.

Part IV: Blood and Urine Specimens

During this visit a 40 ml. *fasting* blood sample should be obtained from the patient. At least 14 ml. of serum should be obtained from this specimen and four vials (numbered 1, 2, 5, and 6) should be filled with 3.5 ml. of serum each. Note that vial numbers 3 and 4 are not used.

Each of the four vials should be sealed and labeled with the following information:

Complete specimen identification number (consisting of patient identifying number, visit number, and vial number); patient's name; and month, day, and year of collection.

A urine specimen also should be obtained from the patient during this visit. A shipping vial (numbered 9) should be filled with about 6 ml. of urine. This vial should be sealed and labeled with the following information:

Complete specimen identification number; total volume of the voided specimen; time of the collection and approximate time of last voiding; and approximate number of hours since the patient's last drug dose.

The serum and urine vials should be immediately frozen and then shipped within a week to the CDP Central Laboratory in Atlanta.

See the Central Laboratory Manual for detailed instructions concerning collection, handling, and shipping of the serum and urine specimens.

15) Date and time blood specimen obtained:

Month	Day	Year	Hour
			33–40

Part V: Other Drug Prescription

16) Are any of the following drugs or types of drugs currently being prescribed for the patient (answer each question):

	Yes	No	
A) Insulin?	(STOP)	( )	41
B) Oral hypoglycemic agents?	( )	( )	42
C) Digitalis?	( )	( )	43
D) Antiarrhythmic agents?	( )	( )	44
E) Diuretics?	( )	( )	45
F) Antihypertensives other than diuretics?	( )	( )	46
G) Nitroglycerin or other coronary dilators?	( )	( )	47
H) Gout medication?	( )	( )	48
I) Anticoagulants?	(STOP)	( )	49
J) Cholesterol lowering drugs other than study medication?	(STOP)	( )	50
K) Other (specify)?	( )	( )	51

Part VI: Clinical Summary

17) In your best judgment (based on the history, physical examination, ECG taken at this visit, and any available laboratory data) has the patient had any of the following since Initial Visit 1 (answer each question):

	Suspect	Yes	No	
A) Congestive heart failure?	(3)	(1)	(2)	52
B) Angina pectoris?	(3)	(1)	(2)	53
C) Acute coronary insufficiency?	(3)	(STOP)	(2)	54
D) A new myocardial infarction?	(3)	(STOP)	(2)	55
E) Intermittent cerebral ischemic attacks?	(3)	(1)	(2)	56
F) Stroke?	(3)	(1)	(2)	57
G) Intermittent claudication?	(3)	(1)	(2)	58
H) Peripheral arterial occlusion?	(3)	(1)	(2)	59
I) Gout?	(3)	(1)	(2)	60

If the "STOP" condition in either of items 17-C or 17-D has been checked, that is, if the patient has had acute coronary insufficiency or a myocardial infarction since Initial Visit 1, he is not eligible to enter the CDP at this time. His sealed treatment allocation envelope should be returned *UNOPENED* to the CDP Coordinating Center. This form need not be completed and should not be sent to the Coordinating Center. The vials of serum and urine collected at this visit may be discarded.

Initial Visits 1 and 2 must be redone before a treatment allocation can again be requested. Initial Visit 1 must not be rescheduled within the first month following the patient's last episode of coronary insufficiency or myocardial infarction.

Part VII: CDP Medication

An assessment of the patient's adherence to the prescribed placebo medication since Initial Visit 2 is made by means of items 18 through 23.

18) How many capsules have been issued to the patient at and since Initial Visit 2? _____

19) How many capsules has the patient returned at this visit? _____

20) Approximately how many capsules have been left at home today or have been lost or accidentally destroyed since Initial Visit 2? _____

21) Approximately how many capsules do you judge the patient has taken since Initial Visit 2 (obtain this number by subtracting items 19 and 20 from item 18 and tempering the result with any other information or impressions obtained from the patient)? _____

I.D. No.

22) How many capsules should the patient have taken since Initial Visit 2 (obtain this number by multiplying the number of days between this visit and Initial Visit 2 by three)? ..... _____

23) What is the patient's percent adherence to the prescribed medication (100 times item 21 divided by item 22)? ..... _____% 61-63

24) Considering the medical history, the physical examination, the patient's adherence to his placebo medication since Initial Visit 2, and any other available information, do you still consider the patient to be eligible for admission into the CDP at this time? ..... ( ) Yes (STOP) No 64

IF ITEM 24 IS CHECKED *YES:*

The envelope containing this patient's treatment allocation may now be opened. This *should not* be done in the presence of the patient. The opening of this envelope officially marks this patient's entry into the study.

The patient should be instructed to take three capsules per day, one after each meal, from bottles having the code number indicated on the treatment allocation form. Unused capsules from bottle 99 should be discarded.

IF ITEM 24 IS CHECKED *NO:*

Do not complete this form nor send it to the Coordinating Center. The patient's treatment allocation should remain in the sealed envelope. The vials of serum and urine collected at this visit should not be sent to the Central Laboratory at this time. If there is some hope of removing the "STOP" condition within the time period of four months following the date of *Initial Visit 1*, the envelope may be retained by the clinic. If the patient becomes eligible for the CDP within this period of time, the envelope may be opened, this form completed, and the vials sent to the Central Laboratory.

If the patient is still ineligible for the CDP after four months have passed since Initial Visit 1, his treatment allocation envelope should be returned *UNOPENED* to the Coordinating Center. If the patient is subsequently reconsidered for entry into the CDP, Initial Visits 1 and 2 must be redone before a treatment allocation can again be requested.

25) Date on which the treatment allocation envelope was opened:

_____ _____ _____ 65-70
Month Day Year

26) The one- or two-digit bottle code number of this patient's medication is: ..... _____ 71-72

27) Name of the physician writing the prescription:

Dr. _____

An appointment for Initial Visit 4 (to take place one month, plus or minus a half month, from the date given in item 25) should be set prior to the conclusion of this visit.

The patient need not make any special dietary preparation for Initial Visit 4. He should be asked to return all his remaining capsules at that time.

Part VIII: Administrative Matters

28) The name of the physician responsible for the medical information recorded on this form is:

Dr. _____

29) This form has been checked for completeness by:

_____

The original copy of this form should be mailed now to:

CDP Coordinating Center
Institute of International Medicine
660 West Redwood Street
Baltimore, Maryland 21201

The carbon copy should be filed in your clinic. A copy of the ECG obtained at this visit should also be sent to the Coordinating Center.

30) The date on which this form is being mailed to the CDP Coordinating Center is:

_____ _____ _____
Month Day Year

I.D. No.

