

CVI | V | I | A | I | (1-5)

CLOSURE VISIT 1 FORM

Subject ID Number (6-14)

Visit Number (15-16)

For CPR Use Only (40-45)

**Instructions:** Enter the visit number and CVI date. If a visit is not completed enter the target visit number and date of contact or contact attempt during CVI pertaining to Question 3 below. For questions 3-8, circle the appropriate response and provide the required information. See instructions for Completing Closure Visit 1 Form.

- 1. Visit or Contact Date:  /  /  (17-22)  
 Month / Day / Year
- 2. Last Name:  (23-34)
- Initials:  (35-36)  
 1st 2nd
- 3. Mode of Contact:
  - 1. Routine visit . . . . . (1)
  - 2. Special visit scheduled (i.e. home visit) . . . . . (2)
  - 3. Participant contact, other than clinic visit (i.e. telephone, mail) . . . . . (3)
  - 4. No participant contact (includes indirect contact). . . . . (4)
  - 5. Deceased (Submit memo to CPR summarizing status of effort.) . . . . . (5)
  - 6. Documentation is complete . . . . . (6)
  - 7. Documentation is incomplete . . . . . (7)
  - 8. Participant contact, go to Q7; if deceased, go to Q4; otherwise go to Q5. . . . . (37)
  - 9. Status of documentation (If complete, go to Q9; if incomplete, go to Q7.) . . . . . (38)
- 4. If a participant has died, date of death was \_\_\_\_\_
- 5. Are there any end points that occurred before or during CVI identified during the visit or contact?
  - a) No . . . . . (8)
  - b) Yes . . . . . (9)

- 6. Has a "silent MI" been diagnosed for participant based on CVI resting ECG?
  - a) No . . . . . 1
  - b) Yes . . . . . 2
  - c) Not Done . . . . . 3

If Yes, what is status of documentation (date DD sent, problems, etc.)?
- 7.1. Are there any end points for participant without a Provisional Diagnosis submitted as of CVI date?
  - a) No . . . . . 4
  - b) Yes . . . . . 5

If Yes, code the number of end points and specify below:

Event Date      Visit No.      End Point Diagnosis

1.    (47)

2.    (48-49)
- 8.1. Are there any end points for participant with a Provisional Diagnosis Form submitted as of CVI date with no follow-up (DD or HF) diagnosis form submitted?
  - a) No . . . . . 6
  - b) Yes . . . . . 7

If Yes, code the number of end points and specify below:

Event Date      Visit No.      Diagnosis on Provisional Form

1.    (50)

2.    (51-52)
- 9. Initials and code number of individual completing this form:   Code:   (53-54)



04877

GRADED EXERCISE TEST FORM

VERSION 3

73127

Form Approved O.M.B. No. 68-S73044  
68-S72041

GXT

E 3 1 (1-5)

Subject ID Number

For CPR Use Only (49-54)

Place ID Number Label in Box Above

A. IDENTIFICATION

1. PATIENT SCHEDULER: Enter the appropriate number in the Form Identifier as indicated:  
Enter "1" - if this is not a Reschedule of a previous Exercise ECG  
Enter "2" - if this is a Reschedule of a previous Exercise ECG

2. For Prevention Trial subjects enter the visit number; for Population Study subjects, enter PS: (15-16)

In items 3-6 enter one character per box, beginning with the leftmost box. Enter all letters as capitals. Mark through the boxes with a single stroke if the item does not apply.

3. Last Name: (17-28)

4. First Name: (29-36)

5. Second Name: (37)

6. Third or Maiden Name: (38-40)  
Code: JR, SR, I, II, etc. here.

B. FASTING AND MEDICATION

7. Date of Visit: (41-46)  
Month Day Year

8. When was the last time you took anything by mouth excepting water? See instructions for use of wheel to determine fasting time. (47-48)

9. During the past two weeks have you taken or had prescribed:	9. No	Yes	Unk
1) High blood pressure pills? . . . . .	1	2	9
2) Diuretics (water pills)? . . . . .	1	2	9
3) Medicine for angina (nitroglycerine or other coronary dilators)? . . . . .	1	2	9
4) Digitalis preparations? . . . . .	1	2	9
5) Medicine for irregular heart beats (antiarrhythmic agents)? . . . . .	1	2	9
6) Inderal (propranolol)? . . . . .	1	2	9

C. CHEST PAIN ON EFFORT

If an answer circled in section C is marked with an asterisk (\*), go to section D.

10. Have you ever had any pain or discomfort in your chest?	10. a.	10. b.
1 No . . . . .	1	
2 Yes . . . . .	2	(61)
If "Yes," go to item 11.		
Have you ever had any pressure or heaviness in your chest?		
1 No . . . . .	1	
2 Yes . . . . .	2	(62)
If "No," go to section E.		

11. Do you get it when you walk uphill or hurry?

1 No* . . . . .	1*
2 Yes . . . . .	2
3 Never hurries or walks uphill . . . . .	3 (63)

NEW CARD--DUPLICATE		AS (1-4)
DUPLICATE COLUMNS		(5) (6-14)
<b>D. POSSIBLE INFARCTION</b>		
<p><i>If an answer circled in this section is marked with an asterisk (*), go to section E.</i></p>		
12. you get it when you walk at an ordinary pace on level?	12.	
1 No . . . . .	1	
2 Yes . . . . .	2	(64)
<p>13. What do you do if you get it while you are walking?</p>		
1 Stop or slow down . . . . .	1	
2 Carry on . . . . .	2	(65)
<p><i>Circle "1," "Stop or slow down" if subject carries on after taking nitroglycerine.</i></p>		
<p>14. If you stand still, what happens to it?</p>		
1 Relieved . . . . .	1	
2 Not relieved . . . . .	2*	
3 Does not stand still . . . . .	3	(66)
<p><i>If "3," "Does not stand still," go to item 16.</i></p>		
<p>15. How soon?</p>		
1 Ten minutes or less . . . . .	1	
2 More than ten minutes . . . . .	2*	(67)
<p>16. Will you show me where it was?</p>		
a. Sternum (upper or middle)? . . . . .	a. 1	2 (68)
b. Sternum (lower)? . . . . .	b. 1	2 (69)
c. Left anterior chest? . . . . .	c. 1	2 (70)
d. Left arm? . . . . .	d. 1	2 (71)
e. Other? . . . . .	e. 1	2 (72)
<p>17. Has there been a change in your chest discomfort during the past four weeks?</p>		
a. Has your chest discomfort become more frequent or more severe?	a. 1*	2 (73)
b. Has your chest discomfort become easier to bring on?	b. 1	2 (74)
c. Has your chest discomfort begun occurring while you are at rest?	c. 1	2 (75)
d. Has your chest discomfort begun occurring while you are at rest?	d. 1	2 (76)
<b>E. SYNCOPE AND DYSPNEA</b>		
<p>18. Have you ever had a severe pain across the front of your chest lasting for half an hour or more?</p>		
18. No	No	Yes
18. Yes	1	2 (15)
<p>19. Did you see a doctor because of this pain?</p>		
a. If "No," go to item 20.	a. 1	2 (16)
b. What did he say it was?	b.	
1 Heart attack . . . . .	1	
2 Other disorder . . . . .	2*	(17)
<p>20. Have you had such a chest pain in the last three months?</p>		
20. No	No	Yes
20. Yes	1	2 (18)
<b>F. TARGET HEART RATE</b>		
<p>21. Have you fainted in the past hour?</p>		
21. No	No	Yes
21. Yes	1	2 (19)
<p>22. Have you ever fainted while exercising?</p>		
22. No	No	Yes
22. Yes	1	2 (20)
<p>23. Do you become more short of breath than others your own age during normal activity?</p>		
23. No	No	Yes
23. Yes	1	2 (21)
<p>24. In the past did you become more short of breath than others your own age during normal activity?</p>		
24. No	No	Yes
24. Yes	1	2 (22)
<p>25. Do you regularly engage in strenuous exercise or hard physical labor?</p>		
25. No	No	Yes
25. Yes	1	2 (23)
<p><i>If "No," classify the subject as sedentary for determining GXT target heart rate and proceed to item 27.</i></p>		

Rec'd

32. Lungs:

a. Moist basilar rales? . . . . .

b. Other abnormalities? . . . . .

If "Yes," specify: \_\_\_\_\_

26. Do you exercise or labor at least three times a week?

1 No . . . . .

2 Yes . . . . .

If "No," classify the subject as sedentary for determining GIT heart rate.

If "Yes," classify the subject as trained for determining GIT target heart rate.

33. a. Does subject have perceptible cardiac apical impulses?

1 No . . . . .

2 Yes . . . . .

9 Uncertain . . . . .

If "No" or "Uncertain," go to item 34.

b. Point of maximum impulse (PMI)

Refer to the figure on page 16 of the instructions.

27. Year of birth:

28. Target heart rate:

c. Diameter of apical impulse in whole centimeters

d. Apical impulse quality or contour

1 Normal . . . . .

2 Prolonged outward systolic component as in left ventricular hypertrophy . . . . .

29. Record the subject's blood pressure (standing, right arm):

Systolic

Diastolic V

30. Does the subject exhibit symptoms of acute illness sufficient to interfere with testing?

1 No . . . . .

2 Yes . . . . .

34. a. Is there a palpable cardiac "bulge"?

1 No . . . . .

2 Yes . . . . .

If "No," proceed to item 35.

b. Specify the location:

Refer to the figure on page 16 of the instructions.

31. a. Does the subject have some difficulty which might interfere with stress testing on the treadmill?

1 No . . . . .

2 Yes . . . . .

If "No," go to item 32.

b. Specify the difficulty: \_\_\_\_\_

C. CARDIOPULMONARY EXAM

a. 1 2 (38)

b. 1 2 (39)

33. a.

b. Letter  (41)

Number  (42)

c.   (43-44)

d. 1 2 (45)

34. a.

b. Letter  (47)

Number  (48)

<p>35. 1 third or ventricular filling gallop present?</p> <p>1 No . . . . .</p> <p>2 Yes . . . . .</p>	<p>35. 1 (49)</p>	<p>1b. Possible Acute Anterior Injury: QS V<sub>1</sub> and V<sub>2</sub> with convex-upward ST-T. <b>ANTINJ</b></p>	<p>1 <input type="checkbox"/></p>	<p>(57)</p>
<p>36. a. Is a grade two or louder systolic murmur present?</p> <p>1 No . . . . .</p> <p>2 Yes . . . . .</p> <p>If "No," go to item 37.</p>	<p>36. 1 (50)</p>	<p>c. Possible Acute Posterior Injury: R/S in V<sub>1</sub> &gt; 1.0, and ST-T depression, <math>\geq</math> 1.0 mm and convex downward. <b>POSTINJ</b></p>	<p>c. <input type="checkbox"/></p>	<p>(58)</p>
<p>b. Quality</p> <p>1 Regurgitant . . . . .</p> <p>2 Ejection . . . . .</p> <p>9. Uncertain . . . . .</p>	<p>36. 1 (51)</p>	<p>d. Possible or Suspected Unhealed M.I. of Any Kind: Large amplitude T wave inversion. <b>UNHEALMI</b></p>	<p>d. <input type="checkbox"/></p>	<p>(59)</p>
<p>37. a. Is a definite diastolic murmur present?</p> <p>1 No . . . . .</p> <p>2 Yes . . . . .</p> <p>If "No," go to item 38.</p>	<p>37. 2 (52)</p>	<p>41. Possible Left Ventricular Hypertrophy: R wave <math>\geq</math> 26 mm in V<sub>5</sub> or V<sub>6</sub> or <math>&gt;</math> 20 mm in I, II, III or AV7.</p>	<p>41. <input type="checkbox"/></p>	<p>(60)</p>
<p>b. Quality</p> <p>1 Regurgitant . . . . .</p> <p>2 Stenotic . . . . .</p>	<p>37. 1 (53)</p>	<p>42. Left Ventricular Conduction Defect: QRS duration <math>&gt;</math> 0.11 sec. in any lead + absence of slurred S wave <math>&gt;</math> .05 sec. in I or V<sub>5</sub> and V<sub>6</sub>.</p>	<p>42. <input type="checkbox"/></p>	<p>(61)</p>
<p>38. Is congenital heart disease suspected?</p> <p>1 No . . . . .</p> <p>2 Yes . . . . .</p>	<p>38. 2 (54)</p>	<p>43. Rhythm/Conductor Disorder:</p> <p>a. Heart cycle length varies <math>&gt;</math> 25% beats at least once in any 6 second interval (sick sinus syndrome). <b>SIN</b></p>	<p>a. <input type="checkbox"/></p>	<p>(62)</p>
<p>b. RESTING ECG</p>	<p>39. 1 (55)</p>	<p>b. Atrial and ventricular rates differ <math>&gt;</math> 25%. (This will not exclude occasional unifora, non R-on-T type PVC's.) (Second degree heart block.) <b>DBLX</b></p>	<p>b. <input type="checkbox"/></p>	<p>(63)</p>
<p>Check all of the appropriate boxes.</p>	<p>40. a. <input type="checkbox"/></p>	<p>c. Multifocal or many PVC's <math>&gt;</math> 10/min. (QRS-T's with QRS <math>&gt;</math> 0.12 sec. not preceded at least 0.12 sec. by P wave.) <b>PVCs</b></p>	<p>c. <input type="checkbox"/></p>	<p>(64)</p>
<p>39. Possible Ischemia: J-ST amplitude <math>\geq</math> 1.0 mm, depression in I, V<sub>4</sub>, V<sub>5</sub>, V<sub>6</sub>.</p>	<p>40. 2 (56)</p>	<p>d. R-on-T type PVC's. <b>RTAVC</b></p>	<p>d. <input type="checkbox"/></p>	<p>(65)</p>
<p>40. Possible Acute Lateral or Inferior Injury: ST elevation with convex-upward contour <math>&gt;</math> 0.5 mm, and low or inverted T wave, in I, II, III, V<sub>4</sub>, V<sub>5</sub>, or V<sub>6</sub>. <b>LAINJ</b></p>	<p>40. 1 (56)</p>	<p>e. Two or more PVC's in a row. (Ventricular tachycardia.) <b>VTACH</b></p>	<p>e. <input type="checkbox"/></p>	<p>(66)</p>
<p>40. Possible Acute Lateral or Inferior Injury: ST elevation with convex-upward contour <math>&gt;</math> 0.5 mm, and low or inverted T wave, in I, II, III, V<sub>4</sub>, V<sub>5</sub>, or V<sub>6</sub>. <b>LAINJ</b></p>	<p>40. 2 (56)</p>	<p>f. Parasystolic focus. <b>PARAFS</b></p>	<p>f. <input type="checkbox"/></p>	<p>(67)</p>
<p>40. Possible Acute Lateral or Inferior Injury: ST elevation with convex-upward contour <math>&gt;</math> 0.5 mm, and low or inverted T wave, in I, II, III, V<sub>4</sub>, V<sub>5</sub>, or V<sub>6</sub>. <b>LAINJ</b></p>	<p>40. 1 (56)</p>	<p>g. Atrial flutter. <b>AFLT</b></p>	<p>g. <input type="checkbox"/></p>	<p>(68)</p>
<p>40. Possible Acute Lateral or Inferior Injury: ST elevation with convex-upward contour <math>&gt;</math> 0.5 mm, and low or inverted T wave, in I, II, III, V<sub>4</sub>, V<sub>5</sub>, or V<sub>6</sub>. <b>LAINJ</b></p>	<p>40. 2 (56)</p>	<p>h. Atrial fibrillation. <b>A FIB</b></p>	<p>h. <input type="checkbox"/></p>	<p>(69)</p>

44. a. Disposition of subject:

1 Exercise Test . . . . . 1

2 Reschedule . . . . . 2

3 Excludes . . . . . 3 (70)

If "Exercise Test," go to item 46.

If "Reschedule," go to item 46.

NEW CARD--DUPLICATE COLUMNS (1-4)  
 (5)  
 DUPLICATE COLUMNS (6-14)

b. Reasons for exclusion (Check the appropriate boxes):

1 Aortic stenosis . . . . .  (15)

2 Congestive heart failure . . . . .  (16)

3 Blood pressure . . . . .  (17)

4 R-on-T type PVC's . . . . .  (18)

5 Ventricular tachycardia . . . . .  (19)

6 Parasympathetic focus . . . . .  (20)

7 Atrial flutter . . . . .  (21)

8 Atrial fibrillation . . . . .  (22)

9 Congenital heart disease . . . . .  (23)

10 Second rescheduling required . . . . .  (24)

11 Other (Specify)  (25)

Please thank the subject and dismiss him.

c. Reason for Rescheduling. (Check the appropriate boxes).  
 NOTE: a Reschedule Form must be completed for every subject rescheduled.

1 Non-fasting (Item 8) . . . . .  (26)

2 Unstable angina (Item 17) . . . . .  (27)

3 Possible recent infarction by history (Item 20) . . . . .  (28)

4 Painstaking (Item 21) . . . . .  (29)

5 Acute illness (Item 30) . . . . .  (30)

6 Possible ischemia, subject not on digitalis (Item 39) . . . . .  (31)

7 Possible acute lateral or inferior injury (Item 40a) . . . . .  (32)

8 Possible acute anterior injury (Item 40b) . . . . .  (33)

9 Possible acute posterior injury (Item 40c) . . . . .  (34)

10 Possible or suspected unhealed M.I. (Item 40d) . . . . .  (35)

11 Equipment malfunction . . . . .  (36)

12 Other. Specify:  (37)

45. Approximate date of re-visit:

No.    Tr. (38-41)

**5. EXERCISE ELECTROCARDIOGRAM**

46. Attending physician: a. Name: \_\_\_\_\_ (42-43)  
 b. Initials:    (44)

47. Is monitoring equipment functioning properly?  
 1 No 2 Yes (46)

In items 48-58, record the subject's systolic and diastolic blood pressure, his heart rate at end of stage, the ST code and rhythm code.

	Systolic	Diastolic	Heart Rate at End of Stage or Termination	ST Code	Rhythm Code
48. Standing at Rest	<input type="checkbox"/> <input type="checkbox"/> (45-47)	<input type="checkbox"/> <input type="checkbox"/> (48-50)	<input type="checkbox"/> <input type="checkbox"/> (51-53)	<input type="checkbox"/> <input type="checkbox"/> (54)	<input type="checkbox"/> (55)
49. Zero (1.7 mph, 0X)	<input type="checkbox"/> <input type="checkbox"/> (56-58)	<input type="checkbox"/> <input type="checkbox"/> (59-61)	<input type="checkbox"/> <input type="checkbox"/> (62-64)	<input type="checkbox"/> <input type="checkbox"/> (65)	<input type="checkbox"/> (66)
50. One-Half (1.7 mph, 5X)	<input type="checkbox"/> <input type="checkbox"/> (67-69)	<input type="checkbox"/> <input type="checkbox"/> (70-72)	<input type="checkbox"/> <input type="checkbox"/> (73-75)	<input type="checkbox"/> <input type="checkbox"/> (76)	<input type="checkbox"/> (77)
NEW CARD--DUPLICATE COLUMNS (1-4) (5) (6-14)					
DUPLICATE COLUMNS (1-4) (5) (6-14)					
51. One (1.7 mph, 10X)	<input type="checkbox"/> <input type="checkbox"/> (15-17)	<input type="checkbox"/> <input type="checkbox"/> (18-20)	<input type="checkbox"/> <input type="checkbox"/> (21-23)	<input type="checkbox"/> <input type="checkbox"/> (24)	<input type="checkbox"/> (25)
52. Two (2.5 mph, 12X)	<input type="checkbox"/> <input type="checkbox"/> (26-28)	<input type="checkbox"/> <input type="checkbox"/> (29-31)	<input type="checkbox"/> <input type="checkbox"/> (32-34)	<input type="checkbox"/> <input type="checkbox"/> (35)	<input type="checkbox"/> (36)
53. Three (3.4 mph, 14X)	<input type="checkbox"/> <input type="checkbox"/> (37-39)	<input type="checkbox"/> <input type="checkbox"/> (40-42)	<input type="checkbox"/> <input type="checkbox"/> (43-45)	<input type="checkbox"/> <input type="checkbox"/> (46)	<input type="checkbox"/> (47)
54. Four (4.2 mph, 16X)	<input type="checkbox"/> <input type="checkbox"/> (48-50)	<input type="checkbox"/> <input type="checkbox"/> (51-53)	<input type="checkbox"/> <input type="checkbox"/> (54-56)	<input type="checkbox"/> <input type="checkbox"/> (57)	<input type="checkbox"/> (58)
55. Five (5.0 mph, 18X)	<input type="checkbox"/> <input type="checkbox"/> (59-61)	<input type="checkbox"/> <input type="checkbox"/> (62-64)	<input type="checkbox"/> <input type="checkbox"/> (65-67)	<input type="checkbox"/> <input type="checkbox"/> (68)	<input type="checkbox"/> (69)
56. Six (5.5 mph, 20X)	<input type="checkbox"/> <input type="checkbox"/> (70-72)	<input type="checkbox"/> <input type="checkbox"/> (73-75)	<input type="checkbox"/> <input type="checkbox"/> (76-78)	<input type="checkbox"/> <input type="checkbox"/> (79)	<input type="checkbox"/> (80)
NEW CARD--DUPLICATE COLUMNS (1-4) (5) (6-14)					
DUPLICATE COLUMNS (1-4) (5) (6-14)					
57. Seven (6.0 mph, 22X)	<input type="checkbox"/> <input type="checkbox"/> (15-17)	<input type="checkbox"/> <input type="checkbox"/> (18-20)	<input type="checkbox"/> <input type="checkbox"/> (21-23)	<input type="checkbox"/> <input type="checkbox"/> (24)	<input type="checkbox"/> (25)
58. Immediate post-exercise	<input type="checkbox"/> <input type="checkbox"/> (26-28)	<input type="checkbox"/> <input type="checkbox"/> (29-31)	<input type="checkbox"/> <input type="checkbox"/> (32-34)	<input type="checkbox"/> <input type="checkbox"/> (35)	<input type="checkbox"/> (36)

Ask:

59. Do you have any discomfort in your chest?  
 1 No . . . . . 1  
 2 Yes . . . . . 2 (37)  
 If "No," go to item 65.

60. If "Yes," circle the number of minutes that elapsed between termination of exercise test and observation of discomfort.  
 0 Immediate post-exercise 0  
 1 One minute . . . . . 1  
 2 Two minutes . . . . . 2  
 3 Three minutes . . . . . 3  
 4 Four minutes . . . . . 4  
 5 Five minutes . . . . . 5  
 6 Six minutes . . . . . 6  
 9 More than 6 minutes post-exercise . . . . . 9 (38)

61. Ask subject to show where it is (or was). Does site include sternum?  
 1 No . . . . . 1  
 2 Yes . . . . . 2 (39)  
 If "No," go to item 65.

