EDIC EPIDEMIOLOGY OF DIABETES INTERVENTION AND COMPLICATIONS

FORM 1 March 22, 1994
EDIC Form 002.2

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EPIDEMIOLOGY OF DIABETES INTERVENTION AND COMPLICATIONS

Annual Medical History and Physical Examination

This form is to be completed at each of the annual follow-up clinic visits. At the time of the annual visit, data will be collected on this form to update information on the status of patients. Unless otherwise indicated, questions on this form refer to the patient's experience since the last completed annual clinic visit.

Send the original of this form to the Data Coordinating Center in the monthly forms mailing, retaining a copy in the clinic's files.

A. IDENTIFYING INFORMATION

CLINIC 1. EDIC Clinic Number __ __

PATIENT 2. Patient ID Number __ __ __ __ __

INITIALS 3. Patient's Initials __ __ __

FORMDATE 4. Date of Visit __ __ __ __ __ __
Month Day Year

EDICYEAR 5. What is the EDIC follow-up year? __ __

6. Enter the date of the LAST COMPLETED annual visit. Unless otherwise specified, all questions on this form refer to the patient's experience since this date.

7. OBLSTVST __ __ __ __ __ __
Month Day Year

B. DEMOGRAPHIC AND GENERAL INFORMATION

1a) Marital status of patient: (CHECK ONLY ONE) 8. OBMARRY

Never married (1)

Married or remarried (2)

Separated (3)

Divorced (4)

Widowed (5)

b) If married, how many times? 9. OBMARNO __

c) If married, remarried, separated, divorced or widowed, when did marital status change? 10. OBMRDATE __ __ __ __
Month Year

2. OCCUPATION OF PATIENT AND HOUSEHOLD PROVIDERS:

(Check only one box for each person described. See Chapter 10 of the Manual of Operations. If the patient is married, indicate the occupation of his/her spouse. If not married and if living with parent(s), indicate occupation(s) of parent(s). If living with guardian, friend, or significant other who provides economic support to the patient's household, indicate occupation of guardian/friend/significant other. Always indicate occupation of patient. If any of these are retired or currently unemployed, check category corresponding to the type of occupation which the individual did or could do; also check the corresponding box marked "unemployed or retired.")

	11. oBPATJoB Patient	12. oBSPJoB Spouse	13. oBMoMJoB Mother	14. oBDADJoB Father	15. oBFRIJoB Guardian/Friend/ Significant Other
a) Professional, technical or similar worker	(01)	(01)	(01)	(01)	(01)
Manager, official, or proprietor	(02)	(02)	(02)	(02)	(02)
Craftsman, foreman, or similar worker	(03)	(03)	(03)	(03)	(03)
Clerical or similar worker	(04)	(04)	(04)	(04)	(04)
Sales Worker	(05)	(05)	(05)	(05)	(05)
Operative or similar worker	(06)	(06)	(06)	(06)	(06)
Service worker	(07)	(07)	(07)	(07)	(07)
Laborer	(08)	(08)	(08)	(08)	(08)
Farmer	(09)	(09)	(09)	(09)	(09)
Homemaker	(10)	(10)	(10)	(10)	(10)
Student	(11)	(11)	(11)	(11)	(11)
Other or unknown	(12)	(12)	(12)	(12)	(12)
b) Unemployed or retired	16. oBPATNoJ (1)	17. oBSPONoJ (1)	18. oBMoMNoJ (1)	19. oBDADNoJ (1)	20. oBFRINoJ (1)
c) Check here if the answer to either (a) or (b) above represents a change in the occupation category during the past year	21. oCPJoBCH (1)	22. oBSJoBCH (1)	23. oBMJoBCH (1)	24. oBDJoBCH (1)	25 oBFJoBCH (1)

3. Education of patient and household providers. (CHECK HIGHEST LEVEL COMPLETED BY EACH PERSON FOR WHOM OCCUPATION IS GIVEN IN QUESTION B.2.)

	26. OBPATED Patient	27. OBSPOED Spouse	28. OBMOMED Mother	29. OBDADED Father	30. OBFRIED Guardian/Friend/ Significant Other
Graduate School	(1)	(1)	(1)	(1)	(1)
College graduate	(2)	(2)	(2)	(2)	(2)
Some college or trade school	(3)	(3)	(3)	(3)	(3)
Secondary school graduate	(4)	(4)	(4)	(4)	(4)
Some secondary school	(5)	(5)	(5)	(5)	(5)
Elementary school	(6)	(6)	(6)	(6)	(6)
None	(7)	(7)	(7)	(7)	(7)
Unknown	(8)	(8)	(8)	(8)	(8)

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C. SMOKING STATUS

1. During the past 12 months, has the patient ever smoked cigarettes or cigarillos?

31. OBSMOKE1 No (1) Yes (2)

Proceed to Question C.5

2. Does the patient currently smoke cigarettes or cigarillos?

32. OBSMOKE2 No (1) Yes (2)

Proceed to Question C.4

3. How long has it been since the patient quit smoking cigarettes or cigarillos?

33. OBSMOKE3 months __ __

4. During the period in the past 12 months when the patient smoked cigarettes or cigarillos, on the average, how many cigarettes and cigarillos a day did he/she smoke?

34. OBSMOKE4 __ __ cigarettes or cigarillos per day

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5. During the past 12 months, has the patient ever smoked pipes or cigars?