(6/73)

CDP Form 27
CDPA Form 527

FOR COORDINATING CENTER USE ONLY:
P
V
SITE:

CDP I.D. No.

Clinic No.

CDPA I.D. No.

MALIGNANT NEOPLASIA SURVEY FORM

This form must be completed for all patients in both the CDP and CDPA who have ever had a diagnosis of malignant neoplasia (either before or since entry into the CDP). This includes deceased patients (even if cause of death was something other than malignant neoplasia) and dropouts as well as currently active patients in the CDP and CDPA. All autopsy reports should be reviewed for evidence of occult malignancies and this form should be used to report such malignant neoplasia. If, for a deceased patient, there is no record of history of malignant neoplasia in the clinic's chart (including autopsy report), there is no need to search his pre-CDP medical records for history of malignant neoplasia.

This form should be completed and forwarded to the Coordinating Center as soon as possible after a new malignant neoplasm has been detected or after a patient has died because of malignant neoplasia. Following the submittal of the CDP Form 27/527 for a living patient, the Coordinating Center will require an updated CDP Form 27/527 at the end of the study or following the death of the patient.

1) Patient's Name: _____
(Please print) First Middle Last

2) CDP Identifying Number: _____

If this patient is now a CDPA patient, also give the CDPA identifying number and name code.

CDPA Identifying Number: _____

NAME CODE

3) Date form completed: _____ _____ _____
Month Day Year

4) Status of patient as of the date given in item 3:

Active ---------- ( )
Dropout ---------- ( )
Dead ---------- ( )

5) Source(s) of information regarding existence of malignant neoplasm (check as many as applicable):

Patient himself ---------- ( )
Patient's personal physician ---------- ( )
Autopsy report ---------- ( )
Death certificate ---------- ( )
Hospital records ---------- ( )
CDP clinic records ---------- ( )
Other (specify) ---------- ( )

_____

6) Has more than one primary malignant neoplasm been diagnosed? ---------- ( ) Yes ( ) No

If YES, complete a Form 27/527 for each primary site and give the number of forms completed: ----------

_____

7) Date of detection (first diagnosis) of this malignant neoplasm: ---------- _____ Month _____ Year

8) Anatomical site(s) of this malignant neoplasm:

a. Primary organ: _____

If the primary organ is unknown, check here ---------- ( )

b. Sites or organs of metastasis involvement: _____

_____

_____

9) Histologic diagnosis (e.g. adenocarcinoma, squamous cell carcinoma, etc.):

_____

_____

_____

CDP I.D. No.

Clinic No.

CDPA I.D. No.

IMPORTANT NOTE:

Please send the following materials (if available) to the Coordinating Center along with this form:

A. A copy or summary of the report for all the items checked in items 10 c through g.

B. Slides if the diagnosis is based on 10-b-ii, 10-c, 10-d-ii or 10-e.

If for any line in item 10 it is impossible to obtain the report(s) or slides confirming the diagnosis of malignant neoplasia, please check the appropriate column(s).

10) Basis of the diagnosis of this malignant neoplasm (Check as many as applicable):	Basis of the diagnosis	Impossible to obtain report(s)	Impossible to obtain slides
a. Death certificate	( )	( )	
b. Autopsy: (i) Macroscopic findings	( )	( )	
(ii) Microscopic findings	( )	( )	( )
c. Biopsy	( )	( )	( )
d. Surgery including exploratory surgery:			
(i) Macroscopic findings	( )	( )	
(ii) Microscopic findings	( )	( )	( )
e. Cytology (e.g. sputum cytology)	( )	( )	( )
f. Roentgenologic study	( )	( )	
g. Other tests (e.g. bronchoscopy, sigmoidoscopy, radioisotopic scanning, etc.)	( )	( )	
Specify _____			
h. Physical examination in the absence of b through g	( )	( )	

If item h is checked, please summarize the physical findings leading to the diagnosis on the lines below:

_____

_____

_____

i. Other (specify) _____

CDP I.D. No.

Clinic No.

CDPA

11) Are slides being forwarded to the Coordinating Center? ---------- ( ) Yes ( ) No

If NO, proceed to item 12.

If YES, answer items (A) and (B) below:

(A) Slides are being mailed (check one of the following):

With this form ---------- ( )
Under separate cover on the date indicated below ---------- ( )

Month ____ Day ____ Year ____

(B) Number of slides mailed ---------- ____

12) Method of treatment of this malignant neoplasm
(Check as many as applicable):

a. Surgery ---------- ( )

Give date: ---------- Month ____ Year ____

b. Radiation ---------- ( )

c. Chemotherapy ---------- ( )

d. Other ---------- ( )

Specify: _____

13) Please give the name and address of the hospital(s) where the malignant neoplasm was diagnosed and treated:

Name	Address

CDP I.D. No.

Clinic No.

CDPA I.D. No.

14) Has the patient's study medication been permanently discontinued or the dosage permanently reduced because of the malignant neoplasm? ---------- ( ) Yes ( ) No

If YES, give the appropriate date(s) below:

Date when the dosage of the study medication was first reduced (but not discontinued) because of the malignant neoplasm ---------- _____ Month _____ Year

Date when the study medication was permanently discontinued ---------- _____ Month _____ Year

15) Please give a summary and sequence of the disease and any additional information which might be relevant to the disease.

16) Name of physician completing this form:

_____ M.D.

The original copy of this form should be mailed to:

CDP Coordinating Center
University of Maryland
Department of Social and Preventive Medicine
Division of Clinical Investigation
610 West Lombard Street
Baltimore, Maryland 21201

A copy of this form should be filed in your clinic.

CDP I.D. No.

Clinic No.

CDPA

P	T
V	R

F.V.

I.D. No.

NON-ANNUAL FOLLOW-UP EXAMINATION FORM

This form should be completed during each of Follow-up Visits 1, 2, 4, 5, 7, 8, 10, 11, 13 and 14, that is, the non-annual visits. The permissible time periods for completing these visits are given in each patient's CDP Appointment Schedule, Form 11. In the event that the time period for completing this visit elapses without the visit being completed, items 1 through 4 should be completed and page 1 of this form mailed immediately to the CDP Coordinating Center. (This last instruction does not apply if the patient has officially dropped out of the study or if he is no longer living.) Do not use red ink or pencil on this form. A completed copy of this form should be retained for your files.

The patient should arrive for this visit in a "fat-free" state (described in the Manual of Operations and in the Dietary Instruction Sheet, Form 12-B). It is preferred that this visit, or at least the collection of the serum and urine specimens, be made in the *morning*.

At some time during this visit the following are required for this patient: A 40 ml. "fat-free" blood sample (for Central Laboratory analyses); and a urine specimen (for glucose and protein tests done locally and for Central Laboratory analyses).