62. If "Yes," ask:  
 Is the discomfort sharp or dull?  
 1 Sharp . . . . . 1  
 2 Dull . . . . . 2 (40)  
 If "Sharp," go to item 66.

63. If "Dull," ask the subject to stop breathing for a few seconds, then ask:  
 Did the pain go away?  
 1 No . . . . . 1  
 2 Yes . . . . . 2 (41)  
 If "Yes," go to item 65.

64. If "No," ask the subject to take two deep breaths, then ask:  
 Is the discomfort worse?  
 1 No . . . . . 1  
 2 Yes . . . . . 2 (42)



Heart Rate at End

of Stage

ST Code

Rhythm C

Systolic

Diastolic

65. Two minute post-exercise

(43-45)

(46-48)

(49-51)

(52)  (53)

66. Four minute post-exercise

(54-56)

(57-59)

(60-62)

(63)  (64)

67. Six minute post-exercise

(65-67)

(68-70)

(71-73)

(74)  (75)

NEW CARD--DUPLICATE COLUMNS (1-4)  
DUPLICATE COLUMNS (5)  
DUPLICATE COLUMNS (6-14)

68. Duration of test (min./sec.)

/   (15-18)

69. Maximum heart rate achieved.

(19-21)

If the answer to item 69 was "Yes," ask:

70. Do you still have any discomfort in your chest?

- 1 No . . . . . 1
- 2 Yes . . . . . 2 (22)

71. Reasons for termination (Check the appropriate boxes):

- 1 Target heart achieved . . . . . TRMGXT ✓  (23)
- 2 Bruce test criteria met (exhaustion) . . . . . BRTST  (24)
- 3 Fatigue/weakness . . . . . FTGUE  (25)
- 4 Dyspnea . . . . . DYSP  (26)
- 5 Leg pain . . . . . LEGP  (27)
- 6 Chest pain . . . . . CHSTP  (28)
- 7 ST changes . . . . . STCNG ✓  (29)

71. Continued

- 8 Supraventricular tachycardia . . . . . SUPRT ✓  (30)
- 9 Ventricular tachycardia . . . . . VENT ✓  (31)
- 10 Other arrhythmias . . . . . OARY ✓  (32)
- 11 Hypotension . . . . . HYPEN ✓  (33)
- 12 Cerebral symptoms . . . . . C.KS/M ✓  (34)
- 13 Intracardiac block . . . . . INCB ✓  (35)
- 14 Hypertension . . . . . HYPET ✓  (36)
- 15 Technical problems (describe in comments) . . . . . TECHPV ✓  (37)
- 16 Difficulty recorded in item 31b . . . . . DIFR ✓  (38)
- 17 Subject refused to continue . . . . . REFCO ✓  (39)
- 18 Other (describe in comments) . . . . . COM ✓  (40)

72. Technician: a. Name: \_\_\_\_\_ b. Initials: \_\_\_\_\_ (41-42)

Comments: \_\_\_\_\_

HOSPITALIZED S LAST VISIT  
\*OBTAIN A RESTING ECG\*

(15-16)

Number of Last Visit

(1-5)

Subject ID Number

(6-14)

For CPR Use Only

(49-54)

**Instructions:** Either this form or the Definitive Clinical Diagnosis Form must be sent to the CPR within 30 days of sending the Provisional Clinical Diagnosis Form. A copy of the hospital record from which the Data Coordinator has expurgated all cholesterol values must be obtained and kept in the subject's individual clinic record.

**Event Identifier:** Enter the appropriate number in the event identifier as indicated:

- Enter "1" if this is the first documented event for this visit number.
- Enter "2" if this is the second documented event for this visit number. Continue consecutively, up to 9 events, for the same visit number.

The event identifier for this event must match the event identifier used on the linking form and on all other End Point forms for this event.

1. Today's Date:    /    /    (17-22)

2. Subject's last name:             (23-34)

3. Initials: 

<input type="checkbox"/>	<input type="checkbox"/>
1st	2nd

 (35-36)

**HOSPITALIZATION INFORMATION**

4. Dates of Hospitalization: a. From:    /    /    (37-42)

b. To:    /    /    (43-48)

Code "00-00-00" as ending date of hospitalization for subjects who are still hospitalized.

5. Hospital Name:

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

(55-66)

NEW CARD Duplicate Columns 1-4  (1-4)  (5) Duplicate Columns 6-16  (6-16)

6. Street Number: \_\_\_\_\_

7. Street Name: \_\_\_\_\_

8. City: \_\_\_\_\_

9. State or Province: \_\_\_\_\_

10. Zip or Canadian Postal Code: \_\_\_\_\_

11. Hospital Phone Number: \_\_\_\_\_

12. Subject's Hospital ID Number: \_\_\_\_\_

Enter below the diagnoses listed on the face sheet of the subject's hospital record. If a face sheet is not obtainable, enter the discharge diagnoses.

13. Primary Diagnosis

Specify: \_\_\_\_\_  
\_\_\_\_\_

14. Additional Diagnoses

a. Specify: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

b. Specify: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

c. Specify: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

OPERATIVE PROCEDURES

Enter below the procedures listed on the face sheet of the subject's hospital record. If a face sheet is not obtainable, list the operative procedures performed as indicated in the hospital record.

15. Procedures

a. Specify: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

For CPR Use Only

13.

\_\_\_\_\_.  
\_\_\_\_\_.  
\_\_\_\_\_.

(17-20)

14.

a. \_\_\_\_\_.

(21-24)

b.

\_\_\_\_\_.

(25-28)

c.

\_\_\_\_\_.

(29-32)

b. Specify:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

b.

\_\_\_\_\_.  
\_\_\_\_\_.

(36-38)

c. Specify:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

c.

\_\_\_\_\_.  
\_\_\_\_\_.

(39-41)

16. Source of diagnoses:

1. Face Sheet

\_\_\_\_\_.  
\_\_\_\_\_.

2. Discharge Diagnoses

\_\_\_\_\_.  
\_\_\_\_\_.

(42)

17. Initials and code number of physician completing this form

a. Initials:

\_\_\_\_\_  
\_\_\_\_\_

b.

\_\_\_\_\_.  
\_\_\_\_\_.

(43-44)

Comments:

18. a. Initials of CPR coder:

\_\_\_\_\_  
\_\_\_\_\_

(45-46)

b. Initials of CPR reviewer

\_\_\_\_\_  
\_\_\_\_\_

(47-48)

(Prevention Trial)  
LIPID RESEARCH CLINICS  
NOSOLOGISTS' CODES

Subject ID No.

(6-14)

Visit Number

(15-16)

For CPR Use

(17-22)

Event identifier

(1-5)

**INSTRUCTIONS: To the Nosologist:** Please be certain the code number in question 2 matches the number in the upper left-hand corner of the death certificate. Once a match is verified, code all available information in items 3-6. Draw a horizontal line through unneeded boxes. Enter your initials, date and revision used in question 7. For each item coded, the three middle boxes must always be coded. The first box may be an "N," "E," "S," or blank. The last box (following the decimal) may be numerical, blank, or an X.

**TO THE CPR:** Before sending to the nosologist, enter the code number in question 2 and attach this form to the death certificate. When the form is returned from the nosologist, review it for legibility. Code subject ID, event identifier, visit number, and event date which correspond to the death. Then enter you initials in question 8. All CPR recorded information should be checked by a second staff person. After verifying all CPR recorded information, enter your initials in question 9.

**INTERPRETATION:** The last box in all codes is used for numbers following decimals or an X. Often it is blank. The first box may be an N, E, or S. Often it is blank. The three middle boxes are always numerical and must always be completed.

1. Event Date: [ ] [ ] / [ ] [ ] / [ ] [ ] (23-28)

2. Subject Code [ ] [ ] [ ] [ ] [ ] [ ] (29-34)

INFORMATION FROM NOSOLOGIST

3. Cause of Death

A.Immediate 1 [ ] [ ] [ ] [ ] . [ ] (35-39)

11 [ ] [ ] [ ] [ ] . [ ] (40-44)

111 [ ] [ ] [ ] [ ] . [ ] (45-49)

1v [ ] [ ] [ ] [ ] . [ ] (50-54)

B.Consequence of (A) 1 [ ] [ ] [ ] [ ] . [ ] (55-59)

11 [ ] [ ] [ ] [ ] . [ ] (60-64)

111 [ ] [ ] [ ] [ ] . [ ] (65-69)

1v [ ] [ ] [ ] [ ] . [ ] (70-74)

C.Consequence of (B) 1 [ ] [ ] [ ] [ ] . [ ] (75-79)

DUPLICATE COLUMNS 1-4 [2] (5) DUPLICATE COLUMNS 6-16 (10-16)

11 [ ] [ ] [ ] [ ] . [ ] (17-21)

111 [ ] [ ] [ ] [ ] . [ ] (22-26)

1v [ ] [ ] [ ] [ ] . [ ] (27-31)

4. Other significant conditions 1 [ ] [ ] [ ] [ ] . [ ] (32-36)

11 [ ] [ ] [ ] [ ] . [ ] (37-41)

111 [ ] [ ] [ ] [ ] . [ ] (42-46)

1v [ ] [ ] [ ] [ ] . [ ] (47-51)

5. Underlying cause [ ] [ ] [ ] [ ] . [ ] (52-56)

6. Place of Accident [ ] [ ] (57)

7.a) Initials of Nosologist [ ] [ ] [ ] (58-60)

Signature: \_\_\_\_\_

b) Date Coded [ ] [ ] / [ ] [ ] / [ ] [ ] (61-66)  
Month Day Year

c) Revision Used [ ] [ ] (67-68)

8. CPR Coder [ ] [ ] (69-70)

9. CPR Checker [ ] [ ] (71-72)

LBC PREVENTION TRIAL

ANNUAL MEDICAL HISTORY QUESTIONNAIRE

PACKNO

Subject ID Number

5 1 1 1 1 (1-5)

(6-14)

1 1 (15-16)

For CPR Use Only (38-43)

VISIT

Please do not fill in items 1 and 2 until you report to the clinic.

1. Date of Clinic Visit: (TV) VT MON Y DAY YR (17-22)

2.a. Subject's Last Name: (23-34)

b. Initials: (35-36)

I. GENERAL Please fill out in pencil.

Circle the appropriate answer.

3. EVMAR What is your present marital status?

- Never married
Married
Separated
Divorced
Widowed

4.a. PHYS A

a. Thinking about the things you do at work, how would you rate yourself as to the amount of physical activity you get compared with others of your age and sex? Would you say you are: Circle the number to the right which best corresponds to your activity.

- Much more active
Somewhat more active
About the same
Somewhat less active
Much less active
Not applicable

b. PHYS B

b. Now, thinking about the things you do outside of work, how would you rate yourself as to the amount of physical activity you get compared with others of your age and sex? Would you say you are:

- Much more active
Somewhat more active
About the same
Somewhat less active
Much less active

(45)

II. SMOKING HISTORY

- 30 Which of the following statements most closely describes your cigarette smoking history?  
 You never smoked cigarettes . . . . .  
 If you circled "1," go to question 6.  
 You presently smoke cigarettes . . . . .  
 If you circled "2" go to question 50.  
 You quit smoking completely and did not start smoking again . . . . .  
 (b) If so, how many years ago did you stop?  
 Code "01" if unknown.  
 Code "01" if less than one year
- 31 Do or did you inhale?  
 No . . . . .  
 Yes . . . . .  
 (d) Do or did you smoke---  
 Filter cigarettes . . . . .  
 Non-filtered cigarettes . . . . .  
 (e) About how many cigarettes do or did you smoke per day?  
 (1 pack = 20 cigarettes)  
 Code "01" if unknown.  
 (f) About how many years have you or did you smoke that amount per day?  
 Code "01" if unknown.  
 (g) Enter the largest number of cigarettes you have regularly smoked per day.  
 Code "01" if unknown.  
 (h) How much of a cigarette do or did you smoke?  
 Smoke 1/4 of it . . . . .  
 Smoke 1/2 of it . . . . .  
 Smoke 3/4 of it . . . . .  
 Smoke all of it . . . . .

5. a. EVSMK  
 1  
 2  
 3  
 b. YQTSMK (46)  
 (47-48)  
 c. INHALE  
 1  
 2 (49)  
 4. FILTER  
 1  
 2 (50)  
 AMSMK  
 e. (51-52)  
 YSMKD (53-54)  
 LNSMK (55-56)  
 b. PTNSMK  
 1  
 2  
 3  
 4 (57)

III. ALCOHOL CONSUMPTION

- Since lipid levels may be affected by the consumption of alcoholic beverages, everyone is being asked the following question or questions concerning alcohol consumption.
6. EVDNK  
 During the past year, have you had at least one drink of beer, wine or liquor?  
 No . . . . . 1  
 Yes . . . . . 2 (58)  
 If "No," go to question 9.
7. a.  
 (a) About how often do you drink some kind of alcoholic beverage?  
 Daily or almost every day . . . . . 1  
 Three or four times a week . . . . . 2  
 Once or twice a week . . . . . 3  
 Once or twice a month . . . . . 4  
 Less often than once a month . . . . . 5  
 Unknown . . . . . 9 (59)  
 For questions b through e code "01" if unknown.  
 (b) When you drink beer, about how many bottles or cans of beer do you drink? . . . . . HMBEER  
 (c) When you drink wine, about how many glasses of wine do you drink? . . . . . HMWINE  
 (d) When you drink, about how many highballs, cocktails or mixed drinks do you drink? HMMIXD  
 (e) When you drink, about how many drinks of liquors or other straight alcoholic drinks do you drink? HMSTRD  
 (f) During this past week about how many bottles or cans of beer did you drink? . . . . . BEER (68-69)  
 (g) During this past week about how many glasses of wine did you drink? . . . . . WINE (70-71)  
 (h) During this past week about how many highballs, cocktails or mixed drinks did you drink? MIXDS (72-73)  
 (i) During this past week about how many drinks of liquors or other straight alcoholic drinks did you drink? STRDS (74-75)

IV. SYM CHECKLIST

9.a. Have you experienced any of the symptoms in 9.b. since the last visit?

	9.a. SYMPTOM	
No . . . . .	1	
Yes . . . . .	2	(17)

9.b. If yes, circle the numbers that best describe your experience since the last visit. If no, go to question 10.

	Mild	Moderate	Severe	
<input type="checkbox"/> Nausea . . . . .	2	3	4	(18)
<input type="checkbox"/> Vomiting . . . . .	2	3	4	(19)
<input type="checkbox"/> Itching . . . . .	2	3	4	(20)
<input type="checkbox"/> Heartburn . . . . .	2	3	4	(21)
<input type="checkbox"/> Diarrhea . . . . .	2	3	4	(22)
<input type="checkbox"/> Rash . . . . .	2	3	4	(23)
<input type="checkbox"/> Unusual hair loss . . . . .	2	3	4	(24)
<input type="checkbox"/> Difficulty swallowing . . . . .	2	3	4	(25)
<input type="checkbox"/> Constipation . . . . .	2	3	4	(26)
<input type="checkbox"/> Drowsiness . . . . .	2	3	4	(27)
<input type="checkbox"/> Abdominal pain . . . . .	2	3	4	(28)
<input type="checkbox"/> Dryness of skin . . . . .	2	3	4	(29)
<input type="checkbox"/> Leg cramps . . . . .	2	3	4	(30)
<input type="checkbox"/> Hives . . . . .	2	3	4	(31)
<input type="checkbox"/> Weakness . . . . .	2	3	4	(32)
<input type="checkbox"/> Belching or bloating . . . . .	2	3	4	(33)
<input type="checkbox"/> Gas . . . . .	2	3	4	(34)
<input type="checkbox"/> Nervousness . . . . .	2	3	4	(35)
<input type="checkbox"/> Unusual heart beat . . . . .	2	3	4	(36)
<input type="checkbox"/> Unusual bleeding . . . . .	2	3	4	(37)
<input type="checkbox"/> Black bowel movements . . . . .	2	3	4	(38)

10. Have you noticed any change in the following since your last visit? Answer each item by circling the appropriate number.

	No Change	Increased	Decreased	
a. Appetite . . . . .	1	2	3	(39)
b. Hearing . . . . .	1	2	3	(40)
c. Vision . . . . .	1	2	3	(41)

11. About how often do you have a bowel movement? Circle only one.

Less than 1 a week . . . . .	1
One a week . . . . .	2
One every 3 - 6 days . . . . .	3
One every 2 days . . . . .	4
One a day . . . . .	5
Two a day . . . . .	6
More than 2 a day . . . . .	7 (42)

V. GENERAL SYMPTOMS

For each of the items in this section, circle the number corresponding to the response that best describes your experience in the past year.

12. GENERAL	Have Not Had in The Past Year		Had in the Past Year		
	Year	Have Now	Had in Past Year	But do Not Have Now	
a. Excessive fatigue . . . . .	1	2	3	9	(43)
b. Unexplained weight loss . . . . .	1	2	3	9	(44)
c. Excessive thirst . . . . .	1	2	3	9	(45)
d. Unusual intolerance for hot weather . . . . .	1	2	3	9	(46)
e. Unusually easy bruising . . . . .	1	2	3	9	(47)
f. Unusually easy bleeding . . . . .	1	2	3	9	(48)
g. Unusual intolerance for cold weather . . . . .	1	2	3	9	(49)

15. Continued	Have Not Had in The Past Year	Have Now	Had in the Past Year		Uncertain
			But Do Not Have Now	Have Now	
k. Wheezing . . . . .	1	2	3	9	(71)
l. Hay Fever . . . . .	1	2	3	9	(72)
m. Other respiratory problems . . . . .	1	2	3	9	(73)

*If Other, specify:*

NEW CARD [S][A][M][E][3] (1-5) Duplicate Columns 6 through 16 (6-16)

16. GASTROINTESTINAL	Have Not Had in The Past Year	Have Now	Had in the Past Year		Uncertain
			But Do Not Have Now	Have Now	
a. Hiatus hernia . . . . .	1	2	3	9	(17)
b. Gallbladder disease . . . . .	1	2	3	9	(18)
c. Jaundice . . . . .	1	2	3	9	(19)
d. Liver disease . . . . .	1	2	3	9	(20)
e. Ulcer . . . . .	1	2	3	9	(21)
f. Colitis . . . . .	1	2	3	9	(22)
g. Diverticulitis . . . . .	1	2	3	9	(23)
h. Hemorrhoids . . . . .	1	2	3	9	(24)
i. Frequent indigestion . . . . .	1	2	3	9	(25)
j. Intolerance of fatty foods . . . . .	1	2	3	9	(26)
k. Persistent constipation . . . . .	1	2	3	9	(27)
l. Frequent diarrhea . . . . .	1	2	3	9	(28)
m. Excessive increase in gas . . . . .	1	2	3	9	(29)
n. Rectal bleeding . . . . .	1	2	3	9	(30)
o. Other rectal problems . . . . .	1	2	3	9	(31)
p. Vomiting of blood . . . . .	1	2	3	9	(32)
q. Anal fissure . . . . .	1	2	3	9	(33)
r. Other gastrointestinal problems . . . . .	1	2	3	9	(34)

*If Other, specify:*

13. HEAD AND NECK	Have Not Had in The Past Year	Have Now	Had in the Past Year		Uncertain
			But Do Not Have Now	Have Now	
a. Frequent or persistent loss of hearing . . . . .	1	2	3	9	(50)
b. Disturbance in vision . . . . .	1	2	3	9	(51)
c. Frequent or persistent nose bleeds . . . . .	1	2	3	9	(52)
d. Frequent or persistent bleeding gums . . . . .	1	2	3	9	(53)
e. Frequent nasal obstruction or discharge . . . . .	1	2	3	9	(54)
f. Other head and neck problems . . . . .	1	2	3	9	(55)

*If Other, specify:*

14. SKIN	Have Not Had in The Past Year	Have Now	Had in the Past Year		Uncertain
			But Do Not Have Now	Have Now	
a. Moles that have changed in size or color . . . . .	1	2	3	9	(56)
b. Skin growths . . . . .	1	2	3	9	(57)
c. Skin ulcerations . . . . .	1	2	3	9	(58)
d. Psoriasis . . . . .	1	2	3	9	(59)
e. Allergic dermatitis (eczema) . . . . .	1	2	3	9	(60)

15. RESPIRATORY	Have Not Had in The Past Year	Have Now	Had in the Past Year		Uncertain
			But Do Not Have Now	Have Now	
a. Asthma . . . . .	1	2	3	9	(61)
b. Tuberculosis . . . . .	1	2	3	9	(62)
c. Cancer of the lungs . . . . .	1	2	3	9	(63)
d. Chronic bronchitis . . . . .	1	2	3	9	(64)
e. Emphysema . . . . .	1	2	3	9	(65)
f. Coughing up of blood . . . . .	1	2	3	9	(66)
g. Abnormal chest X-ray . . . . .	1	2	3	9	(67)
h. Cough lasting over 3 months . . . . .	1	2	3	9	(68)
i. Pneumonia . . . . .	1	2	3	9	(69)
j. Pleurisy . . . . .	1	2	3	9	(70)



17. MISCELLANEOUS

	Have Not Had in The Past Year		Have Now		Had in the Past Year But Do Not Have Now		Uncertain
	Year	Year	Year	Year	Year	Year	

- a. Acids . . . . . 1 2 3 9 (35)
- b. Hernia (other than hiatal) . . . . . 1 2 3 9 (36)
- c. Thyroid disorder . . . . . 1 2 3 9 (37)
- d. Cancer (other than lung) . . . . . 1 2 3 9 (38)
- e. Diabetes . . . . . 1 2 3 9 (39)

f. Drug allergies (If so, specify):

- g. Swollen or painful joints. . . . . 1 2 3 9 (41)
- h. Overweight (obesity) . . . . . 1 2 3 9 (42)
- i. Back trouble . . . . . 1 2 3 9 (43)
- j. Other miscellaneous problems 1 2 3 9 (44)

If Other Symptoms, specify:

18. URINARY

- a. Difficult or painful urination 1 2 3 9 (45)
- b. Poor bladder control . . . . . 1 2 3 9 (46)
- c. Night urination (if twice or more each night) . . . . . 1 2 3 9 (47)
- d. Blood, protein or sugar in urine . . . . . 1 2 3 9 (48)
- e. Passage of kidney stone or gravel . . . . . 1 2 3 9 (49)
- f. Urge to urinate more often than normal . . . . . 1 2 3 9 (50)
- g. Kidney or bladder infection 1 2 3 9 (51)
- h. Frequent urination and large volume of urine . . . . . 1 2 3 9 (52)
- i. Difficulty in starting urination . . . . . 1 2 3 9 (53)

18. Continued

- j. Have you ever had an instrument (cystoscope, etc.) passed into the bladder. . . . . 1 2 3 9 (54)
- k. Other urinary problems. . . . . 1 2 3 9 (55)

If Other, specify:

19. GENITAL

- a. Swelling or tenderness of scrotum or testicle(s) . . . . . 1 2 3 9 (56)
- b. Prostate trouble . . . . . 1 2 3 9 (57)
- c. Other genital problems. . . . . 1 2 3 9 (58)

If Other, specify:

20.

NEUROMUSCULAR

- a. Frequent or severe headaches 1 2 3 9 (59)
- b. Attacks of staggering, loss of balance or dizziness. . . . . 1 2 3 9 (60)
- c. Loss of consciousness or head injury . . . . . 1 2 3 9 (61)
- d. Persistent numbness or tingling of hands or feet 1 2 3 9 (62)
- e. Epilepsy. . . . . 1 2 3 9 (63)
- f. Loss of feeling anywhere. . . . . 1 2 3 9 (64)
- g. Difficulty in sleeping. . . . . 1 2 3 9 (65)
- h. Increasing irritability and mood swings. . . . . 1 2 3 9 (66)
- i. Frequent periods of feeling depressed or "blue" **DEPRS** 1 2 3 9 (67)
- j. Other neuromuscular problems 1 2 3 9 (68)

If Other, specify:

21. Were you hospitalized since your last visit?

No . . . . . 1  
 Yes . . . . . 2 (17)

21. HOSP

b. If "Yes," list dates of hospitalization, if known.

From:     (18-23)

To:     (24-29)

Reason for hospitalization:

22. Have you had any illnesses since your last visit that did NOT require hospitalization?

No . . . . . 1  
 Yes . . . . . 2 (30)

22.

If "Yes," specify:

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

VII. MEDICATION

23. Are you presently taking or have you taken any prescribed medication other than the study medication since your last visit?

No . . . . . 1  
 Yes . . . . . 2 (31)

23. PRES. MED

If "Yes," please have available the names and dosages for the clinic staff.

24. How many packets of study medication are you presently taking each day? (Report fractions if applicable).

\_\_\_\_\_ packets/day

If zero, go to question 27.

25. How many times each day do you presently take your study medication?

One time a day . . . . . 1  
 Two times a day . . . . . 2  
 Three times a day . . . . . 3  
 Four times a day . . . . . 4  
 Five times a day . . . . . 5  
 Six times a day . . . . . 6 (32)

25.

26.a. Since your last visit, were there any days during which you took no study medication?

No . . . . . 1  
 Yes . . . . . 2 (33)

26.

If "No," go to question 27.

b. On how many days did you take no study medication?

b.    (34-36)

27. Do you take laxatives more than once a week?

No . . . . . 1  
 Yes . . . . . 2 (37)

27.

If "Yes," specify which laxatives and how often.

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

28. During the past week, how many of the following tablets or capsules did you take? Enter 00 if none or if not familiar with product.

- a. Aspirin . . . . . ASPRN . . . . .   (38-39)
- b. Alka-Seltzer . . . . . ALKAS . . . . .   (40-41)
- c. Anacin . . . . . ANACN . . . . .   (42-43)
- d. A.P.C. . . . . APC . . . . .   (44-45)
- e. Aspergum . . . . . ASPGM . . . . .   (46-47)
- f. Bufferin . . . . . BUFRN . . . . .   (48-49)
- g. Darvon Compound . . . . . DARVN . . . . .   (50-51)
- h. Dristan . . . . . DRSTN . . . . .   (52-53)
- i. Empirin Compound . . . . . EMPRN . . . . .   (54-55)
- j. Excedrin . . . . . EXDRN . . . . .   (56-57)

VIII. FAMILY HISTORY

29a. For each of your parents circle the appropriate number.

- |                                |        |   |           |        |      |      |
|--------------------------------|--------|---|-----------|--------|------|------|
| 1. Alive . . . . .             | Father | 1 | (58)      | Mother | 1    | (59) |
| Cause of death:                |        |   |           |        |      |      |
| ii. Accident . . . . .         |        | 1 | (60)      |        | 1    | (61) |
| iii. Cancer . . . . .          |        | 1 | (62)      |        | MHRT | (63) |
| iv. Heart attack . . . . .     |        | 1 | FHRT (64) |        | 1    | (65) |
| v. Stroke . . . . .            |        | 1 | (66)      |        | 1    | (67) |
| vi. Other cause, Specify _____ |        | 1 | (68)      |        | 1    | (69) |

NEM CARD [Σ][Δ][Π][Ω][Σ] (1-5) Duplicate Columns 6 through 16 (6-16)

29.b. For brothers and sisters, enter the number of brothers, sisters, half-brothers, half-sisters, in the appropriate boxes. For example, if you have 3 brothers, of whom 2 are alive and one died in an accident, enter "02" in the box labeled "Alive" and "01" in the box labeled "Accident." If you have no brothers, sisters, half-brothers or half-sisters, leave the boxes blank.

	Brothers	Sisters
1. Alive . . . . .	<input type="checkbox"/> <input type="checkbox"/> (17-18)	<input type="checkbox"/> <input type="checkbox"/> (19-20)
Cause of death:		
ii. Accident . . . . .	<input type="checkbox"/> <input type="checkbox"/> (21-22)	<input type="checkbox"/> <input type="checkbox"/> (23-24)
iii. Cancer . . . . .	<input type="checkbox"/> <input type="checkbox"/> (25-26)	<input type="checkbox"/> <input type="checkbox"/> (27-28)
iv. Heart attack . . . . .	<input type="checkbox"/> <input type="checkbox"/> (29-30)	<input type="checkbox"/> <input type="checkbox"/> (31-32)
v. Stroke . . . . .	<input type="checkbox"/> <input type="checkbox"/> (33-34)	<input type="checkbox"/> <input type="checkbox"/> (35-36)
vi. Other cause . . . . .	<input type="checkbox"/> <input type="checkbox"/> (37-38)	<input type="checkbox"/> <input type="checkbox"/> (39-40)
vii. Unknown . . . . .	<input type="checkbox"/> <input type="checkbox"/> (41-42)	<input type="checkbox"/> <input type="checkbox"/> (43-44)

IX. ADDRESSES

30. Give your current mailing address and telephone number if they have changed since your last annual visit.

Address

Number Street

City

State or Province Zip or Canadian Postal Code

Telephone Number

31. Give the name, address, and telephone number of your employer if it has changed since your last annual visit.

Employer or Company Name \_\_\_\_\_

Address \_\_\_\_\_  
 Number \_\_\_\_\_ Street \_\_\_\_\_

\_\_\_\_\_ City \_\_\_\_\_

\_\_\_\_\_ State or Province \_\_\_\_\_ Zip or Canadian Postal Code \_\_\_\_\_

\_\_\_\_\_ Telephone Number \_\_\_\_\_

32. Give your telephone number at work if it has changed since your last annual visit.

\_\_\_\_\_

\_\_\_\_\_

33. Give your physician's name, address, and telephone number if it has changed since your last annual visit.

Physician Name \_\_\_\_\_

Address \_\_\_\_\_  
 Number \_\_\_\_\_ Street \_\_\_\_\_

\_\_\_\_\_ City \_\_\_\_\_

\_\_\_\_\_ State or Province \_\_\_\_\_ Zip or Canadian Postal Code \_\_\_\_\_

\_\_\_\_\_ Telephone Number \_\_\_\_\_

34. Give the name, address, and telephone number of three friends or relatives who are not living with you and who are likely to know your address at all times if this information has changed since your last annual visit.

Name \_\_\_\_\_

Address \_\_\_\_\_  
 Number \_\_\_\_\_ Street \_\_\_\_\_

\_\_\_\_\_ City \_\_\_\_\_

\_\_\_\_\_ State or Province \_\_\_\_\_ Zip or Canadian Postal Code \_\_\_\_\_

\_\_\_\_\_ Telephone Number \_\_\_\_\_

Name \_\_\_\_\_

Address \_\_\_\_\_  
 Number \_\_\_\_\_ Street \_\_\_\_\_

\_\_\_\_\_ City \_\_\_\_\_

\_\_\_\_\_ State or Province \_\_\_\_\_ Zip or Canadian Postal Code \_\_\_\_\_

\_\_\_\_\_ Telephone Number \_\_\_\_\_

Name \_\_\_\_\_

Address \_\_\_\_\_  
 Number \_\_\_\_\_ Street \_\_\_\_\_

\_\_\_\_\_ City \_\_\_\_\_

\_\_\_\_\_ State or Province \_\_\_\_\_ Zip or Canadian Postal Code \_\_\_\_\_

\_\_\_\_\_ Telephone Number \_\_\_\_\_

PREVENTION TRIAL

TWO MONTH CLINIC RECORD

(Visits 6,8,9,11,12,14,15...)

PACKNO

Subject ID Number

S C 2 D 1 (1-5)

Visit Number

VISIT

(15-16)

For CPR Use Only

(65-70)

I. GENERAL

Enter one character per box, beginning with the leftmost box. Enter all letters as capitals. Mark through the boxes with a single horizontal stroke if the question does not apply.

(TV) MONTH DAY YEAR

1. Date of Visit: (17-22)
2. Last Name: (23-34)
3. Initials: (35-36)
4. Date of Last Visit: (37-42)

To be completed by recipient and data coordinator before physician sees the subject.

5. Number of packets--
a. Issued at or since last visit PAC-15 (43-45)
b. Returned by subject this visit PAC-RET (46-48)
c. Left at home or accidentally destroyed PAC-LH (49-51)
d. Not taken (b + c) PAC-NOT (52-54)
e. Subject has taken since last visit (a - d) PAC-TAKE (55-57)
f. Should have taken ... PAC-SHLD (58-61) Usual dosage is 6 packets per day.
g. Percent adherence to nearest whole number PAC (62-64)

6a. When was the last time you took anything by mouth except water? See the instructions for use of fasting wheel to determine fasting time. Enter a two-digit number, using a leading zero when the number is less than 10. IF SUBJECT IS FASTING AT LEAST 12 HOURS, GO TO QUESTION 7.

FAST

(71-72)

b. If non-fasting visit, reschedule appointment and STOP.

Two Month Visit rescheduled for: Month Day Year (73-78)

NEW CARD S C 2 D 2 (1-5) Duplicate Columns 6 through 16 (6-16)

II. CLINIC WORKUP RECORD

7. Weight (to nearest 0.1 kg with outdoor garments and shoes removed): WT (17-20)
8. Pulse at rest (record subject's heart rate for 15 seconds, not 60 seconds): PULSE (21-22)
9. Record subject's blood pressure. (Take using right arm after subject has been sitting quietly for at least 5 minutes. Use standard device; do not use random zero device.)
Systolic SYSBP (23-25)
Diastolic DSTBP (26-28)

SCD

10. In our last visit have you had any pain or discomfort in your chest?

- 1 No . . . . .
- 2 Yes . . . . .

If "Yes," complete the Chest Pain Form; then go to question 12 of this form.

10. CHESPN  
1  
2 (29)

11. Since your last visit have you had any pressure or heaviness in your chest?

- 1 No . . . . .
- 2 Yes . . . . .

If "Yes," complete the Chest Pain Form; then complete this form.

11. .  
1  
2 (30)

12. Initials and code number of person completing section II.

a. Initials: \_\_\_\_\_  
 Physician completes remainder of form.  
 b.   (31-32)

III. PHYSICIAN'S EXAMINATION

13. If the subject's drug adherence as calculated in question 5g is less than 90%, what are the most pressing reasons: (if subject's adherence is  $\geq 90\%$ , go to question 16.)

- a. Dosage recommended by LMC personnel is less than 24 gms/day . . . . . DOSEZ4  1 (33)
- b. Upper G.I. side effect . . . . . UPGI  1 (34)
- c. Lower G.I. side effect . . . . . LOWGI  1 (35)
- d. Sexual problem . . . . . SEXPROB  1 (36)
- e. Hospitalisation . . . . . INHOSP.  1 (37)

13. Continued

f. Intercurrent health problem . . . . . HLTH-PR  1 (38)

Specify: \_\_\_\_\_  
g. Ran out of medication . . . . . NO-MED  1 (39)

Specify: \_\_\_\_\_  
h. Irregular schedule (travel, shift work) . . . . . IRREGSCH  1 (40)

Specify: \_\_\_\_\_  
i. Forgot to take medication (weekend, evening, etc.) . . . . . FORGOTMD  1 (41)

Specify: \_\_\_\_\_  
j. Domestic problem (uncooperative wife, family problem) . . . . . D-PROB  1 (42)

Specify: \_\_\_\_\_  
k. Private physician wishes patient to discontinue . . . . . DISCONT  1 (43)

Specify: \_\_\_\_\_  
l. Information from media or other source . . . . . MEDIA  1 (44)

Specify: \_\_\_\_\_  
m. Unblinded, or reason to believe he is . . . . . UNBLIND  1 (45)

Specify: \_\_\_\_\_  
n. Aversion to medication . . . . . AVERSION  1 (46)

Specify: \_\_\_\_\_  
o. Unconvinced of any benefit . . . . . UNCONV.  1 (47)

Specify: \_\_\_\_\_  
p. "Tired and bored with study" . . . . . BORED  1 (48)

Specify: \_\_\_\_\_  
q. Other . . . . . OTHERADH  1 (49)

14. List in order of importance the reasons checked for adherence of less than 90%. Place the letters corresponding to the reasons as listed in question 13 in the boxes below.

Most important reason . . . . . REASL1  (50)

Second . . . . . REASL2  (51)

Third . . . . . REASL3  (52)

15. Does physician's history agree with adherence in question 5g?

1 No . . . . . 1 (53)

2 Yes . . . . . 2 (53)

16. The subject's current treatment dose is

1 24 grams/day . . . . . 1

2 15 grams/day . . . . . 2

9 Other . . . . . 9 (54)

If "1" or "2," go to part c.

Specify current treatment dose (grams/day).

1   gm/day (55-56)

c. DFREQ

The subject is taking medication

1 2 times a day . . . . . 1

2 3 times a day . . . . . 2

3 4 times a day . . . . . 3

4 Other Specify: . . . . . 4 (57)

17. Palpate pulse for 15 seconds

a. Rate . . . . .   (58-59)

b. Rhythm . . . . .

1 Regular . . . . . 1

2 Irregular . . . . . 2 (60)

18. Is there evidence the subject has had a myocardial infarction since his last visit?

1 No . . . . . 1

2 Yes . . . . . 2 (61)

If "Yes," complete the Provisional Clinical Diagnostic Form and the MI Since Last Visit Forms.

MI

19. Other abnormalities by history or physical exam?

1 No . . . . . 1

2 Yes . . . . . 2 (62)

If "Yes," Specify: \_\_\_\_\_

20. Signature and code number of the physician completing section III.

a. Signature: PHYCD

b. Code Number   (63-64)

Comments:

**PACKNO**

Subject ID Number

SIC3A1 (1-5)

(6-14)

(15-16)

0 3

For CPR Use Only (38-43)

I. GENERAL

Enter one character per box, beginning with the leftmost box. Enter all letters as capitals. Mark through the boxes with a single horizontal stroke if a question does not apply.

1. Date of Visit: MONTH DAY YEAR (17-22)

2. Last Name: (23-34)

3. Initials: (35-36)

5. a. When was the last time you took anything by mouth except water? See the instructions for use of fasting wheel to determine fasting time. Enter a two-digit number, using a leading zero when the number is less than 10. If the subject is fasting at least 12 hours, go to question 6.
- b. If this is the second non-fasting or missed visit, go to question 19 and code "Second non-fasting or missed visit."
- c. If this is the first non-fasting or missed visit, reschedule appointment and STOP.
- Visit 3 rescheduled for: Month Day Year (46-51)

FAST (44-45)

II. CLINIC WORKUP RECORD

4. PSTDSPA

- Disposition based on late data from Visit 2
- Subject is not excluded on data from Visit 2
  - Subject is excluded and does not necessarily need a complete Visit 3 workup because:
    - Chylomicrons found at Visit 2 . . . . .
    - Floating beta lipoprotein present at Visit 2
    - Excluding values on clinical chemistry tests at Visit 2 . . . . .
    - Angina during exercise ECG . . . . .
    - Unwilling or unable to participate . . . . .
  - CPR has notified the LRC that one of the following exists on the resting ECG:
    - Diagnostic or equivocal myocardial infarction, Left bundle branch block, Second or third degree block, Atrial fibrillation, Atrial flutter, Left ventricular hypertrophy (Estes).
- If one of the items 2-7 is marked, the subject is sent to the physician at the beginning of his visit. The physician explains the exclusion and uses his discretion in any further workup.

Items 6-13 are to be completed prior to sending form to physician.

6. Pulse at rest (record subject's heart rate for 15 seconds, not 60 seconds). (52-53)
7. Weight (to nearest 0.1 Kg. with outdoor garments and shoes removed). WT Kg. (54-57)
8. Record subject's blood pressure (take using right arm after patient has been sitting quietly for at least 5 minutes).
- |                 |          |           |
|-----------------|----------|-----------|
| Readings        | Systolic | Diastolic |
| Reading 1 (Std) | SYSBA    | DSTBA     |
| Reading 2 (R-2) | SYSBB    | DSTBB     |
| Zero Reading 2  |          | ZEROA     |
| Net Reading 2   | SYSBP    | DSTBP     |
- (58-60) (61-63) (64-66) (67-69) (70-71) (72-74) (75-77)



NEW CARD [5] [A2] (1-5) Duplicate Columns 6 through 14 (6-14)																	
9. Since your last visit have you had any pain or discomfort in your chest?	1 No	2 Yes	If "Yes," administer the Chest Pain Form and skip to question 11.	1	2	(15)											
10. Since your last visit have you had any pressure or heaviness in your chest?	1 No	2 Yes	If "Yes," administer the Chest Pain Form.	1	2	(16)											
11. Do you plan to move from this area in the next five years?	1 No	2 Yes	9 Uncertain	1	2	(17)											
12. Is a member of your household taking cholestyramine, OR participating in or being considered for this study (Prevention Trial)?	1 No	2 Yes	9 Uncertain	1	2	(18)											
13. Initials and code number of person completing this section:	a. Initials:	b.	Code Number			(19-20)											
III. PHYSICIAN'S INTERVIEW																	
14. Other abnormalities by history or physical exam?	1 No	2 Yes	3 Not done	If "Yes," specify briefly:	1	2	3	(21)									
15. Palpate pulse for one full minute.	a. Rate	b. Rhythm	1 Regular	2 Irregular	1	2	(25)										
c. Premature beats per minute	If the number of premature beats is greater than 6, obtain a resting ECG at this visit.																
5. Is there evidence that the subject has had a myocardial infarction?	1 No	2 Yes	16. Code Number			(28)											
17. Physician's signature and code number.	a. Signature _____ b. _____ (29-30)																
IV. LABORATORY DATA																	
18. White blood count	WBC _____ 18. _____ (31-35)																
V. VISIT 3 DISPOSITION																	
19. Disposition	19. PREDISP3																
01 Appointment made for Visit 4	01 . . . . . 01																
02 Identification of excluding medication.	02 . . . . . 02																
03 Awaiting receipt of hospital or physician record	03 . . . . . 03																
04 Household member being considered for the study	04 . . . . . 04																
Subject is excluded because:																	
05 Second non-fasting or missed visit	05 . . . . . 05																
06 Systolic blood pressure > 180 or diastolic blood pressure > 120 at Visit 3	06 . . . . . 06																
07 Blood pressure exclusion: both 1 and 11 must be present	07 . . . . . 07																
1 DBP > 105 OR SBP > 165 at Visit 2																	
11 DBP > 105 OR SBP > 165 at Visit 3																	
08 Subject plans to move from area within 5 years	08 . . . . . 08																
09 Member of household is taking cholestyramine	09 . . . . . 09																
10 Chylomicrons present at Visit 3	10 . . . . . 10																
11 Average triglycerides for Visits 1, 2, and 3 greater than 300	11 . . . . . 11																
12 LDL Cholesterol < 175 mg% at Visit 3	12 . . . . . 12																
13 Angina or myocardial infarction	13 . . . . . 13																
14 WBC < 1500	14 . . . . . 14																
15 Unwilling or unable to participate	15 . . . . . 15																
16 Other Specify:	16 (36-37)																

PACKNO

Subject ID Number

SC4A1 (1-5)

(6-14)

(15-16)

0 4

(38-43)

I. GENERAL

Enter one character per box, beginning with the leftmost box. Enter all letters as capitals. Mark through the boxes with a single horizontal stroke if a question does not apply.