Part I: Identifying Information

1) Name: _____
First Middle Last

2) Identifying Number: _____

The identifying number should appear also in the larger box in the upper right hand corner of this page and in the larger box in the lower right hand corner of each of the other pages of this form.

3) This is Follow-up Visit Number: _____

The Follow-up Visit Number should appear also in the smaller box in the upper right hand corner of this page and in the smaller box in the lower right hand corner of each of the other pages of this form.

4) Was this Follow-up Visit completed within the time period specified in the patient's CDP Appointment Schedule? .... (Yes) (No) [15]

If *YES*, write the date on which the history and physical examination portions of this visit were completed and then proceed to Part II of this form:

_____ _____ _____ [16-21]
Month Day Year

If *NO*, write the reason the visit was missed on the lines below and send the first page of this form to the Coordinating Center:

_____

_____

If this is the third *consecutive* missed follow-up visit, or else if three consecutive follow-up visits have been missed since Form 08 (the Incomplete Follow-up Form) was last completed, you are required at this time to complete Form 08 and send it to the CDP Coordinating Center.

Part II: Medical History

The information in this part should cover the period since the patient's last *completed* follow-up visit. If the present visit happens to be the first completed follow-up visit, the information summarized here should cover the period since Initial Visit 3.

5) Since the patient's last completed follow-up visit has he had any significant episodes of cardiac pain, aching, tightness, or pressure in the chest? ..... (Yes) (No) [22]

If *NO*, proceed to item 6.

If *YES*, answer items A through J below:

A) Approximately how many episodes *per week* has he had on the average during this period?

Less than 1 ..... (1) [23]
1 to 2 ..... (2)
3 to 5 ..... (3)
6 to 10 ..... (4)
More than 10 ..... (5)

B) Does the pain typically radiate (check only one)?

Does not radiate ..... (1) [24]
Radiates to the left neck, jaw, shoulder, or arm ..... (2)
Radiates to areas other than the left neck, jaw, shoulder, or arm ..... (3)
Radiates to the left neck, jaw, shoulder, or arm *and* to other areas ..... (4)

C) How much exertion would it typically take to precipitate such an episode (check only one)?

Walking at less than ordinary pace ..... (1) [25]
Walking at an ordinary pace ..... (2)
Walking hurriedly or up hill, or climbing stairs ..... (3)
Not related to exertion ..... (4)

Item 5 continued:

D) Can excitement, emotion, or meals precipitate such an episode? ..... (Yes) (No) [26]

E) Does rest typically relieve such an episode?

Not at all ..... (1) [27]
After more than 10 minutes ..... (2)
In less than 10 minutes ..... (3)
Rest not used ..... (4)

F) Does nitroglycerin typically relieve such an episode?

Not at all ..... (1) [28]
After more than 10 minutes ..... (2)
In less than 10 minutes ..... (3)
Nitroglycerin not used ..... (4)

G) What has been the longest duration of such an episode?

Less than 10 minutes ..... (1) [29]
10 to 30 minutes ..... (2)
More than 30 minutes ..... (3)

H) Have any of the episodes been such that rest or nitroglycerin did *NOT* bring relief in the typical manner? .. (Yes) (No) [30]

I) Did the patient get medical attention in connection with any episode of pain, aching, etc., during this period? (Yes) (No) [31]

If *NO*, proceed to item 5-J.

If *YES*, please give the place where such medical information may be found: _____

_____

Then avail yourself of this information and answer items i through viii below. (If medical attention was obtained on more than one occasion, answer the questions in connection with the most serious of the episodes.)

i) Did the patient have a pain suggestive of an episode of coronary insufficiency or a myocardial infarction?

No ..... (1) [32]
Possibly ..... (2)
Definitely ..... (3)

ii) Any evidence of shock? ..... (Yes) (No) [33]

Item 5-I continued:

iii) Arrhythmia? ..... (Yes) (No) [34]

iv) Leucocytosis? ..... (3) Not Done (1) Yes (2) No [35]

If *YES*, what was the highest recorded value (cells/mm³)? .. _____

v) Elevated sedimentation rate? ..... (3) Not Done (1) Yes (2) No [36]

If *YES*, what was the highest recorded value (mm/hr)? ..... _____

vi) Abnormal SGOT? ..... (3) Not Done (1) Yes (2) No [37]

If *YES*, what was the highest recorded value (state units)? _____

vii) Abnormal LDH? ..... (3) Not Done (1) Yes (2) No [38]

If *YES*, what was the highest recorded value (state units)? _____

viii) ECG evidence of a new myocardial infarction?

ECG not done ..... (1) [39]
Negative ..... (2)
Suggestive ..... (3)
Definite ..... (4)

J) Did any of the episodes since the last completed follow-up visit result in a diagnosis of:

	Suspect	Yes	No	
i) Myocardial infarction?	(3)	(1)	(2)	[40]
ii) Acute coronary insufficiency?	(3)	(1)	(2)	[41]
iii) Angina pectoris?	(3)	(1)	(2)	[42]

6) Has the patient required nitroglycerin since his last completed follow-up visit? .. (Yes) (No) [43]

If *YES*, how did his requirement since the last completed follow-up visit compare with his requirement during the four months just prior to the last completed follow-up visit (check one)?

Requirement increased since last visit ..... (1) [44]
Requirement decreased since last visit ..... (2)
Requirement remained unchanged since last visit ..... (3)
Nitroglycerin not taken during the four months prior to last visit ..... (4)

F.V.	I.D. No.

7) Since the patient's last completed follow-up visit, has he had any of the following (answer each question):

	Yes	No	
A) Cardiac asthma?	( )	( )	45
B) An obvious stroke?	( )	( )	46
C) Weakness or paralysis of any part of his body?	( )	( )	47
D) Spells of fainting or blacking out?	( )	( )	48
E) Spells of dizziness?	( )	( )	49
F) Sudden pain or coldness of a foot or leg?	( )	( )	50

8) Does the patient have pains or cramps in his legs when he walks? (Yes) (No) 51

If *YES*, is the pain quickly relieved when he stops walking? (Yes) (No) 52

9) Has the patient ever been hospitalized since his last completed follow-up visit? (Yes) (No) 53

If *YES*, answer items A through C below:

A) Where? _____

_____

B) For what reason?

Heart disease (1) 54
Other circulatory disease (2)
Some other reason (specify) (3)

_____

C) For how many days? _____ 55-56

IF THIS IS THE PATIENT'S FIRST COMPLETED FOLLOW-UP VISIT, PLEASE MAKE SURE THAT ALL OF THE PROBLEMS WHICH THE PATIENT MENTIONED AT INITIAL VISITS 4 AND 5 AND WHICH WERE REPORTED IN FORM 03 ARE ALSO CHECKED IN ITEM 10 BELOW.

10) Has the patient had any problems in connection with his CDP medication since his last completed follow-up visit?

Yes (1) 57
No (2)
No capsules of any CDP medication (including codes 1-30 and 99) were prescribed since the last completed follow-up visit (3)

If *YES*, what sorts of problems has he had? (Summarize the *patient's SPONTANEOUS* remarks to this question by checking the appropriate item or items below.)

A) Forgetfulness or some other non-medical matter which interfered with taking the medication properly ( ) 58
B) Unwillingness to take the prescribed medication ( )
C) Difficulty swallowing the capsules ( )

Item 10 continued:

D) Too many capsules ( ) 61
E) Decrease in appetite ( )
F) Increase in appetite ( )

G) Recent decreased muscle strength ( ) 64
H) Rapid or irregular heartbeat ( )
I) Unexpected loss of weight ( )

J) Quivering or trembling of fingers ( ) 67
K) Sleeplessness ( )
L) Shortness of breath at night ( )

M) Other shortness of breath ( ) 70
N) Excessive sweating or inability to stand heat ( )
O) Diarrhea ( )

P) Nausea without vomiting ( ) 73
Q) Vomiting ( )
R) Black tarry stools ( ) 75

S) Stomach pain ( ) 15
T) Blurring of vision ( )
U) Unusual loss of hair ( )

V) Decreased sexual desire or ability ( ) 18
W) Breast tenderness or enlargement ( )
X) Development or worsening of angina ( )

Y) Flushing ( ) 21
Z) Burning sensation or pain when urinating ( )
AA) Frequent urination ( )

BB) Reduced or delayed flow of urine ( ) 24
CC) Swelling of the ankles ( )
DD) Itching of the skin ( )

EE) Urticaria ( ) 27

FF) Other types of rash which, in the patient's opinion, might be related to the drug (specify) ( ) 28

_____

_____

GG) Other symptoms which, in the patient's opinion, might be related to the drug (specify) ( ) 29

_____

_____

If you have reason to believe that one or more of the problems checked in item 10 above are *not* related to the CDP medication, circle the check marks for those problems and write *NDR* (meaning Not Drug Related) after the check marks.

F.V.	I.D. No.

Part III: Physical Examination

11) Weight (to nearest *POUND*, with all heavy outdoor garments and shoes removed): ..... _____ 30–32

12) Casual blood pressure (with the patient lying down or, if sitting, with forearm at the level of the heart):

Systolic (in mm. Hg.): ..... _____ 33–35

Diastolic (in mm. Hg.) at the disappearance of sound: ..... _____ 36–38

13) Heart rate (per min.): ..... _____ 39–41

14) Is the rhythm regular? ..... (Yes) (No) 42

15) Are any of the following findings present:

A) Peripheral edema? ..... (Yes) (No) 43

B) Ventricular diastolic gallop? ..... (Yes) (No) 44

C) Rales? ..... (1 Dry) (2 Moist) (3 Not Present) 45

D) Gynecomastia? ..... (Yes) (No) 46

E) Icterus in sclera and/or skin? ..... (Yes) (No) 47

16) On the basis of this physical examination and available laboratory data, is there indication of any noteworthy abnormality in the following systems:

	Yes	No	
A) Gastrointestinal?	( )	( )	48
B) Genitourinary?	( )	( )	49
C) Nervous?	( )	( )	50
D) Musculoskeletal?	( )	( )	51
E) Dermal?	( )	( )	52
F) Bronchopulmonary?	( )	( )	53

Part IV: Blood and Urine Specimens

During this visit a 40 ml. "fat-free" blood sample should be obtained from the patient. At least 14 ml. of serum should be obtained from this specimen and four vials (numbered 1, 2, 5, and 6) should be filled with 3.5 ml. of serum each. Note that vial numbers 3 and 4 are not used.

Each of the four vials should be sealed and labeled with the following information:

Complete specimen identification number (consisting of patient identifying number, visit number, and vial number); patient's name; and month, day, and year of collection.

A urine specimen also should be obtained from the patient during this visit. A shipping vial (numbered 9) should be filled with about 6 ml. of urine. This vial should be sealed and labeled with the following information:

Complete specimen identification number; total volume of the voided specimen; time of the collection and approximate time of last voiding; and approximate number of hours since the patient's last drug dose.

The serum and urine vials should be immediately frozen and then shipped within a week to the CDP Central Laboratory in Atlanta.

See the Central Laboratory Manual for detailed instructions concerning collection, handling, and shipping of the serum and urine specimens.

17) Date and time blood specimen obtained:

Month	Day	Year	Hour
_____	_____	_____	_____ 54–61

Using the remainder of the urine specimen, the tests indicated in items 18 and 19 below should be performed locally.

18) Urine glucose (use Ames Clinistix): ..... (+ -) (–) 62

19) Urine protein (use Ames Clinistix):
(1 Negative) (2 Trace) (3 1+) (4 2+) (5 3+) (6 4+) 63

Part V: Other Drug Prescription

The information in item 20 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 Initial Visit 3.

20) Are any of the following drugs or types of drugs being prescribed now or have any of them been prescribed in the period defined in the box above (answer each question):

	Yes	No	
A) Insulin?	( )	( )	64
B) Oral hypoglycemic agents?	( )	( )	65
C) Digitalis?	( )	( )	66
D) Antiarrhythmic agents?	( )	( )	67

F.V.	I.D. No.

Item 20 continued:

	Yes	No	
E) Diuretics?	( )	( )	68
F) Antihypertensives other than diuretics?	( )	( )	69
G) Nitroglycerin or other coronary dilators?	( )	( )	70
H) Gout medication?	( )	( )	71
I) Anticoagulants?	( )	( )	72

If *YES*, answer items i and ii below:

i) For how many weeks during the period defined in the box above were anticoagulants prescribed? _____ 73–74

ii) What was the predominant type of anticoagulant used (check one)?

Heparin (1) 75
Prothrombin-depressing agent (2)

J) Cholesterol lowering drugs other than study medication?	( )	( )	76
K) Other (specify)? _____	( )	( )	77

Part VI: Clinical Summary

The information in item 21 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 Initial Visit 3.