MONTH DAY YEAR

Grid for date of visit

(17-22)

(23-34)

Last Name:

Grid for last name

Initials:

Grid for initials

(35-36)

4. Disposition based on late data from Visit 3:

- 1 Subject is not excluded based on data from Visit 3
2 Chylomicrons found at Visit 3
3 Average triglycerides for Visits 1, 2, and 3 is greater than 300
4 LDL cholesterol < 175 mg/dl at Visit 3
5 WBC < 1500 at Visit 3

If one of the items 2-5 is marked, the subject is sent to the physician at the beginning of his visit. The physician explains the exclusion and uses his discretion in any further workup.

4. PSTDSP3

1

2

3

4

(37)

- 5. a. When was the last time you took anything by mouth except water? See the instructions for use of fasting wheel to determine fasting time. Enter a two-digit number, using a leading zero when the number is less than 10. If the subject is fasting at least 12 hours, go to question 6.
b. If this is the second non-fasting or missed visit, go to question 16 and code "Second non-fasting or missed visit."
c. If this is the first non-fasting or missed visit, reschedule appointment and STOP.

Visit 4 rescheduled for: Month Day Year

(46-51)

II. CLINIC WORKUP RECORD

Items 6-11 are to be completed prior to sending form to physician.

6. Pulse at rest (record subject's heart rate for 15 seconds, not 60 seconds):

Grid for pulse at rest

(52-53)

7. Weight (to nearest 0.1 Kg. with outdoor garments and shoes removed):

Grid for weight

(54-57)

8. Record subject's blood pressure (take using right arm after patient has been sitting quietly for at least 5 minutes).

Readings

Reading 1 (Std)

SYSBA grid

(58-60)

DSTBA grid

(61-63)

SYSBB grid

(64-66)

DSTBB grid

(67-69)

Zero Reading 2

ZEROA grid

(70-71)

Net Reading 2

SYSBP grid

(77-79)

DSTBP grid

(75-77)

c. Premature beats per minute  
If the number of premature beats is greater than 6, obtain a resting ECG at this visit.

14. Is there evidence that the subject has had a myocardial infarction?  
 1 No ..... 1  
 2 Yes ..... 2

15. Physician's signature and code number.  
 a. Signature: \_\_\_\_\_  
 b. Code Number: \_\_\_\_\_

IV. VISIT 4 DISPOSITION  
 (16) Disposition **PREDSP4**  
 01 Appointment made for Visit 5  
*Appointment for next visit delayed because:*  
 02 Identification of excluding medication . . .  
 03 Awaiting receipt of hospital or physician's record . . . . .  
*Subject is excluded because:*  
 04 Second non-fasting or missed visit . . . . .  
 05 Systolic blood pressure > 180 or diastolic blood pressure > 120 at Visit 4 . . . . .  
 06 Both of the following occurred:  
 1 Diastolic blood pressure > 105 or systolic blood pressure > 165 at Visit 2 . . . . .  
 11 Diastolic blood pressure > 105 or systolic blood pressure > 165 at Visit 4 . . . . .  
 07 Both of the following occurred:  
 1 Diastolic blood pressure > 105 or systolic blood pressure > 165 at Visit 3 . . . . .  
 11 Diastolic blood pressure > 105 or systolic blood pressure > 165 at Visit 4 . . . . .  
 08 Chylomicrons present at Visit 4 . . . . .  
 09 LDL cholesterol < 175 mg% at Visit 4 . . . . .  
 10 Angina or myocardial infarction . . . . .  
 11 Unwilling or unable to participate . . . . .  
 12 Other Specify: \_\_\_\_\_

9. Since your last visit have you had any pain or discomfort in your chest?  
 1 No ..... 1 (78)  
 2 Yes ..... 2 (79)  
 If "Yes," administer the Chest Pain Form and skip to question 11.

10. Since your last visit have you had any pressure or heaviness in your chest?  
 1 No ..... 1  
 2 Yes ..... 2 (79)  
 If "Yes," administer the Chest Pain Form.

NEW CARD **S C 4 A 2** (1-5) Duplicates Columns 6 through 14 (6-14)

11. Initials and code number of person completing this section.  
 a. Initials: \_\_\_\_\_  
 b. Code Number: \_\_\_\_\_

III. PHYSICIAN'S INTERVIEW

12. Other abnormalities by history or physical examination?  
 1 No ..... 1  
 2 Yes ..... 2 (17)  
 3 Not done ..... 3  
 If "Yes," specify briefly: \_\_\_\_\_

13. Palpate pulse for one full minute.  
 a. Rate: \_\_\_\_\_ (18-20)  
 b. Rhythm:  
 1 Regular ..... 1  
 2 ..... 2 (21)

SC5

NEW ENGLAND JOURNAL OF MEDICINE

VISIT 5 CLINIC RECORD

(40-45)

For CPR Use Only

05 (15-16)

S C 3 A 1 (1-5)

(6-14)

PACKNO

Subject ID Number

5. Continued

c. If this is the first non-fasting or missed visit, reschedule appointment and STOP.

Month Day Year grid with a wavy line drawn through it.

Visit 5 rescheduled for:

6. Is this a repeat Visit 5? 1 No, 2 Yes grid.

II. CLINIC WORKUP RECORD

Items 7-12 are to be completed prior to sending form to physician.

7. Pulse at rest (record subject's heart rate for 15 seconds, not 60 seconds) 7. PULSE (53-54)

8. Weight (to nearest 0.1 Kg. with outdoor garments and shoes removed) 8. WT (55-58)

9. Record subject's blood pressure (take using right arm after patient has been sitting quietly for at least 5 minutes).

Systolic and Diastolic blood pressure grid: SYSDBA (59-61) and DSTDBA (62-64)

I. GENERAL

1. Enter one character per box, beginning with the leftmost box. Enter all letters as capitals. Mark through the boxes with a single horizontal stroke if a question does not apply.

MONTH DAY YEAR grid with a wavy line drawn through it.

(17-22)

2. Date of Visit:

(23-34)

Last Name grid

3. Initials:

Initials grid (1st, 2nd)

(35-36)

4. PSTDSPA

Disposition based on late data from Visit 4 grid (1, 2, 3) (37)

1 Subject is not excluded based on data from Visit 4

2 Subject is excluded and does not necessarily need a complete Visit 5 workup because:

3 Chylomicrons found at Visit 4

4 LDL cholesterol below 175 mg% at Visit 4

5 If one of the items 2 or 3 is marked, the subject is sent to the physician at the beginning of his visit. The physician explains the exclusion and uses his discretion in any further workup.

6. When was the last time you took anything by mouth except water? See the instructions for use of fasting wheel to determine fasting time. Enter a two-digit number, using a leading zero when the number is less than 10. If the subject is fasting at least 12 hours, go to question 8.

FAST grid (38-39)

7. If this is the second non-fasting or missed visit, go to question 17 and code "Second non-fasting or missed visit."

Post-Randomization Subject ID Number Stamped Here

(15-23)

Identification number to be stamped in this box only if "1" is circled in question 17.

10. Since your last visit have you had any pain or discomfort in your chest?

- 1 No . . . . . 1
- 2 Yes . . . . . 2 (24)

If "Yes," administer the Chest Pain Form and skip to question 12.

11. Since your last visit have you had any pressure or heaviness in your chest?

- 1 No . . . . . 1
- 2 Yes . . . . . 2 (25)

If "Yes," administer the Chest Pain Form.

12. Initials and code number of person completing this section.

- a. Initials: \_\_\_\_\_
- b. Code Number [ ] [ ] [ ] (26-27)

III. PHYSICIAN'S INTERVIEW

13. Other abnormalities by history or physical examination?

- 1 No . . . . . 1
- 2 Yes . . . . . 2
- 3 Not done . . . . . 3 (28)

If "Yes," specify briefly:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

14. Palpate pulse for one full minute.

- a. Rate [ ] [ ] (29-31)
- b. Rhythm
  - 1 Regular . . . . . 1
  - 2 Irregular . . . . . 2 (32)
- c. Premature beats per minute  
If the number of premature beats is greater than 6, obtain a resting ECG at this visit. [ ] [ ] (33-34)

15. Is there evidence that the subject has had a myocardial infarction?

- 1 No . . . . . 1
- 2 Yes . . . . . 2 (35)

16. Physician's signature and code number.

- a. Signature: \_\_\_\_\_
- b. Code Number [ ] [ ] (36-37)

IV. VISIT 5 DISPOSITION

17. PREDSP5

Disposition  
1 Subject cleared the pre-randomization phase and was given treatment at this visit

If "1" is circled, record post-randomization number in upper lefthand corner.

Subject rescheduled for Visit 5 because:

- 2 Identification of excluding medication . . . . . 2
- 3 Awaiting receipt of hospital or physician record . . . . . 3
- 4 Pending examination by another physician at the recall visit . . . . . 4
- 5 Other reason for rescheduling . . . . . 5

Specify:

Subject is excluded because:

- 6 Second non-fasting or missed visit . . . . . 6
- 7 Angina or myocardial infarction . . . . . 7
- 8 Unwilling or unable to participate . . . . . 8
- 9 Other Specify: \_\_\_\_\_ (38)

LRC PREVENTION TRIAL

SIX MONTH CLINIC RECORD

(Visit 7,13,19...)

PACKNO

Subject ID Number

S C 6 0 1 1 (1-5)

(15-16)

Visit

For CPA Use Only

(65-70)

I. GENERAL

Enter one character per box, beginning with the leftmost box. Enter all letters as capitals. Mark through the boxes with a single horizontal stroke if the question does not apply.

1. Date of Visit: (TV) (17-22)
2. Last Name: (23-36)
3. Initials: (35-36)
4. Date of Last Visit: (37-42)

To be completed by receptionist and data coordinator before physician sees the subject.

5. Number of packets:
a. Issued at or since last visit: PAC- IS (43-45)
b. Returned by subject this visit: PAC-RET (46-48)
c. Left at home or accidentally destroyed: PAC-LH (49-51)
d. Not taken (b + c): PAC-NOT (52-54)
e. Subject has taken since last visit (a - d): PAC-TAKE (55-57)
f. Should have taken: PAC-SHLD (58-61)
g. Percent adherence to nearest whole number ((e + f) x 100): PAC (62-64)

6.a. When was the last time you took anything by mouth except water? See the instructions for use of fasting wheel to determine fasting time. Enter a two-digit number, using a leading zero when the number is less than 10. IF SUBJECT IS FASTING AT LEAST 12 HOURS, GO TO QUESTION 7.

6.a. FAST

b. If non-fasting visit, reschedule appointment and STOP.

Six Month Visit rescheduled

II. CHEST PAIN

7. Since your last visit have you had any pain or discomfort in your chest?

1 No (79)
2 Yes (79)

7. CHESPN

8. Since your last visit have you had any pressure or heaviness in your chest?

1 No (80)
2 Yes (80)

If "Yes," complete the Chest Pain Form; then complete this form.

15. Have you ever had any of the following? Use the following definitions to answer the questions.

Abnormal Dyspnea on Exertion - shortness of breath occurring more easily than in others your own age during physical activity

Orthopnea - a condition in which there is need to sit up and elevate one's head to breathe more easily

Paroxysmal Nocturnal Dyspnea (PND) - an acute attack of shortness of breath awaking patient from sleep and requiring him to sit up to ease the shortness of breath. Often associated with choking or suffocation sensation and often causes the patient to go to the nearest window for relief.

Answer items a through g checking the appropriate boxes.	No	Yes	Uncertain
a. Abnormal dyspnea on exertion <b>DYSPPN</b>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
b. Orthopnea	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
c. Paroxysmal nocturnal dyspnea	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
d. Palpitations	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
e. Edema	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
f. Nocturia (more than once a night)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9
g. Enlarged heart	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9

16. Estimate the jugular venous pressure as the vertical height from the top of the jugular venous column to a level 5 cm below the sternal angle.

a. Jugular venous pressure	<input type="checkbox"/>	<input type="checkbox"/>	(43-44)
b. If you cannot measure the jugular venous pressure, check the appropriate response below.			
Elevated above the angle of the mandible	<input type="checkbox"/>	<input type="checkbox"/>	1
Indeterminate	<input type="checkbox"/>	<input type="checkbox"/>	2

NEW CARD **S** **C** **6** **D** **2** (1-5) Duplicate Columns 6 through 16 (6-16)

9. Initials and code number of person completing this section. 9. Code Number

a. Initials: \_\_\_\_\_  
 b.   (17-18)

III. CLINIC WORKUP RECORD

10. Weight (to nearest 0.1 kg with outdoor garments and shoes removed):     kg  
 WT (19-22)

11. Pulse at rest (record subject's heart rate for 15 seconds, not 60 seconds):     PULSE  
 (23-24)

12. Record subject's blood pressure. (Take using right arm after subject has been sitting quietly for at least 5 minutes. Use standard device; do not use random zero device.)

Systolic **SYSBP**        
 Diastolic **DSTBP**

13. Initials and code number of person completing this section. 13. Code Number

a. Initials: \_\_\_\_\_  
 b.   (31-32)

IV. PHYSICIAN'S INTERVIEW

14. Palpate pulse for 15 seconds. a. Rate       (33-34)

b. Rhythm       (35)  
 Regular        
 Irregular

17.a. Lungs . . . . . Normal  1 Abnormal  2 (46)

If "Abnormal," check all of the following abnormalities:  
Answer items b through m.

- b. Tachypnea at rest (respiratory rate > 20) . . . . . Absent  1 Present  2 Uncertain  9 (47)
- c. Anterior chest deformity . . . . . Absent  1 Present  2 Uncertain  9 (48)
- d. Posterior chest or spine deformity . . . . . Absent  1 Present  2 Uncertain  9 (49)
- e. Dullness to percussion . . . . . Absent  1 Present  2 Uncertain  9 (50)
- f. Hyperresonance . . . . . Absent  1 Present  2 Uncertain  9 (51)
- g. Rhonchi . . . . . Absent  1 Present  2 Uncertain  9 (52)
- h. Wheezes . . . . . Absent  1 Present  2 Uncertain  9 (53)
- i. Rales clear on coughing . . . . . Absent  1 Present  2 Uncertain  9 (54)
- j. Rales persistent . . . . . Absent  1 Present  2 Uncertain  9 (55)
- k. Friction rub - lungs . . . . . Absent  1 Present  2 Uncertain  9 (56)
- l. Chest wall tenderness . . . . . Absent  1 Present  2 Uncertain  9 (57)
- m. Other Specify: \_\_\_\_\_ Absent  1 Present  2 Uncertain  9 (58)

NOTE - an increase in amplitude or duration of the normal ventricular impulse

- 18. a. Heaves and thrills . . . . . Absent  1 Present  2 Uncertain  9 (59)
- If "Present," answer items b through g.
- b. Left ventricular heave . . . . . Absent  1 Present  2 Uncertain  9 (60)
- c. Right ventricular heave . . . . . Absent  1 Present  2 Uncertain  9 (61)
- d. Systolic BASAL thrill . . . . . Absent  1 Present  2 Uncertain  9 (62)
- e. Systolic APICAL thrill . . . . . Absent  1 Present  2 Uncertain  9 (63)
- f. Systolic left sternal border thrill . . . . . Absent  1 Present  2 Uncertain  9 (64)
- g. Other thrill . . . . . Absent  1 Present  2 Uncertain  9 (65)

Specify location: \_\_\_\_\_

19. Distance from mid sternal line to apical impulse or edge of cardiac dullness in centimeters:    cm (66-67)  
Code "99" if indeterminate.

- 20. Heart sounds
- a. S<sub>1</sub> . . . . . Single  1 Split  2 Absent  3 (68)
- Physiologically Split  1 Single  2 Absent  3 Fixed Paradoxically Splitting Split  4 Pseudo-split  5 (69)
- b. S<sub>2</sub> . . . . . Single  1 Split  2 Absent  3 (70)
- c. S<sub>3</sub> . . . . . Absent  1 Present  2 (71)
- d. S<sub>4</sub> . . . . . Absent  1 Present  2 (71)



**PITTING EDEMA**

- Grade 1 - with hard pressure get minimal preservation of depression made by a finger for only a brief time
- Grade 2 - with light pressure get preservation of depression made by a finger; with hard pressure get obvious and significant depression which remains for a period of time
- Grade 3 - get depression about one inch in depth with hard pressure
23. a. Dependent edema . . . . . Absent  1 Present  2 (29)  
Grade Number
- b. If "Present," enter the grade number . . . . .  (30)

**NSKIN**

- a. Skin . . . . . Normal  1 Abnormal  2 (31)  
If "Abnormal," answer items b through k.
- b. Psoriasis . . . . . Absent  1 Present  2 Uncertain  9 (32)
- c. Dry Skin . . . . . Absent  1 Present  2 (33)
- d. Scaly skin . . . . . Absent  1 Present  2 (34)
- e. Eczema . . . . . Absent  1 Present  2 (35)
- f. Rash . . . . . Absent  1 Present  2 (36)
- g. Petechiae . . . . . Absent  1 Present  2 (37)
- h. Acanthosis nigricans . . . . . Absent  1 Present  2 (38)
- i. Other (except xanthoma) Specify: . . . . . Absent  1 Present  2 (39)
- ① Xanthoma . . . . . Absent  1 Present  2 (40)  
If xanthomata are present, complete the Xanthoma Form and ask the following question.
- k. At what age did the first xanthoma appear? Code "99," if unknown . . . . .   (41-42)

**Grading of Murmurs**

21. Friction rub, pericardial . . . . . Absent  1 Present  2 (72)

NEW CARD     (1-5) Duplicate Columns 6 through 16 (6-16)  
**GRADING OF MURMURS**

- Grade 1 - audible only after the listener has 'tuned in'
- Grade 2 - faintest murmur audible immediately upon placing the stethoscope on the chest
- Grade 3 - easily heard murmur but not so loud as a Grade 4 murmur. No thrill associated
- Grade 4 - a moderately loud murmur and a significant jump from Grade 3. Thrill may be associated
- Grade 5 - murmur which can be heard with just the rim or edge of the stethoscope touching the chest but which cannot be heard with the stethoscope removed from the chest wall
- Grade 6 - murmur audible with the stethoscope removed from the chest wall

22. a. Murmurs . . . . . Absent  1 Present  2 (17)

If "Absent," go to question 23.  
If "Present," enter the grade number in the appropriate box.

	Systolic (Grade Number)	Diastolic (Grade Number)
b. Apex . . . . .	<input type="checkbox"/> (18)	<input type="checkbox"/> 11. (19)
c. Base . . . . .	<input type="checkbox"/> (20)	<input type="checkbox"/> 11. (21)
d. Left sternal border . . . . .	<input type="checkbox"/> (22)	<input type="checkbox"/> 11. (23)

Is it your impression that this represents:  
Check all appropriate boxes.

	No	Yes
e. Aortic systolic ejection murmur (including aortic stenosis)? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (24)
f. Aortic regurgitation? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (25)
g. Mitral stenosis? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (26)
h. Mitral regurgitation? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (27)
i. Other? Specify: . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (28)

25. Other abnormalities on physical exam? . . . . . Absent  1 Present  2 (43)

If "Present," specify briefly: \_\_\_\_\_

26. **MI**  
 Is there evidence the subject has had a myocardial infarction since his last visit?  
 1 No . . . . . 1  
 2 Yes . . . . . 2 (44)  
 If "Yes," complete the Provisional Clinical Diagnosis Form and the MI Since Last Visit Forms.

27. Rate the subject's motivation  
 Excellent  1 Good  2 Fair  3 Poor  4 (45)  
**MOTIVTN**

28. If the subject's drug adherence as calculated in question 58 is less than 90%, what are the most pressing reasons: (If subject's adherence is  $\geq$  90%, go to question 30.)

- Ⓐ Dosage recommended by LAC personnel is less than 24 gms/day . **DOSE 24**  1 (46)  
Specify: \_\_\_\_\_
- Ⓑ Upper G.I. side effect . . . . . **UPGI**  1 (47)  
Specify: \_\_\_\_\_
- Ⓒ Lower G.I. side effect . . . . . **LOWGI**  1 (48)  
Specify: \_\_\_\_\_
- Ⓓ Sexual problem . . . . . **SEXPROB**  1 (49)  
Specify: \_\_\_\_\_
- Ⓔ Hospitalization . . . . . **IN-HOSP.**  1 (50)  
Specify: \_\_\_\_\_

- Ⓐ Intercurrent health problem . . . . . **HLTH-PR**  1 (51)  
Specify: \_\_\_\_\_
- Ⓑ Ran out of medication . . . . . **NO-MED.**  1 (52)  
Specify: \_\_\_\_\_
- Ⓒ Irregular schedule (travel, shift work) **IRREGSCH**  1 (53)  
Specify: \_\_\_\_\_
- Ⓓ Forgot to take medication (weekend, evening, etc.). **FORGOTMD**  1 (54)  
Specify: \_\_\_\_\_
- Ⓔ Domestic problem (uncooperative wife, family problem) . . . . . **D-PROB**  1 (55)  
Specify: \_\_\_\_\_
- Ⓕ Private physician wishes patient to discontinue: **DISCONT**  1 (56)  
Specify: \_\_\_\_\_
- Ⓖ Information from media or other sources: **MEDIA**  1 (57)  
Specify: \_\_\_\_\_
- Ⓖ Unblinded, or reason to believe he is **UNBLIND**  1 (58)
- Ⓖ Aversion to medication . . . . . **AVERSION**  1 (59)
- Ⓖ Unconvinced of any benefit. . . . . **UNCONV.**  1 (60)
- Ⓖ "Tired and bored with study" . . . . . **BORED**  1 (61)
- Ⓖ Other . . . . . **OTHERADH**  1 (62)  
Specify: \_\_\_\_\_

29 List in order of importance the reasons checked for adherence of less than 90%. Place the letters corresponding to the reasons as listed in question 28 in the boxes below.

Most important reason . . . . . REASL1  (63)  
 Second . . . . . REASL2  (64)  
 Third . . . . . REASL3  (65)

30. Does physician's history agree with adherence in 5g?

1 No . . . . . 1  
 2 Yes . . . . . 2 (66)

31. The subject's current treatment dose is

1 24 grams/day . . . . . 1  
 2 16 grams/day . . . . . 2  
 9 Other . . . . . 9 (67)

If "1" or "2," go to part a.

b) Specify current treatment dose (grams/day)

TD DOSE  
 b.   gm/day (68-69)

c) The subject is taking medication

1 2 times a day . . . . . 1  
 2 3 times a day . . . . . 2  
 3 4 times a day . . . . . 3  
 4 Other Specify: \_\_\_\_\_ (70)

Current treatment dose is defined as dosage since last visit to present.

32. Signature and code number of physician completing Section IV. PHYCD

a. Signature: \_\_\_\_\_  
 b.   Code Number (71-72)

LABORATORY DATA

33 Hematocrit. . . . .    HCT (73-74)

COMMENTS:



III. ALCOHOL CONSUMPTION

Since lipid levels may be affected by the consumption of alcoholic beverages, everyone is being asked the following question or questions concerning alcohol consumption.

- Ⓐ During the past year, have you had at least one drink of beer, wine or liquor?
  - No . . . . . 1
  - Yes . . . . . 2 (57)
- If "No," go to question 8.
- Ⓑ About how often do you drink some kind of alcoholic beverage?
  - Daily or almost every day . . . . . 1
  - Three or four times a week . . . . . 2
  - Once or twice a week . . . . . 3
  - Once or twice a month . . . . . 4
  - Less often than once a month . . . . . 5
  - Unknown . . . . . 9 (58)
- Ⓒ When you drink beer, about how many bottles or cans of beer do you drink? . . . . .
  - HM BEEB [ ] [ ] (59-60)
  - HM WINE [ ] [ ] (61-62)
  - HM MIXD [ ] [ ] (63-64)
  - HM STRD [ ] [ ] (65-66)
- Ⓓ When you drink, about how many highballs, cocktails or mixed drinks do you drink? . . . . .
  - BEER [ ] [ ] (67-68)
  - WINE [ ] [ ] (69-70)
  - MIXDS [ ] [ ] (71-72)
- Ⓔ During this past week about how many bottles or cans of beer did you drink? . . . . .
- Ⓕ During this past week about how many glasses of wine did you drink? . . . . .
- Ⓖ During this past week about how many highballs, cocktails or mixed drinks did you drink? . . . . .

NEW CARD [S][H][2][B][2] (1-5) Duplicate Columns 6 through 14 (6-14)

Ⓓ During this past week about how many drinks of liqueurs or other straight alcoholic drinks did you drink?

STADS  
d. [ ] [ ] (15-16)

IV. WEIGHT HISTORY

- 8. a. Has your weight changed in the past two weeks?
  - No . . . . . 1
  - Gained . . . . . 2
  - Lost . . . . . 3
  - Unknown . . . . . 9 (17)
- If "No" or "unknown," go to item 8a.
- b. What was the change in pounds? If you do not know, leave the boxes blank.
  - [ ] [ ] (18-20)
- c. How many pounds did you weigh when you were 18 years old?
  - [ ] [ ] (21-23)
- d. What is the most you have ever weighed? If you do not know, leave the boxes blank.
  - [ ] [ ] (24-26)

V. MEDICATION

Ⓘ Are you now taking or have you ever taken any of the following medicines? For each medicine, circle the number corresponding to your best answer.

	Have you ever taken--		Never Taken		Not Taking Now But Have Taken		Uncertain
	Yes	No	Yes	No	Yes	No	
Ⓐ Atromid-S (Clofibrate)	1	2	3	9	9		(27)
Ⓑ Colestipol . . . . .	1	2	3	9	9		(28)
Ⓒ Nicotinic Acid . . . . .	1	2	3	9	9		(29)
Ⓓ Cholestyramine (Questran) . . . . .	1	2	3	9	9		(30)
Ⓔ Estrogens (Premarin, ESTRO Stilbesterol) . . . . .	1	2	3	9	9		(31)
Ⓕ Corticosteroids (Cortisone) . . . . .	1	2	3	9	9		(32)
Ⓖ Heparin . . . . .	1	2	3	9	9		(33)
Ⓓ Thyroxine (Thyroid) . . . . .	1	2	3	9	9		(34)

9. Continued

Ⓔ Digitalis . . . . .	DIGIT	1	2	3	9	(35)
Ⓕ Insulin . . . . .	INSUL	1	2	3	9	(36)
Ⓖ Oral Hypoglycemics (pills for diabetes) . . . . .	OHYPO	1	2	3	9	(37)
Ⓗ Anticoagulants (blood thinners) . . . . .	ANTICO	1	2	3	9	(38)
Ⓙ Diuretics (water pills) . . . . .	DIUR	1	2	3	9	(39)
Ⓚ Beta Sitosterol (Cytellin) . . . . .	BETASI	1	2	3	9	(40)
Ⓛ Tranquillizers . . . . .	TRANQ	1	2	3	9	(41)
Ⓜ High Blood Pressure Pills (not tranquilizers) . . . . .	HBP	1	2	3	9	(42)
Ⓨ Medicine for Irregular Heartbeat (Quinidine, Pronesty) . . . . .	IRRHM	1	2	3	9	(43)
Ⓩ Dipyrindamole (Persantine) . . . . .	DIPYR	1	2	3	9	(44)
ⓐ Phenylbutazone (Butazolidin) . . . . .	PHENYL	1	2	3	9	(45)
ⓑ Vitamin A (alone) . . . . .	VITMA	1	2	3	9	(46)
Ⓒ Multiple Vitamins (containing Vitamin A) . . . . .	MULVIT	1	2	3	9	(47)

If you are NOW taking any prescribed medicines, other than those above, list them:

---

10. During the past week how many of the following tablets or capsules did you take? Enter 00 if none or if not familiar with product.

Ⓐ Aspirin . . . . .	ASPRN			(48-49)
Ⓑ Alka-Seltzer . . . . .	ALKAS			(50-51)
Ⓒ Anacin . . . . .	ANACN			(52-53)
Ⓓ A.P.C. . . . .	APC			(54-55)
Ⓔ Aspergum . . . . .	ASPGM			(56-57)

VI. SYMPTOM CHECKLIST

11. For each of the following items, circle the number corresponding to the response that best describes your experience over the last three months.

	Absent	Mild	Moderate	Severe	
Nausea . . . . .	1	2	3	4	(15)
Vomiting . . . . .	1	2	3	4	(16)
Itching . . . . .	1	2	3	4	(17)
Heartburn . . . . .	1	2	3	4	(18)
Diarrhea . . . . .	1	2	3	4	(19)
Rash . . . . .	1	2	3	4	(20)
Unusual hair loss . . . . .	1	2	3	4	(21)
Difficulty swallowing . . . . .	1	2	3	4	(22)
Constipation . . . . .	1	2	3	4	(23)
Drowsiness . . . . .	1	2	3	4	(24)
Abdominal pain . . . . .	1	2	3	4	(25)
Dryness of skin . . . . .	1	2	3	4	(26)
Leg cramps . . . . .	1	2	3	4	(27)
Hives . . . . .	1	2	3	4	(28)
Weakness . . . . .	1	2	3	4	(29)
Belching or bloating . . . . .	1	2	3	4	(30)

(Continued)

Ⓔ Bufferin . . . . . BUFRN

Ⓕ Darvon Compound . . . . . DARVN

Ⓖ Dristan . . . . . DRSTN

Ⓗ Empirin Compound . . . . . EMPRN

Ⓙ Excedrin . . . . . EXDRN

NEW CARD **S****H****2****B****3** (1-5) Duplicate Columns 6 through 14 (6-14)

1. Continued

	Absent	Mild	Moderate	Severe
Gas . . . . . <b>GAS</b>	1	2	3	4 (31)
Nervousness . . . . . <b>NERVE</b>	1	2	3	4 (32)
Unusual heart beat. <b>H.BEAT</b>	1	2	3	4 (33)
Unusual bleeding. . . <b>BLEED</b>	1	2	3	4 (34)
Black bowel movements <b>BOWEL</b>	1	2	3	4 (35)

12. Have you noticed any changes in the following over the last three months? Answer each item by circling the appropriate number.

	No Change	Increased	Decreased
Appetite. . . . .	1	2	3 (36)
Hearing . . . . .	1	2	3 (37)
Vision. . . . .	1	2	3 (38)

13. Do you take laxatives more than once a week?  
 No. . . . . 1  
 Yes . . . . . 2 (39)  
 If "Yes," specify which laxatives and how often.

14. About how often do you have a bowel movement? Circle only one.  
 Less than 1 a week. . . . . 1  
 One a week . . . . . 2  
 One every 3 - 6 days . . . . . 3  
 One every 2 days . . . . . 4  
 One a day . . . . . 5  
 Two a day . . . . . 6  
 More than 2 a day . . . . . 7 (40)

11. GENERAL SYMPTOMS

15. For each of the following items, circle the number corresponding to the response that best describes your experience.

	Never Had	Have Now	Had in Past but Do Not Have Now		Uncertain
			Had	Now	
Excessive fatigue . . . <b>X.FAT</b>	1	2	3	9	(41)
Unexplained weight loss <b>UNWTLS</b>	1	2	3	9	(42)
Excessive thirst. <b>X.THRST</b>	1	2	3	9	(43)
Unusual intolerance for hot weather . . . <b>IN.T.H.T</b>	1	2	3	9	(44)
Unusually easy bruising <b>EZ.BRUZ</b>	1	2	3	9	(45)
Unusually easy bleeding <b>EZ.BLED</b>	1	2	3	9	(46)
Unusual intolerance for cold weather. . . <b>INT.CAL</b>	1	2	3	9	(47)

a. HEAD AND NECK

	Never Had	Have Now	Had in Past but Do Not Have Now	Uncertain
Frequent or persistent loss of hearing. . . . .	1	2	3	9 (48)
Disturbance in vision . . . . .	1	2	3	9 (49)
Frequent or persistent nose bleeds. . . . .	1	2	3	9 (50)
Frequent or persistent bleeding gums . . . . .	1	2	3	9 (51)
Frequent nasal obstruction or discharge. . . . .	1	2	3	9 (52)
Difficulty in swallowing. . . . .	1	2	3	9 (53)
Unusual hair loss . . . . .	1	2	3	9 (54)
Other head and neck problems. . . . .	1	2	3	9 (55)

If Other, specify: \_\_\_\_\_

General Symptoms (Continued)	Never Had	Have Now	Had in Past but Not Now	Uncertain
<b>b. SKIN</b>				
Moles that have changes in size or color . . . . .	1	2	3	9 (15)
Persistent itching . . . . .	1	2	3	9 (16)
Skin growths . . . . .	1	2	3	9 (17)
Skin ulcerations . . . . .	1	2	3	9 (18)
Psoriasis . . . . .	1	2	3	9 (19)
Allergic dermatitis (eczema) . . . . .	1	2	3	9 (20)
<b>c. RESPIRATORY</b>				
Asthma . . . . .	1	2	3	9 (21)
Tuberculosis (TB) . . . . .	1	2	3	9 (22)
Cancer of the lungs . . . . .	1	2	3	9 (23)
Chronic bronchitis . . . . .	1	2	3	9 (24)
Emphysema . . . . .	1	2	3	9 (25)
Coughing up of blood . . . . .	1	2	3	9 (26)
Abnormal chest X-ray . . . . .	1	2	3	9 (27)
Cough lasting over 3 months . . . . .	1	2	3	9 (28)
Pneumonia . . . . .	1	2	3	9 (29)
Pleurisy . . . . .	1	2	3	9 (30)
Wheezing . . . . .	1	2	3	9 (31)
Hay fever . . . . .	1	2	3	9 (32)
Other respiratory problems . . . . .	1	2	3	9 (33)
<i>If Other, specify:</i>				
<b>d. GASTROINTESTINAL</b>				
Hiatus hernia . . . . .	1	2	3	9 (34)
Gallbladder disease . . . . .	1	2	3	9 (35)
Jaundice (other than at birth) <b>JAUND</b>	1	2	3	9 (36)
Liver disease . . . . . <b>L.I.V.P.</b>	1	2	3	9 (37)
Ulcer . . . . .	1	2	3	9 (38)

General Symptoms (Continued)	Never Had	Have Now	Had in Past but Not Now	Uncertain
Colitis . . . . .	1	2	3	9 (39)
Diverticulitis . . . . .	1	2	3	9 (40)
Hemorrhoids . . . . .	1	2	3	9 (41)
Frequent indigestion . . . . .	1	2	3	9 (42)
Frequent heartburn . . . . .	1	2	3	9 (43)
Frequent belching or regurgitation . . . . .	1	2	3	9 (44)
Frequent or persistent abdominal pain . . . . .	1	2	3	9 (45)
Tarry stool (black bowel movement) . . . . .	1	2	3	9 (46)
Frequent nausea or vomiting . . . . .	1	2	3	9 (47)
Intolerance of fatty foods . . . . .	1	2	3	9 (48)
Change in bowel habits . . . . .	1	2	3	9 (49)
Persistent constipation <b>PCONST</b>	1	2	3	9 (50)
Frequent diarrhea . . . . .	1	2	3	9 (51)
Excessive increase in gas . . . . .	1	2	3	9 (52)
Rectal bleeding . . . . .	1	2	3	9 (53)
Other rectal problems . . . . .	1	2	3	9 (54)
Vomiting of blood . . . . .	1	2	3	9 (55)
Anal fissure . . . . .	1	2	3	9 (56)
Other gastrointestinal problems . . . . .	1	2	3	9 (57)
<i>If Other, specify:</i>				
<b>e. MISCELLANEOUS</b>				
Anemia . . . . .	1	2	3	9 (58)
Hernia (other than hiatus) . . . . .	1	2	3	9 (59)
Thyroid disorder <b>DTSHY</b>	1	2	3	9 (60)
Cancer . . . . .	1	2	3	9 (61)



**General Symptoms (Continued)**

	Never Had	Have Now	Had in Past but Do Not Have Now	Uncertain
Diabetes . . . . . <b>DIABET</b>	1	2	3	9
Penicillin allergy . . . . .	1	2	3	9
Drug allergies (other than penicillin) . . . . .	1	2	3	9
Swollen or painful joints . . . . .	1	2	3	9
Overweight (obesity) . . . . .	1	2	3	9
Back trouble . . . . .	1	2	3	9

*If Other Symptoms, specify:* \_\_\_\_\_

**NEW CARD [N] [2] [B] [5] (1-5) Duplicate Columns 6 through 14 (6-14)**

**URINARY**

Difficult or painful urination . . . . .	1	2	3	9
Poor bladder control . . . . .	1	2	3	9
Night urination (if twice or more each night) . . . . .	1	2	3	9
Blood, protein or sugar in urine . . . . . <b>URBLD</b>	1	2	3	9
Passage of kidney stone or gravel . . . . .	1	2	3	9
Urge to urinate more often than normal . . . . . <b>URABN</b>	1	2	3	9
Kidney or bladder infection . . . . .	1	2	3	9
Frequent urination and large volume of urine . . . . .	1	2	3	9
Difficulty in starting urination . . . . .	1	2	3	9
Have you ever had an instrument (cystoscope, etc.) passed into the bladder . . . . .	1	2	3	9
Other urinary problems . . . . .	1	2	3	9

*If Other, specify:* \_\_\_\_\_

**General Symptoms (Continued)**

	Never Had	Have Now	Had in Past but Do Not Have Now	Uncertain
<b>8. GENITAL</b>				
Swelling or tenderness of scrotum or testicle(s) . . . . .	1	2	3	9
Prostate trouble . . . . .	1	2	3	9
Other genital problems . . . . .	1	2	3	9
<i>If Other, specify:</i> _____				
<b>9. NEUROMUSCULAR</b>				
Frequent or severe headaches . . . . . <b>HEAD A</b>	1	2	3	9
Attacks of staggering, loss of balance or dizziness . . . . .	1	2	3	9
Loss of consciousness or head injury . . . . .	1	2	3	9
Persistent numbness or tingling of hands or feet . . . . .	1	2	3	9
Epilepsy . . . . .	1	2	3	9
Loss of feeling anywhere . . . . .	1	2	3	9
Difficulty in sleeping <b>DIFSLP</b>	1	2	3	9
Increasing irritability and mood swings . . . . . <b>MOODY</b>	1	2	3	9
Frequent periods of feeling depressed or "blue" <b>DEPRS</b>	1	2	3	9
Other neuromuscular problems . . . . .	1	2	3	9

*If Other, specify:* \_\_\_\_\_

**16. a. Has your doctor ever said you had a stroke (apoplexy, cerebral vascular accident)?**

No . . . . .	1
Yes . . . . .	2
Uncertain . . . . .	9

*If "No," go to question 17.*

16. Continue

b. Age at time of first stroke? . . . . . (40-41)

c. Were you hospitalized for your most recent stroke?

No . . . . . 1

Yes . . . . . 2

Uncertain . . . . . 9 (42)

VIII. HOSPITALIZATIONS

17. How many times have you been hospitalized? (43-44)

Please list all hospitalizations and/or operations below. Use back of preceding page if more space is needed.

Date	Hospital	Illness, Injury	Operation or Treatment	Type of

IX. FAMILY HISTORY

18. For each of your parents circle the appropriate number.

	FALIV Father	MALIV Mother
Alive . . . . .	1	1
Cause of death:		
Accident . . . . .	2	2
Cancer . . . . .	3	3
Heart attack . . . . .	4	4
Stroke . . . . .	5	5
Other or unknown cause . . . . .	6	6
Unknown . . . . .	9 (45)	9 (46)

b. For brothers and sisters, enter the number of brothers, half-brothers, half-sisters in the appropriate boxes. For example, if you have 3 brothers, of whom 2 are alive and one died in an accident, enter "02" in the box labeled "Alive" and "01" in the box labeled "Accident." If you have no brothers, sisters, half-brothers or half-sisters, leave the boxes blank.

**BALIV** **SALIV**  
Brothers Sisters

● Alive . . . . . (47-48) (49-50)

Cause of death:

  Accident . . . . . (51-52) (53-54)

  Cancer . . . . . (55-56) (57-58)

  Heart attack . . . . . (59-60) (61-62)

  Stroke . . . . . (63-64) (65-66)

  Other or unknown cause . . . . . (67-68) (69-70)

  Unknown . . . . . (71-72) (73-74)

19. a. **MAGE** (75-76)

How old is your mother or how old was your mother when she died? . . . . .

b. **FAGE** (77-78)

How old is your father or how old was your father when he died? . . . . .

If you do not know the ages of your father and/or mother when they died, leave the boxes blank.

c. **NUMSIB** (79-80)

How many brothers, sisters, half-brothers or half-sisters do you have? . . . . .

20. a) For your parents circle the numbers which correspond to disorders they have had.

	Father	Mother
Heart attack or angina (before age 60) . . . . .	<b>FHRT</b> 1 (15)	<b>MHRT</b> 2 (16)
High blood pressure or hypertension (before age 60) . . . . .	<b>FHYP</b> 1 (17)	<b>MHYP</b> 2 (18)
Strokes, apoplexy, cerebral vascular disease . . . . .	<b>FSTR</b> 1 (19)	<b>MSTR</b> 2 (20)
High cholesterol, high triglycerides, high blood fats . . . . .	<b>FHILIP</b> 1 (21)	<b>MHILIP</b> 2 (22)
Diabetes . . . . .	<b>FDIAB</b> 1 (23)	<b>MDIAB</b> 2 (24)
Trouble with circulation in legs other than varicose veins, that is peripheral vascular disease . . . . .	<b>FCIRC</b> 1 (25)	<b>MCIRC</b> 2 (26)
None of the above . . . . .	<b>FNONE</b> 1 (27)	<b>MNONE</b> 2 (28)

b) For your brothers and sisters enter the number of brothers, sisters, half-brothers and half-sisters who have had these disorders. For example, if you have 2 brothers, both of whom have high blood pressure and one of whom also has had a heart attack, you should enter "02" in the box labeled "High blood pressure or hypertension," and "01" in the box labeled "Heart attack or angina" under brothers. If you have no brothers, half-brothers, sisters or half-sisters, leave the boxes blank.

	Brothers	Sisters
Heart attack or angina (before age 60) . . . . .	<b>BHRT</b> (29-30)	<b>SHRT</b> (31-32)
High blood pressure or hypertension (before age 60) . . . . .	<b>BHYP</b> (33-34)	<b>SHYP</b> (35-36)
Strokes, apoplexy, cerebral vascular disease . . . . .	<b>BSTR</b> (37-38)	<b>SSTR</b> (39-40)
High cholesterol, high triglyceride, high blood fats . . . . .	<b>BHILIP</b> (41-42)	<b>SHILIP</b> (43-44)
Diabetes . . . . .	<b>BDIAB</b> (45-46)	<b>SIDIAB</b> (47-48)
Trouble with circulation in the legs other than varicose veins, that is peripheral vascular disease . . . . .	<b>BCIRC</b> (49-50)	<b>SCIRC</b> (51-52)
None of the above . . . . .	<b>BNONE</b> (53-54)	<b>SNONE</b> (55-56)

21. Do you have sons or brothers aged 35 - 59? . . . . .

No . . . . . 1

Yes . . . . . 2 (57)

If "Yes," give their names and addresses. Use back of preceding page if more space is needed.