21) Based on the history, physical examination, and any available laboratory data, has the patient had any of the following events in the period defined in the box above (answer each question; see the Manual of Operations for definitions of criteria for making the following diagnoses):

	Suspect	Yes	No	
A) Congestive heart failure?	(3)	(1)	(2)	15
B) Angina pectoris?	(3)	(1)	(2)	16
C) Acute coronary insufficiency?	(3)	(1)	(2)	17
If *YES*, how many episodes? _____				18
D) Myocardial infarction?	(3)	(1)	(2)	19
If *YES*, how many? _____				20
E) Intermittent cerebral ischemic attacks with neurological deficit lasting less than 24 hours?	(3)	(1)	(2)	21
F) Stroke with neurological deficit lasting more than 24 hours?	(3)	(1)	(2)	22
If *YES*, how many? _____				23
G) Intermittent claudication?	(3)	(1)	(2)	24

Item 21 continued:

	Suspect	Yes	No	
H) Peripheral arterial occlusion?	(3)	(1)	(2)	25
I) Gout?	(3)	(1)	(2)	26
J) Venous pulmonary embolism?	(3)	(1)	(2)	27
K) Thrombophlebitis?	(3)	(1)	(2)	28
L) Atrial fibrillation?	(3)	(1)	(2)	29
M) Arrhythmias other than atrial fibrillation?	(3)	(1)	(2)	30

22) Was the patient seen by a consultant in connection with any of the events listed in item 21? ( )Yes ( )No 31

If *YES*, give the names of all such consultants and the diagnoses they made on the lines below:

_____

_____

_____

Part VII: CDP Medication

In item 23 a record of every change in prescription of the assigned CDP medication from the time of the patient's last *completed* follow-up visit through the present date is required.

NOTE: If no capsules per day were prescribed for any interval during this period, or IF THE PATIENT WAS SWITCHED FROM HIS STUDY DRUG TO THE KNOWN PLACEBO, a *ZERO* should be written on the line indicating "No. of capsules per day."

23) Patient's prescription record:

A) Write the date and prescription given in part B of the prescription record of the patient's last completed follow-up visit form (Form 04 or 05) on the lines below. (If the present visit is the first completed follow-up visit, give THE DATE THE TREATMENT ALLOCATION ENVELOPE WAS OPENED and the prescription given at that time.)

Month	Day	Year	No. of capsules per day	
_____	_____	_____	_____	32–38

B) Write the present date and the prescription from this time forward:

Month	Day	Year	No. of capsules per day	
_____	_____	_____	_____	39–45

C) Have any changes been made in the prescription between the two dates given in items A and B above? ( )Yes ( )No 46

If *YES*, give the date of each change and the prescription made on that date on the lines below:

F.V.	I.D. No.

Item 23-C continued:

	Date of prescription (month, day, year)	No. of capsules per day
a.		
b.		
c.		
d.		
e.		
f.		
g.		
h.		

24) Using the prescription record in item 23, calculate the total number of capsules prescribed during the period covered by that record (see Manual of Operations for instructions). Write the total number of capsules here: _____ 47–50

25) In your best judgment (based on a capsule count and/or any other information or impressions obtained from the patient at this visit) what percentage of the total prescribed number of capsules (the number given in item 24) has the patient actually taken?

At least 80% ..... (1) 51
At least 60% but less than 80% ..... (2)
At least 40% but less than 60% ..... (3)
At least 20% but less than 40% ..... (4)
Less than 20% ..... (5)

If no capsules of ALLOCATED medication were prescribed, check here ..... (6)

26) If the percent adherence checked in item 25 is less than 80%, what is the *main* reason for the reduced level of adherence? (If more than one reason is given, please indicate which *ONE* you judge to be the *most important* reason by circling the appropriate letter or reason given below.)

If it is impossible to determine the reason, check here: ..... ( ) 52–61

If the main reason is one of the problems listed in item 10, write the letter designation of that problem here: ..... ____

If some other reason, specify:

_____

_____

27) During the period covered by the prescription record in item 23, has the prescription of ALLOCATED medication ever been less than nine capsules per day? (If this is the patient's *first completed* follow-up visit, check *YES either* if the prescription has ever been decreased since Initial Visit 3 *or* if the prescription has never yet reached 9 capsules per day.) ..... (Yes) (No) 62

If *YES*, what is the *main* reason for this? (If more than one reason is checked, please indicate by circling the appropriate check mark the *ONE* reason you judge to be the *most important*.)

A) Hepatic signs and/or symptoms ..... (1) 63–72
B) Renal signs and/or symptoms ..... (2)
C) Abnormality in the hematopoietic system .. (3)
D) Development or worsening of a peptic ulcer (4)
E) Gastrointestinal irritation ..... (5)
F) Gout signs and/or symptoms ..... (6)
G) Development or suspicion of toxic amblyopia ..... (7)
H) Development or worsening of diabetes mellitus ..... (8)
I) Development or worsening of angina pectoris ..... (9)
J) Congestive heart failure ..... (10)
K) Arrhythmia ..... (11)
L) Def. ACI, or def. or susp. MI, stroke, pulmonary embolism, pulmonary infarction, arterial embolism ..... (12)
M) Clinical hyperthyroidism ..... (13)
N) Decreased libido or potentia ..... (14)
O) Feminization ..... (15)
P) Flushing ..... (16)
Q) Itching ..... (17)
R) Rash or other dermatologic problems ..... (18)
S) Serious complaints of the patient possibly related to side effects of the drug ..... (19)
T) Unwillingness of the patient or his personal physician to accept the prescribed dosage (20)

F.V.	I.D. No.

Item 27 continued:

U) Other (specify) ..... (21)

_____

_____

V) ESG2 ..... (22)
W) Baseline VPBs, D-T4 group ..... (23)
X) D-T4 ..... (24)

INTERNAL USE ONLY

Y) Non-medical reasons (missed visits, re-instated dropouts, etc.) ..... (25)

Z) Patient taking other cholesterol-lowering medication ..... (26)

AA) ESG and D-T4 patients not enrolled in the CDPA ..... (27)

28) What is the bottled code number of the medication being dispensed to the patient at this time?

No capsules of any medication ..... (00) 73-74
Codes 65, 86, or 99 ..... (99)
Codes 1 to 60 (specify code): ..... ——

29) Has the patient's sealed medication code ever been broken? ..... (Yes) (No) 75

If *YES*, you should immediately inform the CDP Coordinating Center of the reason for this if you have not done so already.

Unless contraindicated, the patient should be instructed to continue taking nine capsules per day of the assigned medication.

At this time an appointment for the next follow-up visit should be made for a date as close as possible to the date indicated in the patient's CDP Appointment Schedule, Form 11.

If the next scheduled visit is one of Follow-up Visits 2, 5, 8, 11, or 14, the patient should be instructed to arrive for that visit in a "fat-free" state and should be given the appropriate Dietary Instruction Sheet (Form 12-B). It is strongly preferred that this next visit, or at least the collection of the serum and urine specimens, be made in the *morning*.

If the next visit is one of Follow-up Visits 3, 6, 9, 12, or 15, he should be instructed to arrive for that visit in a fasting state and should be given the appropriate Dietary Instruction Sheet (Form 12-A). This next visit, or at least the collection of the serum and plasma specimens, *must* be made in the *morning*.

The patient should be reminded to return all his remaining capsules at the next visit. He should also be instructed not to take any capsules on the day of the next visit until after the visit is completed.

Part VIII: Administrative Matters

30) The name of the physician responsible for the medical information recorded on this form is:

Dr. _____

31) This form has been checked for completeness by:

_____

The original copy of this form should be mailed now to:

CDP Coordinating Center
Division of Clinical Investigation
610 W. Lombard Street
Baltimore, Maryland 21201

The carbon copy should be filed in your clinic.

32) The date on which this form is being mailed to the CDP Coordinating Center is:

_____ — _____ — _____
Month Day Year

33) Since the patient's last completed follow-up visit has he taken aspirin or other drugs containing aspirin (for example, Anacin, Alka-Seltzer, A.P.C., Bufferin, Darvon-compound, Empirin-compound and Excedrin)? ..... (Uncertain) (Yes) (No) 76

If *YES*, give the patient's best estimate of the frequency of taking such drugs since the last completed follow-up visit:

Less than one day a week ..... (1) 77
One day a week ..... (2)
Two or three days a week ..... (3)
Four or more days a week ..... (4)

F.V.	I.D. No.

ADDITIONAL ITEMS TO BE COMPLETED AT CV3

34) Has the patient returned all of his unused study medication? ---------- ( ) Yes ( ) No [78]

If NO, the patient should be asked to return all unused study medication to the clinic as soon as possible.

35) Since CV2, has the patient been prescribed:

		Yes	No	
A)	CPIB ----------	( )	( )	[79]
B)	Nicotinic acid ----------	( )	( )	[80]

If a Form 76 was requested for this patient on the Form 76 checklist, please forward the completed CDP Form 76 including the name and address of the patient's private physician to the Coordinating Center. If the patient does not have a private physician, the study physician should assist the patient in establishing a continuing source of personal medical care.

(-71) CDP Form 14

P

SMOKING HISTORY QUESTIONNAIRE

I.D. NO.

This form should be completed for every CDP patient, whether active, deceased or a dropout. If the patient is deceased, his family, friends, employer, and/or personal physician should be contacted in order to obtain the desired information.

There are spaces provided below for indicating information not available. However, it is urged that these be used only after all the possible sources of information (see item 5 for a partial list) have been exhausted.

1) Patient's Name..... _____

2) Patient's Identifying Number..... _____

3) Date smoking history information obtained..... _____ 16-21
Month Day Year

4) Status of patient as of the date given in item 2:

Active..... (1) 22
Dropout..... (2)
Deceased..... (3)

5) Source(s) of smoking history information (check one or more):

Patient himself..... ( ) 25
Patient's family or relatives..... ( )
Patient's friend..... ( )
Patient's employer..... ( ) 26
Patient's personal physician..... ( )
Other (specify on line below)..... ( )

_____

No smoking history information available..... ( ) 29

6) Has the patient ever been a cigarette smoker (that is, has he smoked more than 100 cigarettes in his lifetime)?..... ( ) ( ) ( ) 30
Unknown Yes No

If NO or UNKNOWN, skip to item 7; If YES, answer A, B, and C below:

A) For how many years has he been a cigarette smoker? (If he has been a smoker on and off, do not count the years he has been a non-smoker.)

Less than 1 year..... (1) 31-32
1 - 5 years..... (2)
6 - 10 years..... (3)
11 - 20 years..... (4)

21 - 30 years..... (5)
31 - 40 years..... (6)
41 - 50 years..... (7)
> 50 years..... (8)

Item 6 continued:

B) During his years as a smoker, approximately what was the average number of cigarettes he smoked per day?

Less than 1	(1)	33-34
1 - 10	(2)	
11 - 20	(3)	
21 - 30	(4)	
31 - 40	(5)	
More than 40	(6)	

C) At the present time (or at the time of his death) is (was) he a cigarette smoker? ( ) Yes ( ) No 35

If NO, in what year did he stop smoking? (If he "stopped" more than once, give the year he last stopped.) 19____ 36-37

7) Which of the following statements best describes the patient's CIGAR smoking history (check one only)?

Currently (or at time of death) a cigar smoker	(1)	38
Formerly but not currently (or at time of death) a cigar smoker	(2)	
Never a cigar smoker	(3)	
Unknown	(4)	

8) Which of the following statements best describes the patient's PIPE smoking history (check one only)?

Currently (or at time of death) a pipe smoker	(1)	39
Formerly but not currently (or at time of death) a pipe smoker	(2)	
Never a pipe smoker	(3)	
Unknown	(4)	

The original copy of this form should be mailed to:

CDP Coordinating Center
Institute of International Medicine
660 West Redwood Street
Baltimore, Maryland 21201

A copy should be filed in your clinic.

I.D. NO.

(9-67)

CDP Form 03

P	T
V	R

TREATMENT ADJUSTMENT FORM

I.D. No.

This form should be completed during Initial Visits 4 and 5. The permissible time periods for completing these visits are given in each patient's individual CDP Appointment Schedule, Form 11. If, for some reason, neither Initial Visit 4 nor Initial Visit 5 are completed, items 1, 2, 3, 12, 24, and 25 should be completed and this form should be sent to the CDP Coordinating Center after the defined time period for completing Initial Visit 5 has elapsed. Do not use red ink or pencil on this form. A completed copy of this form should be retained for your files.

The patient need not make any special dietary preparation for either of these visits.

Part I: Identifying Information

1) Name: _____ (First / Middle / Last)

2) Identifying Number: _____

The identifying number should appear also in the box in the upper right hand corner of this page and in the box in the lower right hand corner of each of the other pages of this form.

Part II: Initial Visit 4

Initial Visit 4 is made one month (plus or minus a half month) after Initial Visit 3. (See the patient's CDP Appointment Schedule, Form 11.) Ideally, this is the time at which the prescription is changed from 3 capsules per day to 6 per day.

3) Was Initial Visit 4 completed within the time period specified in the patient's CDP Appointment Schedule? ..... ( ) Yes ( ) No [15]

If *YES*, write the date on which this visit was completed and proceed to item 4:

_____ (Month) _____ (Day) _____ (Year) [16–21]

If *NO*, write the reason on the lines below and proceed to Part III, item 12:

_____

_____

The determinations indicated in items 4 through 6 below should be obtained during this visit.