X. MISCELLANEOUS

22. Have you ever served in the armed forces? . . . . .

No . . . . . 1

Yes . . . . . 2 (58)

If "Yes," answer the following:

Branch of service \_\_\_\_\_

Rank or rating \_\_\_\_\_

Serial number \_\_\_\_\_

23. Give the name, address and telephone number of three friends or relatives who are not living with you and who are likely to know your address at all times.

Name \_\_\_\_\_  
Address \_\_\_\_\_ Number \_\_\_\_\_ Street \_\_\_\_\_ City \_\_\_\_\_  
State \_\_\_\_\_ Zip Code \_\_\_\_\_ Phone Number \_\_\_\_\_

Name \_\_\_\_\_  
Address \_\_\_\_\_ Number \_\_\_\_\_ Street \_\_\_\_\_ City \_\_\_\_\_  
State \_\_\_\_\_ Zip Code \_\_\_\_\_ Phone Number \_\_\_\_\_

Name \_\_\_\_\_  
Address \_\_\_\_\_ Number \_\_\_\_\_ Street \_\_\_\_\_ City \_\_\_\_\_  
State \_\_\_\_\_ Zip Code \_\_\_\_\_ Phone Number \_\_\_\_\_

24. Give the name, address and telephone number of your employer:

Name \_\_\_\_\_  
Address \_\_\_\_\_ Number \_\_\_\_\_ Street \_\_\_\_\_ City \_\_\_\_\_  
State \_\_\_\_\_ Zip Code \_\_\_\_\_ Phone Number \_\_\_\_\_

S L D I A 2

(1-5)

PACKNO

Subject ID Number

(6-14)

LIPID LABORATORY DATA FORM

VISA Visit No. (15-16)

For CPR Use Only

(49-54)

1. Date of Visit: (17-22) Month Day Year

2. Last Name: MSLD D S L D Y S L D (23-34)

Initials: 1st 2nd (35-36)

3. CHYLOM a. Chylomicron layer: 1 Present . . . . . 2 Absent . . . . . 9 Not done . . . . .

b. Appearance of plasma: 1 Clear . . . . . 2 Turbid . . . . . 9 Not done . . . . .

4. a. Cholesterol (Record in mg%): (39-42) CHOL

b. Date of cholesterol determination: (43-48) MCHOL DCHOL YCHOL

5. Triglycerides (Record in mg%): (55-58) RAWTG

6. Triglyceride blank (To be done only if triglyceride value is greater than 300 mg%): (59-60) TG BLK

7. Triglyceride less blank: (61-64) TG

8. Date of triglyceride determination: (65-70) MTG DTG YTG

9. HDL cholesterol (By heparin-manganese precipitation): (71-74) HDL

10. Date of HDL cholesterol determination: (75-80) MHDL DHDL YHDL

11. Estimated LDL cholesterol (LDL = CHOL - HDL - TG/5): (15-17) LDL

12. Code number and initials of person completing this form: (18-19)

For CPR Use Only (15-20)

**PACK NO**  
Subject ID Number (6-14)

**VISIT**  
0 2 (15-16)

SLL/JL  
(1-5)

<p>1. Date of Visit: (17-22)</p> <p>2. Last Name: (23-34)</p> <p>Initials: (35-36)</p>	<p>6. a. HDL cholesterol (By heparin-manganese precipitation): (21-24)</p> <p>b. Date of HDL cholesterol determination: (25-30)</p>	<p>1. Date of Visit: (17-22)</p> <p>2. Last Name: (23-34)</p> <p>Initials: (35-36)</p>	<p>7. Estimated LDL cholesterol (LDL = CHOL - HDL - TG/5): (31-33)</p>	<p>3. CHYLOM</p> <p>a. Chylomicron layer: (37)</p> <p>b. Appearance of plasma: (38)</p>	<p>8. Lipoprotein quantification (To be done only at the second pre-randomization visit):</p> <p>a. Floating beta present? (34)</p> <p>b. Sinking pre-beta present? (34)</p>	<p>4. Cholesterol (Record in mg%): CHOL (39-42)</p> <p>5. a. Triglycerides (Record in mg%): TG (49-52)</p> <p>b. Triglyceride blank (To be done only if triglyceride value is greater than 300 mg%): (53-54)</p> <p>c. Triglyceride less blank: TG (55-58)</p> <p>d. Date of triglyceride determination: (59-64)</p>	
<p>6. a. HDL cholesterol (By heparin-manganese precipitation): (21-24)</p> <p>b. Date of HDL cholesterol determination: (25-30)</p>		<p>7. Estimated LDL cholesterol (LDL = CHOL - HDL - TG/5): (31-33)</p>		<p>8. Lipoprotein quantification (To be done only at the second pre-randomization visit):</p> <p>a. Floating beta present? (34)</p> <p>b. Sinking pre-beta present? (34)</p>		<p>9. Initials and code number of person completing this form: Initials (58-59) Code Number (52-57)</p>	

10174

SRA

TWO, FOUR, SIX, EIGHT, AND TEN MONTH SUBJECT RECORD

For CPR Use Only

(49-

PACK NO  
Subject ID Number

S R 2 B 1 (1-5)

(6-14)

VISIT

(15-16)

Visit Number

(TV) VIMON VIDAY VTYR

(17-22)

(23-34)

(35-36)

1. Date of visit:

Subject's Last Name:

3. Initials:

4.a. SYMPTOM

Have you experienced any of the symptoms in 4.b. since the last visit?

No .....  
Yes .....

b. If yes, circle the numbers that best describe your experience since the last visit. If no, go to question 5.

	Mild	Moderate	Severe
• Nausea . . . . .	2	3	4
• Vomiting . . . . .	2	3	4
• Itching . . . . .	2	3	4
• Heartburn . . . . .	2	3	4
• Diarrhea . . . . .	2	3	4
• Rash . . . . .	2	3	4
• Unusual hair loss	2	3	4
• Difficulty swallowing	2	3	4
• Constipation . . . . .	2	3	4
• Drowsiness . . . . .	2	3	4
• Abdominal pain . . . . .	2	3	4

NAUSEA  
VOMIT.  
ITCH  
HEARTB.  
DIARR.  
RASH  
HAIRL  
DIFSW  
CONST.  
DROWS  
ABDOM

	Mild	Moderate	Severe
• Dryness of skin	2	3	4
• Leg cramps . . . . .	2	3	4
• Hives . . . . .	2	3	4
• Weakness . . . . .	2	3	4
• Belching or bloating	2	3	4
• Gas . . . . .	2	3	4
• Nervousness . . . . .	2	3	4
• Unusual heartbeat	2	3	4
• Unusual bleeding . . . . .	2	3	4
• Black bowel movements	2	3	4

DRYSK  
CRAMP.  
HIVES  
WEAK  
BELCH  
GAS  
NERVE  
HEART.  
BLEED.  
BOWEL

5. Have you noticed any change in the following since your last visit?

	No Change	Increased	Decreased
a. Appetite . . . . .	1	2	3
b. Hearing . . . . .	1	2	3
c. Vision . . . . .	1	2	3

6. Since your last visit, have you had any problems, symptoms, or changes in habit other than those listed in 4-5 above?

No ..... 1  
Yes ..... 2

If "Yes," list briefly:

7. VHDSP  
 1  
 2 (17)

11. How many times each day do you presently take your study medication

- One time a day
- Two times a day
- Three times a day
- Four times a day
- Five times a day
- Six times a day

(32)

12.a. Since your last visit, were there any days during which you took no study medication?

- No
- Yes

1  
2 (33)

If "No," STOP.

b. On how many days did you take no study medication?

--	--	--

(34-36)

7. VHDSP

1  
2 (17)

b. If "yes," list dates of hospitalization, if known.

From: / /  / /

To: / /  / /

Month Day Year

(18-23)

(24-29)

Reason for hospitalization: \_\_\_\_\_

8. Have you had any illnesses since your last visit that did NOT require hospitalization?

- No
- Yes

1  
2 (30)

If "Yes," specify briefly: \_\_\_\_\_

9. Are you presently taking or have you taken any prescribed medication other than the study medication since your last visit?

- No
- Yes

If "Yes," please have available the names and dosages for clinic staff.

9. PRES\_MED

1  
2 (31)

10. How many packets of study medication are you presently taking each day? (Report fractions if applicable.)

\_\_\_\_\_ packets/day

If zero, STOP.



VISIT 3, 4, OR 5 SUBJECT RECORD

(15-16)

(58-63)

For CPR Use Only

Visit Number

VISIT

PACK NO  
Subject ID Number

SIRIALL

(1-5)

(6-14)

1. Date of Visit: Month Day Year (17-22)  
 2. Last Name: (23-34)  
 3. Initials: 1st 2nd (35-36)

In each of the following questions circle only one number. If you make a mistake put an "X" over the mistake and circle the correct number. The numbers in parentheses are for coding purposes ONLY.

4. For each of the following items circle the number that best describes your experience since the last visit.

	Absent	Mild	Moderate	Severe
Nausea	1	2	3	4 (37)
Vomiting	1	2	3	4 (38)
Itching	1	2	3	4 (39)
Heartburn	1	2	3	4 (40)
Diarrhea	1	2	3	4 (41)
Rash	1	2	3	4 (42)
Unusual hair loss	1	2	3	4 (43)
Difficulty swallowing	1	2	3	4 (44)
Constipation	1	2	3	4 (45)
Drowsiness	1	2	3	4 (46)
Abdominal pain	1	2	3	4 (47)
Dryness of skin	1	2	3	4 (48)
Leg cramps	1	2	3	4 (49)
Hives	1	2	3	4 (50)
Weakness	1	2	3	4 (51)
Belching or bloating	1	2	3	4 (52)
Gas	1	2	3	4 (53)
Nervousness	1	2	3	4 (54)
Unusual heartbeat	1	2	3	4 (55)
Unusual bleeding	1	2	3	4 (56)
Black bowel movement	1	2	3	4 (57)

5. Have you noticed any change in the following since your last visit? Answer each item by circling the appropriate number.

	No Change	Increased	Decreased
Appetite	1	2	3 (64)
Hearing	1	2	3 (65)
Vision	1	2	3 (66)

6. Have you been hospitalized since your last visit? If "Yes," give the reason: No Yes

7. Have you had any illnesses since your last visit that did NOT require hospitalization? If "Yes," specify briefly: No Yes

8. Since your last visit, have you had any problems, symptoms, or changes in habit other than those listed in 4-7 above? If "Yes," list briefly: No Yes

9. Are you presently taking any prescribed medicine? If "Yes," please list all of these: No Yes

List the prescribed medicines STOPPED since the last visit:

PACKNO  
Subject ID Number

S I I I B I I (1-5)  
(6-14)

VISIT 1 DATA FORM

0 1 (15-16)  
Visit Number

VISIT

For CPR Use Only  
(50-55)

I. GENERAL

Enter one character per box, beginning with the leftmost box. Enter all letters as capitals. Mark through the boxes with a single horizontal stroke if a question does not apply.

1. Date of Visit: MONTH DAY YEAR (17-22)  
Month Day Year (TV)

2. Subject's Last Name: (23-34)

First Name: (35-42)

Second Name: (43)

Third Name (Code JR, SR, I, II, etc. here): (44-46)

3. When was the last time you took anything by mouth except water? See the instructions for use of fasting wheel to determine fasting time. Enter a two digit number, using a leading zero when the number is less than 10. If subject is fasting at least 12 hours, go to question 5.  
FAST (47-48)

4. Is this your:  
1 First visit to the clinic? . . . . . 1  
If the subject is fasting for less than 12 hours, go to question 39.  
2 Second visit to the clinic? . . . . . 2 (49)  
If this is the second visit and subject is fasting less than 12 hours, go to question 37 and code "second non-fasting or missed visit."

Mailing Address: For Lot or Box numbers, print LOT or BOX in the first three blanks for question 5 and then write the number in question 6.

5. House Number, Lot or Box: (56-61)

6. Apartment, Lot, or Box Number: (62-66)

7. Street Name, Apartment Complex, Mobile Court Name or Rural Route (RR) and Number: (67-79)  
NEW CARD S T I B 2 (1-5) DUPLICATE COLUMNS (6-14)

8. City: (15-27)

9. State or Province (Use abbreviations given in the instructions): (28-29)

10. Zip Code or Canadian Postal Code: (30-35)

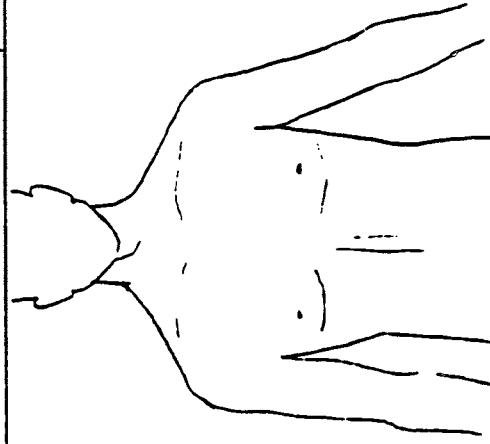
11. Home Phone Number: (36-45)  
Area Code

Work Phone Number: (46-55)  
Area Code

Work Phone Extension: (56-59)

12. Birthdate: (60-65)  
Month Day Year (MARTH DBRTH YBRTH) (TBRTH)

13. Social Security Number: (66-74)  
NEW CARD S T I B 3 (1-5) DUPLICATE COLUMNS (6-14)  
SOC SN

<p>11. CHEST PAIN</p> <p><i>If an answer marked with an asterisk (*) is circled in this section, go directly to question 23.</i></p> <p>14. a. Have you ever had any pain or discomfort in your chest?</p> <p>1 No . . . . .</p> <p>2 Yes . . . . . (15)</p> <p><i>If "Yes," go to question 15.</i></p> <p>b. <i>If "No," ask: Have you ever had any pressure or heaviness in your chest?</i></p> <p>1 No* . . . . .</p> <p>2 Yes . . . . . (16)</p>	<p>14. a. . . . . 1</p> <p>. . . . . 2 (15)</p> <p>b. . . . . 1*</p> <p>. . . . . 2 (16)</p>	<p>19. How soon?</p> <p>1 Ten minutes or less . . . . .</p> <p>2 More than ten minutes* . . . . . (21)</p>	<p>19. . . . . 1</p> <p>. . . . . 2* (21)</p>
<p>15. Do you get it when you walk uphill or hurry?</p> <p>1 No* . . . . .</p> <p>2 Yes . . . . .</p> <p>9 Never hurries or walks uphill . . . . .</p>	<p>15. . . . . 1*</p> <p>. . . . . 2</p> <p>. . . . . 9 (17)</p>	<p>20. Will you show me where it was? Answer items a through e.</p> <p>a. Sternum (upper or middle)?</p> <p>1 No . . . . .</p> <p>2 Yes . . . . . (22)</p> <p>b. Sternum (lower)?</p> <p>1 No . . . . .</p> <p>2 Yes . . . . . (23)</p> <p>c. Left anterior chest?</p> <p>1 No . . . . .</p> <p>2 Yes . . . . . (24)</p> <p>d. Left arm?</p> <p>1 No . . . . .</p> <p>2 Yes . . . . . (25)</p> <p>e. Other? (If "Yes," mark on diagram.)</p> <p>1 No . . . . .</p> <p>2 Yes . . . . . (26)</p>	<p>20. . . . . 1</p> <p>. . . . . 2 (22)</p> <p>. . . . . 1</p> <p>. . . . . 2 (23)</p> <p>. . . . . 1</p> <p>. . . . . 2 (24)</p> <p>. . . . . 1</p> <p>. . . . . 2 (25)</p> <p>. . . . . 1</p> <p>. . . . . 2 (26)</p>
<p>16. Do you get it when you walk at an ordinary pace on the level?</p> <p>1 No . . . . .</p> <p>2 Yes . . . . . (18)</p>	<p>16. . . . . 1</p> <p>. . . . . 2 (18)</p>		
<p>17. What do you do if you get it while you are walking?</p> <p>1 Stop or slow down . . . . .</p> <p>2 Carry on* . . . . . (19)</p> <p><i>Circle "1," "Stop or Slow Down," if subject carries on after taking nitroglycerine.</i></p>	<p>17. . . . . 1</p> <p>. . . . . 2* (19)</p>	<p>18. If you stand still, what happens to it?</p> <p>1 Relieved . . . . .</p> <p>2 Not relieved* . . . . . (20)</p>	

27. Record subject's heart beat for 15 seconds (not 60 seconds) 27. PUL15 (42-43)

28. Record subject's blood pressure (take using right arm after patient has been sitting quietly for at least 5 minutes).

Readings	Systolic	Diastolic
Reading 1 (Std) (44-46)	SYSBA [ ][ ]	DSTBA [ ][ ]
Reading 2 (R-2) (50-52)	SYSBB [ ][ ]	DSTBB [ ][ ]
Zero 2 (56-57)	ZEROA [ ][ ]	
Net 2 (58-60)	SYSBP [ ][ ]	DSTBP [ ][ ]
NEW CARD [S][I][L][B][4] (1-5) DUPLICATE COLUMNS (6-14)		
Reading 3 (Std) (15-17)	SYSBC [ ][ ]	DSTBC [ ][ ]
Reading 4 (R-2) (21-23)	SYSBD [ ][ ]	DSTBD [ ][ ]
Zero 4 (27-28)	ZEROB [ ][ ]	
Net 4 (32-34)		

29. Initials and code number of person completing this section: Initials [ ][ ] Code Number [ ][ ] (35-36)

21. Do you feel it anywhere else?  
 1 No (27)  
 2 Yes

22. a. Did you see a doctor because of this pain (or discomfort)?  
 1 No (28)  
 2 Yes

b. If "Yes," ask: What did he say it was?  
 1 Angina (29)  
 2 Other

23. Does the subject have angina by the Rose Questionnaire criterion? The subject has angina if any one of the following criteria is met:  
 (i) item 20a is answered "yes," or  
 (ii) item 20b is answered "yes," or  
 (iii) both items 20c and 20d are answered "yes."  
 1 No (30)  
 2 Yes

24. Initials and code number of person completing this section: Initials [ ][ ] Code Number [ ][ ] (31-32)

III. CLINIC WORKUP RECORD

25. Height: HT [ ][ ] [ ][ ] cm (33-36)

26. Weight: WT [ ][ ] [ ][ ] kg (37-40)

b. Is this greater than the allowed weight for height?  
 1 No (41)  
 2 Yes

*Refer to Table VI-1 of the Protocol or the table included in the instructions for this form.*





<p>9. In your origin or descent--</p> <p>1 Mexican? . . . . .</p> <p>2 Puerto Rican? . . . . .</p> <p>3 Cuban? . . . . .</p> <p>4 Central or South American? . . . . .</p> <p>5 Other Spanish? . . . . .</p> <p>6 Italian? . . . . .</p> <p>7 Other European? . . . . .</p> <p>9 None of these or unknown? . . . . .</p>	<p>9. DESCEN</p> <p>1 . . . . .</p> <p>2 . . . . .</p> <p>3 . . . . .</p> <p>4 . . . . .</p> <p>5 . . . . .</p> <p>6 . . . . .</p> <p>7 . . . . .</p> <p>9 (56)</p>	<p>12. Continued</p> <p>02 Business manager, proprietor of medium-sized business, lesser professional . . . . .</p> <p>03 Administrative personnel, small independent business, minor professional . . . . .</p> <p>04 Clerical or sales worker, technical worker, owner of little business . . . . .</p> <p>05 Skilled manual employee . . . . .</p> <p>06 Machine operator, semi-skilled employee . . . . .</p> <p>07 Unskilled employee, small farmer . . . . .</p> <p>08 Unemployed for more than two (2) years . . . . .</p> <p>09 Student . . . . .</p> <p>10 Other . . . . .</p> <p>99 Unknown . . . . .</p>	<p>12. Occupation Code</p> <p>02</p> <p>03</p> <p>04</p> <p>05</p> <p>06</p> <p>07</p> <p>08</p> <p>09</p> <p>10</p> <p>99 (59-60)</p>	
<p>10. Of which racial group are you a member?</p> <p>1 White . . . . .</p> <p>2 Negro or black . . . . .</p> <p>3 Oriental . . . . .</p> <p>4 American Indian . . . . .</p> <p>9 Other Specify: _____</p>	<p>10. RACE</p> <p>1 . . . . .</p> <p>2 . . . . .</p> <p>3 . . . . .</p> <p>4 . . . . .</p> <p>9 (57)</p>	<p>13. Since your last visit have you had any pain or discomfort in your chest? If "Yes," administer the Chest Pain Form and do not ask question 14.</p> <p>1 No . . . . .</p> <p>2 Yes . . . . .</p>	<p>13. CHESPN</p> <p>1</p> <p>2 (61)</p>	
<p>11. How much education have you had?</p> <p>1 College graduate with professional training . . . . .</p> <p>2 College graduate . . . . .</p> <p>3 At least 1 year of college training . . . . .</p> <p>4 High school graduate . . . . .</p> <p>5 Completed tenth grade in high school training . . . . .</p> <p>6 Completed 7 years of school . . . . .</p> <p>7 Completed less than 7 years of school . . . . .</p> <p>9 Unknown . . . . .</p>	<p>11. EDUC</p> <p>1 . . . . .</p> <p>2 . . . . .</p> <p>3 . . . . .</p> <p>4 . . . . .</p> <p>5 . . . . .</p> <p>6 . . . . .</p> <p>7 . . . . .</p> <p>9 (58)</p>	<p>14. Since your last visit have you had any pressure or heaviness in your chest?</p> <p>1 No . . . . .</p> <p>2 Yes . . . . .</p> <p>If "Yes," administer the Chest Pain Form.</p>	<p>14. CHESPR</p> <p>1 . . . . .</p> <p>2 (62)</p>	
<p>12. What is your usual occupation? _____</p> <p>01 High executive, proprietor of large concern, major professional . . . . .</p>		<p>11. INTERMITTENT CLAUDICATION</p> <p>These questions should be asked of the subject exactly as they are written. If an answer marked with an asterisk (*) is circled in this section, skip to question 24.</p> <p>15. Do you get pain in either leg on walking?</p> <p>1 No* . . . . .</p> <p>2 Yes . . . . .</p>		<p>15. ICA</p> <p>1*</p> <p>2 (63)</p>

<p>16. ICB</p> <p>1 No . . . . . (64)</p> <p>2 Yes* . . . . . (64)</p>	<p>16. Does this pain ever begin when you are standing still or sitting?</p> <p>1 No . . . . .</p> <p>2 Yes* . . . . .</p>	<p>24. IIC</p> <p>1 No . . . . . 1</p> <p>2 Yes . . . . . 2</p> <p>9 Uncertain . . . . . 9 (72)</p>	<p>24. Does the subject have intermittent claudication according to the Rose Questionnaire criterion? The subject has intermittent claudication if the answers to questions 22 and 23 are "Relieved" and "10 minutes or less."</p>
<p>17. ICC</p> <p>1 No* . . . . . (65)</p> <p>2 Yes . . . . . (65)</p>	<p>17. In what part of the leg do you feel it?</p> <p>1 Pain includes calf/calves . . . . .</p> <p>2 Pain does not include calf/calves* . . . . .</p>	<p>25. Initials and code number of person completing this section. Initials: <input type="text"/> <input type="text"/> Code Number <input type="text"/> <input type="text"/> (73-74)</p>	<p>25. Initials and code number of person completing this section. Initials: <input type="text"/> <input type="text"/> Code Number <input type="text"/> <input type="text"/> (73-74)</p>
<p>18. ICD</p> <p>1 No* . . . . . 1*</p> <p>2 Yes . . . . . 2</p> <p>9 Never hurries or walks uphill . . . . . 9 (66)</p>	<p>18. Do you get it if you walk uphill or hurry?</p> <p>1 No* . . . . .</p> <p>2 Yes . . . . .</p> <p>9 Never hurries or walks uphill . . . . .</p>	<p>26. Record subject's heart beat for 15 seconds (not 60 seconds) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> PULSE (15-16)</p>	<p>26. Record subject's heart beat for 15 seconds (not 60 seconds) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> PULSE (15-16)</p>
<p>19. ICE</p> <p>1 No . . . . . 1</p> <p>2 Yes . . . . . 2 (67)</p>	<p>19. Do you get it if you walk at an ordinary pace on the level?</p> <p>1 No . . . . .</p> <p>2 Yes . . . . .</p>	<p>27. Weight (in kilograms) WT <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Kg (17-20)</p>	<p>27. Weight (in kilograms) WT <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Kg (17-20)</p>
<p>20. ICF</p> <p>1 No . . . . . 1</p> <p>2 Yes* . . . . . 2* (68)</p>	<p>20. Does the pain disappear while you are walking?</p> <p>1 No . . . . .</p> <p>2 Yes* . . . . .</p>	<p>28. Record subject's blood pressure. (Take using right arm after subject has been sitting quietly for at least 5 minutes).</p> <p>Readings</p> <p>Systolic</p> <p>Reading 1 (Std) SYSBA <input type="text"/> <input type="text"/> <input type="text"/> (21-23) Diastolic DSTBA <input type="text"/> <input type="text"/> <input type="text"/> (24-26)</p> <p>Reading 2 (R-Z) SYSBB <input type="text"/> <input type="text"/> <input type="text"/> (27-29) Diastolic DSTBB <input type="text"/> <input type="text"/> <input type="text"/> (30-32)</p> <p>Zero Reading 2 <input type="text"/> <input type="text"/> <input type="text"/> ZEROA <input type="text"/> <input type="text"/> <input type="text"/> (33-34)</p> <p>Net (Reading 2 - Zero Reading 2) SYSBP <input type="text"/> <input type="text"/> <input type="text"/> (35-37) Diastolic DSTBP <input type="text"/> <input type="text"/> <input type="text"/> (38-40)</p>	<p>28. Record subject's blood pressure. (Take using right arm after subject has been sitting quietly for at least 5 minutes).</p> <p>Readings</p> <p>Systolic</p> <p>Reading 1 (Std) SYSBA <input type="text"/> <input type="text"/> <input type="text"/> (21-23) Diastolic DSTBA <input type="text"/> <input type="text"/> <input type="text"/> (24-26)</p> <p>Reading 2 (R-Z) SYSBB <input type="text"/> <input type="text"/> <input type="text"/> (27-29) Diastolic DSTBB <input type="text"/> <input type="text"/> <input type="text"/> (30-32)</p> <p>Zero Reading 2 <input type="text"/> <input type="text"/> <input type="text"/> ZEROA <input type="text"/> <input type="text"/> <input type="text"/> (33-34)</p> <p>Net (Reading 2 - Zero Reading 2) SYSBP <input type="text"/> <input type="text"/> <input type="text"/> (35-37) Diastolic DSTBP <input type="text"/> <input type="text"/> <input type="text"/> (38-40)</p>
<p>21. ICG</p> <p>1 No . . . . . 1</p> <p>2 Carry on* . . . . . 2* (69)</p>	<p>21. What do you do if you get it when you are walking?</p> <p>1 Stop or slow down . . . . .</p> <p>2 Carry on* . . . . .</p>	<p>29. Initials and code number of person completing this section. Initials: <input type="text"/> <input type="text"/> Code Number <input type="text"/> <input type="text"/> (41-42)</p>	<p>29. Initials and code number of person completing this section. Initials: <input type="text"/> <input type="text"/> Code Number <input type="text"/> <input type="text"/> (41-42)</p>
<p>22. ICH</p> <p>1 Relieved . . . . . 1</p> <p>2 Not relieved . . . . . 2 (70)</p>	<p>22. What happens to it if you stand still?</p> <p>1 Relieved . . . . .</p> <p>2 Not relieved . . . . .</p>	<p>30. How soon?</p> <p>1 10 minutes or less . . . . . 1</p> <p>2 More than 10 minutes . . . . . 2 (71)</p>	<p>30. How soon?</p> <p>1 10 minutes or less . . . . . 1</p> <p>2 More than 10 minutes . . . . . 2 (71)</p>
<p>23. ICI</p> <p>1 10 minutes or less . . . . . 1</p> <p>2 More than 10 minutes . . . . . 2 (71)</p>	<p>23. How soon?</p> <p>1 10 minutes or less . . . . .</p> <p>2 More than 10 minutes . . . . .</p>	<p>31. Initials and code number of person completing this section. Initials: <input type="text"/> <input type="text"/> Code Number <input type="text"/> <input type="text"/> (41-42)</p>	<p>31. Initials and code number of person completing this section. Initials: <input type="text"/> <input type="text"/> Code Number <input type="text"/> <input type="text"/> (41-42)</p>

III. CLINIC WORKUP RECORD



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32. Continued

Never Had  Now  Had in Past  But Not Now  Uncertain

32. Cholelithiasis or **CHOLEL**     (56)

Cholecystitis

33. GOUT     (57)

Rheumatic heart disease **RHEUHD**     (58)

or other non-coronary heart disease

33. Have you ever had surgery on your heart?  No  Yes **HRTOP** (59)

If "Yes," was the surgery for:

34. Coronary bypass **CB-OP**   (60)

35. Valve replacement **VAL-OP**   (61)

36. Pacemaker **PCE-OP**   (62)

37. Aneurysm **AN-OP**   (63)

38. Other Specify: **OTH-OP**   (64)

39. Unknown **UNK-OP**   (65)

Check the appropriate box. No Yes Uncertain

34. Do you have a heart murmur?    (66)

If "Yes," at what age was it discovered?    (67-68)

Code 99 if unknown.

35. Have you ever been told you have high cholesterol?  No  Yes  (69)

If "Yes," enter the age at which you were first told    (70-71)

36. Have you ever been treated with medication for high cholesterol?  No  Yes  (72)

NEW CARD **S T 2 B 3** (1-5) Duplicate Columns 6 through 14 (6-14)

30. Have you signed the Consent to Participate Form?  Yes  No  (43)

31. **INTCL**   (44)

31. Is your clinical impression that the subject has intermittent claudication?  No  Yes

32. Have you ever had:  Never Had  Have Had in Past  Uncertain

**MI**

33. Myocardial infarction or coronary occlusion. If "Uncertain," record should be obtained from his physician or the hospital for review. If the diagnosis of MI is still uncertain, the subject is excluded from the study.     (45)

34. Abnormal Electrocardiogram     (46)

35. Diabetes **DIAB**     (47)

36. Glycosuria **GLYC**     (48)

37. Hyperthyroidism **HYTHY**     (49)

38. Myxedema **MYXD**     (50)

39. Nephrosis **NEPH**     (51)

40. Pancreatitis **PANC**     (52)

41. Biliary cirrhosis **BCIRH**     (53)

42. Other liver disease **OTHLM**     (54)

43. Gastrointestinal disease **GSDIS**     (55)

JB. Continued

17. Have you ever had any of the following? Use the following definitions in answering the questions.

Abnormal dyspnea on Exertion - shortness of breath occurring more easily than in others your own age during physical activity

Orthopnea - a condition in which there is need to sit up and elevate one's head to breathe more easily

Paroxysmal Nocturnal Dyspnea (PND) - an acute attack of shortness of breath waking patient from sleep and requiring him to sit up to ease the shortness of breath. Often associated with choking or suffocating sensation and often causes the patient to go to the nearest window for relief.

Answer items a through g, checking appropriate boxes. DYSPN

- a. Abnormal dyspnea on exertion
b. Orthopnea
c. Paroxysmal nocturnal dyspnea
d. Palpitations
e. Edema
f. Nocturia (more than once a night)
g. Enlarged heart

18. Have you ever been told you have high blood pressure? HBP

Age you were first told you had high blood pressure. Code 99 if unknown.

Blood pressure is ... Labile Always Unknown

Have you ever had treatment with medication for high blood pressure?

d. How long have (or had) you been treated for high blood pressure?
e. Are you on any treatment now?

V. PHYSICAL EXAMINATION

39. Fundi ... Normal Abnormal Not Well Seen

If Abnormal, which of the following abnormalities are present? Answer items a through i, checking the appropriate boxes.

- a. Widened light reflex
b. General arterial narrowing
c. A-V nicking
d. Focal arterial narrowing
e. Hemorrhage
f. Exudate
g. Papilledema
h. Microaneurysms
i. Other

If "Yes," specify treatment(s) and date(s), then answer items d and e.

40. Are the appropriate boxes checked?  
 a. Left eye  No  Yes (40)  
 b. Right eye  No  Yes (41)

41. Corneal arcus present? **CORNEA**  1  2 (42)

42. Xanthelasma present? **XANTHE**  1  2 (43)  
*If present, complete Xanthelasma Form.*

43. Carotid pulses unequal? **CARPLS**  1  2 (44)

44. Carotid bruits present?  
 Neither  1  2  
 Left Only  3  4  
 Right Only  3  4  
 Both  3  4 (45)

45. THYROID  
 Thyroid  1  2  3  4  9 (46)  
*If "Other," specify: \_\_\_\_\_*

46. Palpate pulse for one full minute.  
 a. Rate    (47-49)  
 b. Rhythm  1  2 (50)  
 Regular Irregular  
 c. Premature beats per minute   (51-52)

47. Estimate the jugular venous pressure as the vertical height from the top of the right atrial venous column to a level 5 cm below the sternal angle.  
 Jugular venous pressure   (53-54)  
 If you cannot measure the jugular venous pressure, check the appropriate response below.  
 Elevated above the angle of the mandible  1  
 Indeterminate  2 (55)

48. Lungs  Normal  1 (56)

If "Abnormal," Which of the following abnormalities are present? Answer items a through m. Present

a. Tachypnea at rest (respiratory rate > 20)  2 (57)

b. Anterior chest deformity  2 (58)

c. Posterior chest or spine deformity  2 (59)

d. Dullness to percussion  2 (60)

e. Hyperresonance  2 (61)

f. Rhonchi  2 (62)

g. Wheezes  2 (63)

h. Rales clear on coughing  2 (64)

i. Rales persistent  2 (65)

j. Friction rub - lungs  2 (66)

k. Chest wall tenderness  2 (67)

l. Other Specify: \_\_\_\_\_ (68)

NEW CARD **S** **T** **2** **B** **4** (1-5) Duplicate Columns 6 through 14 (6-14)

GRADING OF MURMURS

- Grade 1 - murmur only after the listener has 'tuned in'
- Grade 2 - faintest murmur audible immediately upon placing the stethoscope on the chest
- Grade 3 - easily heard murmur but not as loud as a Grade 4 murmur. No thrill associated
- Grade 4 - a moderately loud murmur and a significant jump from Grade 3. Thrill may be associated
- Grade 5 - murmur which can be heard with just the rim or edge of the stethoscope touching the chest but which cannot be heard with the stethoscope removed from the chest wall
- Grade 6 - murmur audible with the stethoscope removed from the chest wall

53. Murmurs . . . . .  1  2 (29)

If "Absent," go to question 54.

a. If "Present," Enter the grade number in the appropriate box.

	Systolic	Diastolic
	(Grade Number)	(Grade Number)
Apex . . . . .	<input type="checkbox"/> (30)	<input type="checkbox"/> (31)
Base . . . . .	<input type="checkbox"/> (32)	<input type="checkbox"/> (33)
Left sternal border . . . . .	<input type="checkbox"/> (34)	<input type="checkbox"/> (35)

b. Is it your impression that this represents:  
 Check all appropriate boxes:

Aortic systolic ejection murmur (including aortic stenosis)? . . . . .  1 (36)

Aortic regurgitation? . . . . .  1 (37)

Mitral stenosis? . . . . .  1 (38)

Mitral regurgitation? . . . . .  1 (39)

Other? Specify: \_\_\_\_\_ (40)

49. Heaves and thrills in amplitude or duration of the normal ventricular impulse

Absent	Present
<input type="checkbox"/> 1	<input type="checkbox"/> 2

(15)

If "Present," answer item a through f.

a. Left ventricular heave . . . . .  2 (16)

b. Right ventricular heave . . . . .  2 (17)

c. Systolic BASAL thrill . . . . .  2 (18)

d. Systolic APICAL thrill . . . . .  2 (19)

e. Systolic left sternal border thrill . . . . .  2 (20)

f. Other thrill . . . . .  2 (21)

Specify Location: \_\_\_\_\_

50. Distance from mid sternal line to apical impulse at edge of cardiac dullness in centimeters: \_\_\_\_\_ cm (22-23)

"0.0" if indeterminate.

51. Heart sounds

Single Split	Absent
<input type="checkbox"/> 1	<input type="checkbox"/> 2 <input type="checkbox"/> 3

(24)

Physiologically Split	Fixed Splitting	Paradoxically Split
<input type="checkbox"/> 1	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 5

(25)

Absent	Present
<input type="checkbox"/> 1	<input type="checkbox"/> 2

(26)

Absent	Present
<input type="checkbox"/> 1	<input type="checkbox"/> 2

(27)

52. Friction rub, pericardial . . . . .  1  2 (28)

Absent Present

FLEETING EDEMA

Grade 1 - with hard pressure get minimal penetration of depression made by a finger for only a brief time

Grade 2 - with light pressure get preservation of depression made by a finger; with hard pressure get obvious and significant depression which remains for a period of time

Grade 3 - get depression about one inch in depth with hard pressure

54. Dependent edema . . . . .  1 (41)  
 Absent

Enter the grade number . . . . .  Grade Number (42)

55. Liver size (measured at midclavicular line to nearest centimeter). Code: "99" if indeterminate. **LIVER**   (43-44)

56. Splenomegaly. Check one.

Not palpable . . . . .  1

< 1 cm below the left costal margin . . . . .  2

1 cm below the left costal margin . . . . .  3

2 cm below the left costal margin . . . . .  4

3 cm below the left costal margin . . . . .  5

> 3 cm below the left costal margin . . . . .  6 (45)

57. Abdomen . . . . . **ABSTAT**  1 (46)  
 Normal

If "Abnormal," Are the following abnormalities Present

a. Aneurysm . . . . . **ABANUR**  2 (47)

b. Bruit . . . . . **ABBRUIT**  2 (48)

c. Other Specify: **A BOTH**  2 (49)

58. Congestive heart failure - CHF is defined as any TWO of the following at the time of hospitalization or clinic visit:

- i Cardiac enlargement by X-ray (cardiothoracic ratio > 0.6) OR apex at least in the 6th intercostal space in the anterior axillary line
- ii Third or ventricular gallop
- iii Acute pulmonary edema
- iv Paroxysmal nocturnal dyspnea
- v Orthopnea

A chest X-ray is obtained if at least one of the four criteria ii, iii, iv, or v is present.

a. By these criteria is CHF present? . . . . .  1  2 (50)  
 No Yes

b. Was a chest X-ray done? . . . . .  1  2 (51)

c. By clinical impression is CHF present? . . . . .  1  2 (52)

59. Femoral bruit

a. Left . . . . . **LFM BRUIT**  1  2 (53)  
 Absent Present

b. Right . . . . . **RFM BRUIT**  1  2 (54)

60. Femoral pulses

	Normal	Diminished	Absent	Limb Missing
a. Left	<b>PULFL</b> <input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 9
b. Right	<b>PULFR</b> <input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 9

61. Dorsalis pedis pulses

a. Left **PULDL**  1  2  3  9 (57)

b. Right **PULDR**  1  2  3  9 (58)

62. Posterior tibial pulses

a. Left **PULPL**  1  2  3  9 (59)

b. Right **PULPR**  1  2  3  9 (60)

63. Radial pulses

Normal	Diminished	Absent	1 limb Missing
a. Left PULSR.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3 <input type="checkbox"/> 9
b. Right PULSR.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3 <input type="checkbox"/> 9

64. Skin . . . . . NSKIN . . . . . Present (63)

If "Abnormal," Answer items a through i:

a. Psoriasis . . . . .  2 (64)

b. Dry skin . . . . .  2 (65)

c. Scaly skin . . . . .  2 (66)

d. Eczema . . . . .  2 (67)

e. Rash . . . . .  2 (68)

f. Petechiae . . . . .  2 (69)

g. Acanthosis nigricans . . . . .  2 (70)

h. Other (except xanthoma) Specify: \_\_\_\_\_ (71)

① Xanthoma . . . . . XANTH . . . . .  2 (72)

At what age did the first xanthoma appear?  
Code "99," if unknown. . . . .   (73-74)

If xanthomata are present, complete the Xanthoma Form.

65. Continued

c. Abnormal motor . . . . . Present  2 (78)

d. Other abnormality . . . . .  2 (79)

Specify: \_\_\_\_\_

e. Is it your clinical impression that the subject has had a cerebral vascular accident? . . . . . No  1 Yes  2 (80)

If "No" to part e, specify the etiology of the abnormalities: \_\_\_\_\_

NEW CARD **S T B S** (1-5) Duplicate Columns 6 through 14 (6-14)

66. Testicles . . . . . Normal  1 Abnormal  2 Absent  3 (15)

If "Abnormal," specify: \_\_\_\_\_

67. Rectal exam . . . . . Normal  1 Present  2 (16)

If "Abnormal," answer items a through f.

a. Hemorrhoids . . . . .  2 (17)

b. Fissure . . . . .  2 (18)

c. Prostatic enlargement . . . . .  2 (19)

d. Prostatic nodule . . . . .  2 (20)

e. Other Specify: \_\_\_\_\_ (21)

f. Occult blood . . . . .  2 (22)

68. Other abnormalities on physical exam . . . . . Absent  1 Present  2 (23)

If "Present," specify briefly: \_\_\_\_\_

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73. Physician's comments concerning disposition ambiguities or medical problems.

69. Rate the patient's motivation  1  2  3  4 (24)

70. Physician's signature and code number PHYCD   (25-26)

Signature: \_\_\_\_\_

VI. DISPOSITION

71. Disposition (To be completed by Data Coordinator) 71. PREDSP2

- 1 Appointment made for Visit 3 . . . . .
- 2 Subject's disposition is pending awaiting receipt of hospital or physician record  
Subject is excluded because:
- 3 Second non-fasting or missed visit . . . . .
- 4 Systolic blood pressure > 180 mm Hg or diastolic blood pressure > 120 mm Hg . . . . .
- 5 Previous experience with cholestyramine (Questran) . . . . .
- 6 Disease likely to limit life span to less than 7 years *Specify:* \_\_\_\_\_
- 7 Angina during exercise ECG . . . . .
- 8 Unwilling or unable to continue in the study
- 9 Other *Specify:* \_\_\_\_\_

72. Initials and code number of person completing disposition. Initials: \_\_\_\_\_ Code Number   (28-29)

ARC PRE-ION TRIAL ANNUAL VISIT CLINIC RECORD (Visit 10, 16, 22 . . .)

O.M.A. 68-521044

For CPR Use Only (65-70)

PACKNO

Subject ID Number

STYCL (1-5) (6-14)

Visit Number VISIT

(15-16)

I. GENERAL

Enter one character per box, beginning with the leftmost box. Enter all letters as capitals. Mark through the boxes with a single horizontal stroke if the question does MONTH DAY YEAR

(CTN)

1. Date of Visit: (17-22) 2. Last Name: (23-34) 3. Initials: (35-36) 4. Date of Last Visit: (37-42)

To be completed by receptionist and data coordinator before physician sees the subject.

5. Number of packets-- a. (43-45) b. (46-48) c. (49-51) d. (52-54) e. (55-57) f. (58-61) g. (62-64)

6.a. When was the last time you took anything by mouth except water? See the instructions for use of fasting wheel to determine fasting time. Enter a two-digit number, using leading zero when the number is less than 10. IF SUBJECT IS FASTING AT LEAST 12 HOURS, GO TO QUESTION 7.

(6.a.)

FAST

FAST (71-72)

b. If non-fasting visit, reschedule appointment and STOP.