4) Weight (to nearest *POUND*, with all heavy outdoor garments and shoes removed): ..... _____ [22–24]

5) Casual blood pressure (with the patient lying down or, if sitting, with forearm at the level of the heart):

Systolic (in mm. Hg.): ..... _____ [25–27]

Diastolic (in mm. Hg.) at the disappearance of sound: ..... _____ [28–30]

6) Heart rate (per min.): ..... _____ [31–33]

7) Has the patient had any problems in connection with his CDP medication since Initial Visit 3? ..... ( ) Yes ( ) No [34]

If *YES*, what sorts of problems has he had? (Summarize the *patient's SPONTANEOUS* remarks to this question by checking the appropriate item or items below.)

A) Forgetfulness or some other non-medical matter which interfered with taking the medication properly ..... ( ) [35]

B) Unwillingness to take the prescribed medication ..... ( )

C) Difficulty swallowing the capsules ..... ( )

D) Too many capsules ..... ( ) [38]
E) Decrease in appetite ..... ( )
F) Increase in appetite ..... ( )

G) Recent decreased muscle strength ..... ( ) [41]
H) Rapid or irregular heartbeat ..... ( )
I) Unexpected loss of weight ..... ( )

J) Quivering or trembling of fingers ..... ( ) [44]
K) Sleeplessness ..... ( )
L) Shortness of breath at night ..... ( )

M) Other shortness of breath ..... ( ) [47]
N) Excessive sweating or inability to stand heat ( )
O) Diarrhea ..... ( )

P) Nausea without vomiting ..... ( ) [50]
Q) Vomiting ..... ( )
R) Black tarry stools ..... ( )

S) Stomach pain ..... ( ) [53]
T) Blurring of vision ..... ( )
U) Unusual loss of hair ..... ( )

V) Decreased sexual desire or ability ..... ( ) [56]
W) Breast tenderness or enlargement ..... ( )
X) Development or worsening of angina ..... ( )

Item 7 continued:

Y) Flushing ..... ( )[59]
Z) Burning sensation or pain when urinating .. ( )
AA) Frequent urination ..... ( )

BB) Reduced or delayed flow of urine ..... ( )[62]
CC) Swelling of the ankles ..... ( )
DD) Itching of the skin ..... ( )

EE) Urticaria ..... ( )[65]

FF) Other types of rash which, in the patient's opinion, might be related to the drug (specify) ..... ( )[66]

_____

_____

GG) Other symptoms which, in the patient's opinion, might be related to the drug (specify) ..... ( )[67]

_____

_____

If you have reason to believe that one or more of the problems checked in item 7 above are *not* related to the CDP medication, circle the check marks for those problems and write *NDR* (meaning Not Drug Related) after the check marks.

8) In your best judgment (based on a capsule count and/or any other information or impressions obtained from the patient at this visit), what percentage of the capsules of ALLOCATED medication (i.e., from bottles 1-30) prescribed since Initial Visit 3 has the patient actually taken?

At least 80% ..... (1)[15]
At least 60% but less than 80% ..... (2)
At least 40% but less than 60% ..... (3)
At least 20% but less than 40% ..... (4)
Less than 20% ..... (5)

9) If the percent adherence checked in item 8 is less than 80%, what is the *main* reason for the reduced level of adherence? (If more than one main reason is given, please indicate which *ONE* you judge to be the *most important* reason by circling the appropriate letter or reason given below.)

If it is impossible to determine the reason, check here: ..... ( )[16-25]

If the main reason is one of the problems listed in *ITEM 7* above, write the letter designation of that problem here: ..... ____

If some other reason, specify:

_____

_____

10) Since Initial Visit 3, has the prescription of ALLOCATED medication ever been less than 3 capsules per day? ..... (Yes) (No)[26]

If *YES*, what was the *main* reason for the decrease? (If more than one reason is checked, please indicate by circling the appropriate check mark the *ONE* reason you judge to be the *most important*.)

A) Hepatic signs and/or symptoms ..... (1)[27-36]
B) Renal signs and/or symptoms ..... (2)
C) Abnormality in the hematopoietic system .. (3)

D) Development or worsening of a peptic ulcer (4)
E) Gastrointestinal irritation ..... (5)
F) Gout signs and/or symptoms ..... (6)

G) Development or suspicion of toxic amblyopia ..... (7)
H) Development or worsening of diabetes mellitus ..... (8)
I) Development or worsening of angina pectoris ..... (9)

J) Congestive heart failure ..... (10)
K) Arrhythmia ..... (11)
L) New myocardial infarction ..... (12)

M) Clinical hyperthyroidism ..... (13)
N) Decreased libido or potentia ..... (14)
O) Feminization ..... (15)

P) Flushing ..... (16)
Q) Itching ..... (17)
R) Rash or other dermatologic problems ..... (18)

S) Serious complaints of the patient possibly related to side effects of the drug ..... (19)
T) Unwillingness of the patient to accept the prescribed dosage ..... (20)
U) Other (specify) ..... (21)

_____

_____

11) Will the prescription of ALLOCATED medication be increased at this time to 6 capsules per day? ..... (Yes) (No)[37]

If *NO*, what is the *main* reason for this? (If more than one main reason is given, please indicate which *ONE* you judge to be the *most important* reason by circling the appropriate letter or reason given below.)

If the main reason is one of the problems *A* through *T* in *ITEM 10* above, write the letter designation of that problem here: ..... ____[38-47]

If some other reason, specify:

_____

_____

I.D. No.

At this time an appointment for Initial Visit 5 should be made for a date as close as possible to the date indicated in the patient's CDP Appointment Schedule, Form 11.

The patient need not make any special dietary preparation for Initial Visit 5. He should be reminded to return all his remaining capsules at that time.

Part III: Initial Visit 5

Initial Visit 5 is made two months (plus or minus a half month) after Initial Visit 3. (See the patient's CDP Appointment Schedule, Form 11.) Ideally, this is the time at which the prescription is changed from 6 capsules per day to 9 per day.

12) Was Initial Visit 5 completed within the time period specified in the patient's CDP Appointment Schedule? ..... (Yes) (No) [48]

If *YES*, write the date on which this visit was completed and proceed to item 13:

_____ _____ _____ [49–54]
Month Day Year

If *NO*, write the reason on the lines below and proceed to item 24:

_____

_____

The determinations indicated in items 13 through 15 below should be obtained during this visit.

13) Weight (to nearest *POUND*, with all heavy outdoor garments and shoes removed): ..... _____ [55–57]

14) Casual blood pressure (with the patient lying down or, if sitting, with forearm at the level of the heart):

Systolic (in mm. Hg.): ..... _____ [58–60]

Diastolic (in mm. Hg.) at the disappearance of sound: ..... _____ [61–63]

15) Heart rate (per min.): ..... _____ [64–66]

16) Has the patient had any problems in connection with his CDP medication since Initial Visit 4 (or during the past month if Initial Visit 4 was missed)?

Yes ..... (1) [67]
No ..... (2)
No capsules of any CDP medication (including codes 1-30 and 99) were prescribed since I.V. 4 ..... (3)

If *YES*, what sorts of problems has he had? (Summarize the *patient's SPONTANEOUS* remarks to this question by checking the appropriate item or items below.)

Item 16 continued:

A) Forgetfulness or some other non-medical matter which interfered with taking the medication properly ..... ( ) [68]
B) Unwillingness to take the prescribed medcation ..... ( )
C) Difficulty swallowing the capsules ..... ( )

D) Too many capsules ..... ( ) [71]
E) Decrease in appetite ..... ( )
F) Increase in appetite ..... ( )

G) Recent decreased muscle strength ..... ( ) [74]
H) Rapid or irregular heartbeat ..... ( )
I) Unexpected loss of weight ..... ( ) [76]

J) Quivering or trembling of fingers ..... ( ) [15]
K) Sleeplessness ..... ( )
L) Shortness of breath at night ..... ( )

M) Other shortness of breath ..... ( ) [18]
N) Excessive sweating or inability to stand heat ..... ( )
O) Diarrhea ..... ( )

P) Nausea without vomiting ..... ( ) [21]
Q) Vomiting ..... ( )
R) Black tarry stools ..... ( )

S) Stomach pain ..... ( ) [24]
T) Blurring of vision ..... ( )
U) Unusual loss of hair ..... ( )

V) Decreased sexual desire or ability ..... ( ) [27]
W) Breast tenderness or enlargement ..... ( )
X) Development or worsening of angina ..... ( )

Y) Flushing ..... ( ) [30]
Z) Burning sensation or pain when urinating ( )
AA) Frequent urination ..... ( )

BB) Reduced or delayed flow of urine ..... ( ) [33]
CC) Swelling of the ankles ..... ( )
DD) Itching of the skin ..... ( )

EE) Urticaria ..... ( ) [36]

FF) Other types of rash which, in the patient's opinion, might be related to the drug (specify) ..... ( ) [37]

_____

_____

GG) Other symptoms which, in the patient's opinion, might be related to the drug (specify) ..... ( ) [38]

_____

_____

I.D. No.

If you have reason to believe that one or more of the problems checked in item 16 above are *not* related to the CDP medication, circle the check marks for those problems and write *NDR* (meaning, Not Drug Related) after the check marks.

17) In your best judgment (based on a capsule count and/or any other information or impressions obtained from the patient at this visit), what percentage of the capsules of ALLOCATED medication prescribed since Initial Visit 4 (or since Initial Visit 3 if Initial Visit 4 was missed) has the patient actually taken?

At least 80% ..... (1) 39
At least 60% but less than 80% ..... (2)
At least 40% but less than 60% ..... (3)
At least 20% but less than 40% ..... (4)
Less than 20% ..... (5)

If no capsules of ALLOCATED medication were prescribed, check here ..... (6)

18) If the percent adherence checked in item 17 is less than 80%, what is the *main* reason for the reduced level of adherence? (If more than one reason is given, please indicate which *ONE* you judge to be the *most important* reason by circling the appropriate letter or reason given below.)

If it is impossible to determine the reason, check here: ..... ( ) 40-49

If the main reason is one of the problems listed in *ITEM 16* above, write the letter designation of that problem here: ..... _____

If some other reason, specify:

_____

_____

19) Has the prescription of ALLOCATED medication given at Initial Visit 4 (or at Initial Visit 3 if Initial Visit 4 was missed), ever been *decreased* for any reason? ..... ( ) Yes ( ) No 50

If *YES*, what was the *main* reason for the decrease? (If more than one reason is checked, please indicate by circling the appropriate check mark the *ONE* reason you judge to be the *most important*.)

A) Hepatic signs and/or symptoms ..... (1) 51-60
B) Renal signs and/or symptoms ..... (2)
C) Abnormality in the hematopoietic system .. (3)
D) Development or worsening of a peptic ulcer (4)
E) Gastrointestinal irritation ..... (5)
F) Gout signs and/or symptoms ..... (6)

Item 19 continued:

G) Development or suspicion of toxic amblyopia ..... (7)
H) Development or worsening of diabetes mellitus ..... (8)
I) Development or worsening of angina pectoris ..... (9)
J) Congestive heart failure ..... (10)
K) Arrhythmia ..... (11)
L) New myocardial infarction ..... (12)
M) Clinical hyperthyroidism ..... (13)
N) Decreased libido or potentia ..... (14)
O) Feminization ..... (15)
P) Flushing ..... (16)
Q) Itching ..... (17)
R) Rash or other dermatologic problems ..... (18)
S) Serious complaints of the patient possibly related to side effects of the drug ..... (19)
T) Unwillingness of the patient to accept the prescribed dosage ..... (20)
U) Other (specify) ..... (21)

_____

_____

20) How many capsules per day of *ALLOCATED* medication (i.e., from bottles 1-30) have been *prescribed* just prior to this visit? ..... _____ 61-62

21) How many capsules per day of *ALLOCATED* medication will be prescribed at this time? ..... _____ 63-64

22) Is the prescription of ALLOCATED medication being *increased* at this time by at least three capsules per day? .... ( ) Yes ( ) No 65

If *NO*, what is the *main* reason for this? (If more than one main reason is given, please indicate which *ONE* you judge to be the *most important* reason by circling the appropriate letter or reason given below.)

If the main reason is one of the problems *A* through *T* in *ITEM 19* above, write the letter designation of that problem here: ..... _____ 66-75

If some other reason, specify:

_____

_____

23) The one- or two-digit bottle code number of this patient's medication is: ..... _____ 76-77

I.D. No.

At this time an appointment for Follow-up Visit 1 should be made for a date as close as possible to the date indicated in the patient's CDP Appointment Schedule, Form 11.

The patient should be instructed to arrive for Follow-up Visit 1 in a "fat-free" state and should be given the appropriate Dietary Instruction Sheet (Form 12-B). It is strongly preferred that Follow-up Visit 1, or at least the collection of the serum and urine specimens, be made in the *morning*.

The patient should be reminded to return all his remaining capsules at the next visit. He should also be instructed not to take any capsules on the day of the next visit until after the visit is completed.

24) This form has been checked for completeness by:

_____

The original copy of this form should be mailed now to:

CDP Coordinating Center
Institute of International Medicine
660 West Redwood Street
Baltimore, Maryland 21201

The carbon copy should be filed in your clinic.

25) The date on which this form is being mailed to the CDP Coordinating Center is:

Month	Day	Year
_____	_____	_____

I.D. No.