Annual Visit rescheduled for: (73-78)

7. What is your usual occupation? OCCUP

7. Occupation Code OCCUP

- 01 High executive, proprietor of large concern, major professional . . . . . 01
02 Business manager, proprietor of medium-sized business, lesser professional . . . . . 02
03 Administrative personnel, small independent business, minor professional . . . . . 03
04 Clerical or sales worker, technical worker, owner of little business . . . . . 04
05 Skilled manual employee. . . . . 05
06 Machine operator, semi-skilled employee . . . . . 06
07 Unskilled employee, small farmer . . . . . 07
08 Unemployed for more than two (2) years . . . . . 08
09 Student. . . . . 09
10 Other . . . . . 10
99 Unknown . . . . . 99



NEW CARD [ ] [ ] [ ] [ ] [ ] [ ] (1-5) Duplicate Columns 6 through 16 (6-16)

II. CHEST PAIN

8. Since your last visit have you had any pain or discomfort in your chest?

- 1 No . . . . .
- 2 Yes . . . . .

If "Yes," complete the Chest Pain Form; then go to question 10 of this form.

8. CHESPN

- 1 . . . . .
- 2 . . . . .

9. Since your last visit have you had any pressure or heaviness in your chest?

- 1 No . . . . .
- 2 Yes . . . . .

If "Yes," complete the Chest Pain Form; then complete this form.

- 1 . . . . .
- 2 . . . . .

III. INTERMITTENT CLAUDICATION

These questions should be asked of the subject exactly as they are written. If an answer marked with an asterisk (\*) is circled in this section, skip to question 19.

10. Do you get pain in either leg on walking?

- 1\* No . . . . .
- 2 Yes . . . . .

10. ICA

- 1\* . . . . .
- 2 . . . . .

11. Does this pain ever begin when you are standing still or sitting?

- 1 No . . . . .
- 2\* Yes . . . . .

11.

ICB

- 1 . . . . .
- 2\* . . . . .

12. In what part of the leg do you feel it?

- 1 Pain includes calf/calves . . . . .
- 2\* Pain does not include calf/calves. . . . .

12.

ICC

- 1 . . . . .
- 2\* . . . . .

13. Do you get it if you walk uphill or hurry?

- 1\* No . . . . .
- 2 Yes . . . . .
- 9 Never hurries or walks uphill . . . . .

13.

ICD

- 1\* . . . . .
- 2 . . . . .
- 9 . . . . .

14. Do you get it if you walk at an ordinary pace on the level?

- 1 No . . . . .
- 2 Yes . . . . .

14.

ICE

- 1 . . . . .
- 2 . . . . .

15. Does the pain disappear while you are walking?

- 1 No . . . . .
- 2\* Yes . . . . .

15.

ICF

- 1 . . . . .
- 2\* . . . . .

16. What do you do if you get it when you are walking?

- 1 Stop or slow down . . . . .
- 2\* Carry on . . . . .

16.

ICG

- 1 . . . . .
- 2\* . . . . .

17. What happens to it if you stand still?

- 1 Relieved . . . . .
- 2 Not relieved . . . . .

17.

ICH

- 1 . . . . .
- 2 . . . . .

18. How soon?

- 1 10 minutes or less . . . . .
- 2 More than 10 minutes . . . . .

18.

ICI

- 1 . . . . .
- 2 . . . . .

19. Does t. subject have intermittent claudication according to the Rose Questionnaire criterion? The subject has intermittent claudication if the answers to questions 17 and 18 are "Relieved" and "10 minutes or less."

1 No . . . . . 1

2 Yes . . . . . 2

9 Uncertain . . . . . 9 (28)

IC

20. Initials and code number of person completing sections II and III.

a. Initials: \_\_\_\_\_

b. Code Number   (29-30)

IV. CLINIC WORKUP RECORD

21. Weight (to nearest 0.1 kg. with outer door garments and shoes removed):

WT    (31-34)

22. Pulse at rest (record subject's heart rate for 15 seconds, not 60 seconds):

PULSE    (35-36)

23. Record subject's blood pressure. (Take using right arm after subject has been sitting quietly for at least 5 minutes).

Readings	Systolic	Diastolic
Reading 1 (Std)	1. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (37-39)	11. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (40-42)
Reading 2 (R-2)	1. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (43-45)	11. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (46-48)
Zero Reading 2	_____	ZEROA <input type="text"/> <input type="text"/> (49-50)
Net 2 (Reading 2 - Zero Reading 2)	1. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (51-53)	11. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (54-56)

NEW CARD     (1-5) Duplicate Columns 6 through 16 (6-16)

23. Continued

	Systolic	Diastolic
Reading 3 (Std)	1. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (17-19)	11. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (20-22)
Reading 4 (R-2)	1. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (23-25)	11. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (26-28)
Zero 4	ZEROB <input type="text"/> <input type="text"/> (29-30)	
Net 4 (Reading 4 - Zero Reading 4)	1. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (31-33)	11. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (34-36)

24. Initials and code number of person completing this section.

a. Initials: \_\_\_\_\_

b. Code Number   (37-38)

V. PHYSICIAN'S INTERVIEW

25. Is it your clinical impression that the subject has intermittent claudication?

Have Not Had In Past Year But Not Now

Have Not Had In Past Year But Not Now Uncertain

Yes     (39)

No

26. Answer items a through n, checking the appropriate boxes.

	Have Not Had In Past Year But Not Now	Have Not Had In Past Year But Not Now Uncertain
a. Myocardial infarction or coronary occlusion? If "uncertain," record should be obtained from his physician or the hospital for review. . . . .	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 1	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 2
b. Abnormal electrocardiogram? . . . . .	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 1	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 2
c. Diabetes? . . . . .	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 1	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 2
d. Glycosuria? . . . . .	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 1	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 2
e. Hyperthyroidism? . . . . .	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 1	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 2

MI

26. Cont'd

Have you had in the past year:	Have Not Had In Past Year	Have Had In Past Year But Not Now	Had In Past Year But Not Now	Uncertain	
f. Myxedema? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 9	(45)
g. Nephrosis? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 9	(46)
h. Pancreatitis? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 9	(47)
i. Biliary cirrhosis? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 9	(48)
j. Other liver disease? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 9	(49)
k. Gastrointestinal disease? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 9	(50)
l. Cholelithiasis or Cholecystitis? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 9	(51)
m. Gout? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 9	(52)
n. Rheumatic heart disease or other non-coronary heart disease? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 9	(53)

27. In the past year have you had surgery on your heart? **HSURG**

If "Yes," was the surgery for:

	No	Yes	
a. Coronary bypass? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	(54)
b. Valve replacement? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	(55)
c. Pacemaker? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	(56)
d. Aneurysm? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	(57)
e. Other? Specify: _____	<input type="checkbox"/> 1	<input type="checkbox"/> 2	(58)
f. Unknown? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	(59)
	<input type="checkbox"/> 1	<input type="checkbox"/> 2	(60)

28. Have you had any of the following in the past year? Use the following definitions to answer the questions.

**Abnormal Dyspnea on Exertion** - shortness of breath occurring more easily than in others your own age during physical activity.

**Orthopnea** - a condition in which there is need to sit up and elevate one's head to breathe more easily.

**Paroxysmal Nocturnal Dyspnea (PND)** - an acute attack of shortness of breath awaking patient from sleep and requiring him to sit up to ease the shortness of breath. Often associated with choking or suffocating sensation and often causes the patient to go to the nearest window for relief.

Answer items a through g, checking No Yes Uncertain the appropriate boxes.

a. Abnormal dyspnea on exertion	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9	(61)
b. Orthopnea . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9	(62)
c. Paroxysmal nocturnal dyspnea	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9	(63)
d. Palpitations . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9	(64)
e. Edema . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9	(65)
f. Nocturia (more than once a night) . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9	(66)
g. Enlarged heart . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9	(67)

**DYSPN**

**CORNEA**

31. Corneal arcus present? . . . . .  No  1  Yes  2 (19)

32. Xanthelasma present? . . . . .  1  2 (20)  
*If present, complete Xanthoma Form.*

33. Carotid pulses unequal? . . . . .  1  2 (21)

34. Carotid bruits present  
 Neither  1 Left Only  2 Right Only  3 Both  4 (22)

35. Thyroid . . . . .  1  2  3  4  9 (23)  
*If "Other," specify: \_\_\_\_\_*

Normal	Abnormal			
	Diffusely Enlarged	Single Nodule	Multiple Nodules	Other
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

36. Palpate pulse for 15 seconds.  
 a. Rate . . . . .   (24-25)

b. Rhythm . . . . .  1  2 (26)  
 Regular Irregular

37. a. Jugular venous pressure as the vertical height from the top of the jugular venous column to a level 5 cm below the sternal angle.   (27-28)

*If you cannot measure the jugular venous pressure, check the appropriate response below.*  
 b. Elevated above the angle of the mandible . . . . .  1  
 Indeterminate . . . . .  2 (29)

**VI. PHYSIC EXAMINATION**

29. a. Fundi . . . . .  Normal  Abnormal  Not Well Seen  9 (68)

*If "Normal" or "Not Well Seen," go to question 30.*  
 If abnormal, which of the following abnormalities are present? Answer items b through j, checking the appropriate boxes.

b. Widened light reflex . . . . .  Absent  Present  Uncertain  9 (69)

c. General arterial narrowing . . . . .  1  2  9 (70)

d. A-V nicking . . . . .  1  2  9 (71)

e. Focal arterial narrowing . . . . .  1  2  9 (72)

f. Hemorrhage . . . . .  1  2  9 (73)

g. Exudate . . . . .  1  2  9 (74)

h. Papilledema . . . . .  1  2  9 (75)

i. Microaneurysms . . . . .  1  2  9 (76)

j. Other Specify: \_\_\_\_\_  1  2  9 (77)

NEW CARD **SITIC** (1-5) Duplicate Columns 6 through 16 (6-16)

*Check the appropriate boxes.*  
 30. Are cataracts present?  No  Yes  Eye Missing   
 a. Left Eye . . . . .  1  2  9 (17)

HEAVE - an increase in amplitude or duration of the normal venous pulse

39. Heaves and thrills . . . . . Absent  1 Present  2 Uncertain  9 (43)  
 If "Present," answer items b through g.
- b. Left ventricular heave . . . . .  1  2  9 (44)
- c. Right ventricular heave . . . . .  1  2  9 (45)
- d. Systolic BASAL thrill . . . . .  1  2  9 (46)
- e. Systolic APICAL thrill . . . . .  1  2  9 (47)
- f. Systolic left sternal border thrill . . . . .  1  2  9 (48)
- g. Other thrill . . . . .  1  2  9 (49)

Specify location: \_\_\_\_\_

40. Distance from mid sternal line to apical impulse or edge of cardiac dullness in centimeters:   cm (50-51)  
 Code "99" if indeterminate.

41. Heart sounds
- a. S<sub>1</sub> . . . . . Single Split Absent  1  2  3 (52)  
 Physiologically Fixed Paradoxically  
 Split Split Split  
 b. S<sub>2</sub> . . . . . Single Split Absent  1  2  3  4  5 (53)  
 Absent Present  
 c. S<sub>3</sub> . . . . . Absent  1  2 (54)  
 Absent Present  
 d. S<sub>4</sub> . . . . . Absent  1  2 (55)

42. Friction rub, pericardial . . . . . Absent  1 Present  2 (56)

Normal  1 Abnormal  2

38.a. Lungs . . . . .  1  2 (30)

If "Abnormal," which of the following abnormalities are present?  
 Answer items b through m.

- b. Tachypnea at rest (respiratory rate > 20) . . . . . Absent  1 Present  2 Uncertain  9 (31)
- c. Anterior chest deformity . . . . .  1  2  9 (32)
- d. Posterior chest or spine deformity . . . . .  1  2  9 (33)
- e. Dullness to percussion . . . . .  1  2  9 (34)
- f. Hyperresonance . . . . .  1  2  9 (35)
- g. Rhonchi . . . . .  1  2  9 (36)
- h. Wheezes . . . . .  1  2  9 (37)
- i. Rales clear on coughing . . . . .  1  2  9 (38)
- j. Rales persistent . . . . .  1  2  9 (39)
- k. Friction rub - lungs . . . . .  1  2  9 (40)
- l. Chest wall tenderness . . . . .  1  2  9 (41)
- m. Other Specify: \_\_\_\_\_  1  2  9 (42)

**GRADING OF MURS**

- Grade 1 - audible only after the listener has 'tuned in'
- Grade 2 - faintest murmur audible immediately upon placing the stethoscope on the chest
- Grade 3 - easily heard murmur but not so loud as a Grade 4 murmur. No thrill associated
- Grade 4 - a moderately loud murmur and a significant jump from Grade 3. Thrill may be associated
- Grade 5 - murmur which can be heard with just the rim or edge of the stethoscope touching the chest but which cannot be heard with the stethoscope removed from the chest wall
- Grade 6 - murmur audible with the stethoscope removed from the chest wall

43. a. Murmurs . . . . . Absent Present  1  2 (57)

If "Absent," go to question 44.

If "Present," enter the grade number in the appropriate box.

	Systolic (Grade Number)	Diastolic (Grade Number)
b. Apex . . . . .	<input type="checkbox"/> 1. (58)	<input type="checkbox"/> 11. (59)
c. Base . . . . .	<input type="checkbox"/> 1. (60)	<input type="checkbox"/> 11. (61)
d. Left sternal border . . . . .	<input type="checkbox"/> 1. (62)	<input type="checkbox"/> 11. (63)

Is it your impression that this represents:

Check all appropriate boxes.

	No	Yes
e. Aortic systolic ejection murmur (including aortic stenosis)? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (64)
f. Aortic regurgitation? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (65)
g. Mitral stenosis? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (66)
h. Mitral regurgitation? . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (67)
i. Other? Specify: _____	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (68)

**PITTING EDEMA**

- Grade 1 - with hard pressure get minimal preservation of depression made by a finger for only a brief time
- Grade 2 - with light pressure get preservation of depression made by a finger; with hard pressure get obvious and significant depression which remains for a period of time
- Grade 3 - get depression about one inch in depth with hard pressure

44.a. Dependent edema . . . . . Absent Present  1  2 (69)  
Grade Number

b. If "Present," enter the grade number . . . . .  (70)

45. Liver size. Measured at midclavicular line to nearest centimeter. Code "99" if indeterminate.  cm (71-72)  
**LIVER**

46. Splenomegaly. (Check one)

- Not palpable . . . . .  1
- < 1 cm below the left costal margin . . . . .  2
- 1 cm below the left costal margin . . . . .  3
- 2 cm below the left costal margin . . . . .  4
- 3 cm below the left costal margin . . . . .  5
- > 3 cm below the left costal margin . . . . .  6 (73)

Normal Abnormal

47.a. Abdomen . . . . .  1  2 (74)  
If "Abnormal," are the following abnormalities present?

	Absent	Present	Uncertain
b. Aneurysm . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9 (75)
c. Bruit . . . . .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9 (76)
d. Other Specify: _____	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 9 (77)

NEW CARD I Y G S (1-5) Duplicate Columns 6 through 16

48. Congestive heart failure - CHF is defined as any TWO of the following at the time of hospitalization or clinic visit:

i Cardiac enlargement by X-ray (cardiothoracic ratio > 0.6) OR apex at least in the 6th intercostal space in the anterior axillary line

ii Third or ventricular gallop

iii Acute pulmonary edema

iv Paroxysmal nocturnal dyspnea

v Orthopnea

A chest X-ray is obtained if at least one of the four criteria ii, iii, iv, or v is present.

a. By these criteria is CHF present? . CHF

If so, complete Congestive Heart Failure Form.

b. Was a chest X-ray done? . . . . .

c. By clinical impression is CHF present? . . . . .

49. Femoral bruit

a. Left . . . . . Absent Present

b. Right . . . . . Absent Present

50.

Femoral pulses Normal Diminished Absent Limb Missing

a. Left PUL-F-L 1 2 3 9

b. Right PUL-F-R 1 2 3 9

51.

Dorsalis pedis pulses

a. Left PUL-D-L 1 2 3 9

b. Right PUL-D-R 1 2 3 9

52.

Posterior tibial pulses

a. Left PUL-T-L 1 2 3 9

b. Right PUL-T-R 1 2 3 9

53.

Radial pulses

a. Left PUL-R-L 1 2 3 9

b. Right PUL-R-R 1 2 3 9

54.

NSKIN

Skin . . . . . Normal Abnormal

If "Abnormal," answer items b through k.

b. Peoriasis . . . . . Absent Present Uncertain

c. Dry skin . . . . . Absent Present Uncertain

d. Scaly skin . . . . . Absent Present Uncertain

e. Eczema . . . . . Absent Present Uncertain

f. Rash . . . . . Absent Present Uncertain

g. Petechiae . . . . . Absent Present Uncertain

h. Acanthosis nigricans . . . . . Absent Present Uncertain

i. Other (except xanthoma) Specify: . . . . . Absent Present Uncertain

J. Xanthoma . XANTH. . . . . Absent Present Uncertain

If xanthomas are present, complete the Xanthoma Form and ask the following question:

k. At what age did the first xanthoma appear? . . . . . (40-41)

Code "99" if unknown.

55. a. Neuromuscular . . . . . Normal  1 Abnormal  2 (42)
- If "Abnormal," answer items b through f.*
- b. Abnormal reflexes . . . . . Absent  1 Present  2 Uncertain  9 (43)
- c. Abnormal sensory . . . . .  1  2  9 (44)
- d. Abnormal motor . . . . .  1  2  9 (45)
- e. Other abnormality . . . . .  1  2  9 (46)

*Specify:* \_\_\_\_\_

**STROKE**

No  1 Yes  2

f. Is it your clinical impression that the subject has had a stroke? . . . . .  1  2 (47)

*If "Yes" to part f, complete Stroke Form.*

*If "No" to part f, specify the etiology of the abnormalities:*

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

56. Testicles . . . . . Normal  1 Abnormal  2 Absent  3 (48)

*If "Abnormal," specify:* \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

57. a. Rectal exam . . . . . Normal  1 Abnormal  2 (49)
- If "Abnormal," answer items b through g.*
- b. Hemorrhoids . . . . . Absent  1 Present  2 Uncertain  9 (50)
- c. Fissure . . . . .  1  2  9 (51)
- d. Prostatic enlargement . . . . .  1  2  9 (52)
- e. Prostatic nodule . . . . .  1  2  9 (53)
- f. Occult blood . . . . .  1  2  9 (54)
- g. Other *Specify:* \_\_\_\_\_  1  2  9 (55)

58. Other abnormalities on physical examf. . . . . Absent  1 Present  2 (56)

*If "Present," specify briefly:* \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

59. MYOIN

Is there evidence the subject has had a myocardial infarction since his last visit?

1 No . . . . . 1

2 Yes . . . . . 2

*If "Yes," complete the Provisional Clinical Diagnosis Form and the MI Since Last Visit Forms.*



60. Write the subject's motivation . . . . . Excellent Good Fair Poor  
MOTIVTN  1  2  3  4 (58)

61. If the subject's drug adherence as calculated in question 58 is less than 90%, what are the most pressing reasons: (If subject's adherence is  $\geq$  90%, go to question 63.)

a) Dosage recommended by LRC personnel is less than 24 gms/day . . . . . DOSE24  1 (59)

b) Upper G.I. side effect . . . . . UPGI  1 (60)

c) Lower G.I. side effect . . . . . LOWGI  1 (61)

d) Sexual problem . . . . . SEXPROB  1 (62)

e) Hospitalization . . . . . IN-HOSP.  1 (63)

f) Intercurrent health problem . . . . . HLTH-PR  1 (64)

g) Ran out of medication . . . . . NO-MED.  1 (65)

h) Irregular schedule (travel, shift work) . . . . . IRRREGSCH  1 (66)

i) Forgot to take medication (weekend, evening, etc) . . . . . FORGOTMD  1 (67)

j) Domestic problem (uncooperative wife, family problem) . . . . . D. PROB  1 (68)

k) Private physician wishes patient to discontinue . . . . . DISCONT  1 (69)

61. Continued  
Information from media or other source . . . . . MEDIA  1 (70)

Specify:  
Unblinded, or reason to believe he is UNBLIND  1 (71)

Aversion to medication . . . . . AVERSION  1 (72)

Unconvinced of any benefit . . . . . UNCONVIN  1 (73)

"Tired and bored with study" . . . . . BORED  1 (74)

Other . . . . . OTHERADH  1 (75)

Specify:  
\_\_\_\_\_

62. List in order of importance the reasons checked for adherence of less than 90%. (Place the letters corresponding to the reasons as listed in question 61 in the boxes below.)

Most important reason . . . . . REASL1.  (76)

Second . . . . . REASL2.  (77)

Third . . . . . REASL3.  (78)

VII. LABORATORY DATA

66. White blood count . . . . . 66. WBC (24-28)

Grid for white blood count results

67. Hematocrit . . . . . HCT (29-30)

Grid for hematocrit results

68. Urine protein dipstick reading

- 1 Negative . . . . . 1
2 Trace . . . . . 2
3 30 mgZ or + . . . . . 3
4 100 mgZ or ++ . . . . . 4
5 300 mgZ or +++ . . . . . 5
6 1000 mgZ or ++++ . . . . . 6 (31)

Comments:

63. 1 (17) 2 (17)

- 1 No . . . . . 1 (17)
2 Yes . . . . . 2 (17)

Ambiguities or medical problems:

Blank lines for medical problems

64. a. TRDOSE

- 1 . . . . . 1
2 . . . . . 2
9 . . . . . 9 (18)

b. TDOSE gm/day (19-20)

Grid for TDOSE

- c. DFREQ 1 . . . . . 1
2 . . . . . 2
3 . . . . . 3
9 . . . . . 9 (21)

65. Code number

Grid for code number

65. Signature and code number of physician completing sections V and VI. PHVCD

a. Signature: \_\_\_\_\_