35. OBSMOKE5 No (1) Yes (2)

Proceed to Question C.9

6. Does the patient currently smoke pipes or cigars?

36. OBSMOKE6 No (1) Yes (2)

Proceed to Question C.8

7. How long has it been since the patient quit smoking pipes or cigars?

37. OBSMOKE7 months __ __

8. During the period in the past 12 months when the patient smoked pipes or cigars, on the average, how many pipefuls or cigars per week did the patient smoke?

38. OBSMOKE8 __ __ pipefuls or cigars per week

9a) During the past 12 months has the patient lived in a residence where there were individuals who smoked? 39. OBSMOK9A

No (1) Yes (2)

b) During the past 12 months has the patient worked in an environment where co-workers smoked? 40 OBSMOK9B

No (1) Yes (2)

D. DRINKING STATUS

1. During the past 12 months, has the patient consumed an average of at least one alcoholic beverage per week? 41. OBDRINK1

No (1) Yes (2)

Proceed to Section E

2. How many 12-ounce bottles of beer (excluding "light" beer) did the patient consume during the past 7 days? (IF THE PAST 7 DAYS WERE ATYPICAL CHARACTERIZE A TYPICAL WEEK.) 42. OBDRINK2 (A)

Bottles

3. How many 12-ounce bottles of "light" beer did the patient consume during the past 7 days? (IF THE PAST 7 DAYS WERE ATYPICAL, CHARACTERIZE A TYPICAL WEEK.) 43. OBDRINK3 (B)

Bottles

4. How many 4-ounce glasses of wine did the patient consume during the past 7 days? (IF THE PAST 7 DAYS WERE ATYPICAL, CHARACTERIZE A TYPICAL WEEK.) 44. OBDRINK4 (C)

Glasses

5. How many 1 1/2-ounce shots of straight hard liquor and 1 1/2-ounce mixed drinks did the patient consume during the past 7 days? (IF THE PAST 7 DAYS WERE ATYPICAL, CHARACTERIZE A TYPICAL WEEK.) 45. OBDRINK5 (D)

6. Does the total amount of alcohol consumed by the patient in the past 7 days (OR IN A TYPICAL WEEK) exceed 560 grams? 46. OBDRINK6

No (1) Yes (2)

Use this table if necessary:

Amount X Grams

(A) _____ X 13 = _____

(B) _____ X 10 = _____

(C) _____ X 12 = _____

(D) _____ X 15 = _____

TOTAL GRAMS OF ALCOHOL _____

E. EXERCISE AND ACTIVITY

1. Which of the following best describes the patient's level of activity on the job, at school or, for homemakers, in homemaking?

Sedentary (such as office work with occasional inter-office walking, etc., e.g., secretary) 47. OBEXER1 (1)

Moderate activity (requires considerable, but not constant, lifting, walking, bending, pulling, etc.; e.g., homemaker with family and without domestic assistance, policeman, student taking physical education course) (2)

Strenuous activity (requires almost constant lifting, bending, pulling, scrubbing, etc.; e.g., furniture mover, heavy domestic work) (3)

pa45

2. During the past seven days, how many hours and minutes did the patient spend in the following types of leisure time activities? (IF THE PAST SEVEN DAYS WERE ATYPICAL, CHARACTERIZE A TYPICAL WEEK.)

Light activity (Examples: billiards, bowling, ballroom dancing, golf with power cart, non-competitive volleyball) 48. OBEXER2

Hours Minutes

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Patient ID _____

Moderate activity
(This level is marked by modest increases in heart rate and breathing. Most healthy individuals find these activities comfortable and can continue them for a few hours without undue fatigue. Examples: leisure cycling (5.5 mph), frisbee playing, horseback riding, sailing, table tennis, croquet, golf without power cart)

49. OBEXER3 52
Hours Minutes 53

Hard activity
(When exercising at this intensity, most people will likely perspire. Most untrained people could not exercise at this intensity without taking frequent rest periods. Examples: cycling (9.4 mph), half-court basketball, water skiing, downhill skiing, karate or judo, doubles tennis, roller skating, gymnastics)

54
55
56
57

50. OBEXER4
Hours Minutes

Very hard activity
(Includes strenuous sports involving a lot of movement or running. Only a well-trained individual can perform at this intensity for extended periods of time. Examples: racing cycling, football, full-court basketball, rapid marching, squash, continuous, moderate to fast swimming, rope jumping, cross country running, singles tennis, field hockey)

51. OBEXER5
Hours Minutes

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F. DIABETES MANAGEMENT

Answer Section F for all patients except where specified. When completing this section, refer to the previous day's insulin dosage only. However, if in your judgement the previous day's dosage was atypical of the patient's regimen, use another recent day that you would consider typical.

1. Specify types of insulins used by this patient:
(CHECK ALL THOSE THAT APPLY)

OBHUREG Human regular	(1) Pork Regular	(1) OBPOREG 58
OBHUSEMI Human Semilente	(1) Pork Semilente	(1) OBPOSEMI 59
OBHUNPH Human NPH	(1) Pork NPH	(1) OBPONPH 60
OBHULEN Human Lente	(1) Pork Lente	(1) OBPOLEN 61
OBHUULT Human Ultralente	(1)	
OBHU7030 Human 70/30	(1)	

Beef/pork Regular 62 (1) OBBPREG

Beef/pork Semilente 63 (1) OBBPSEMI

Beef/pork NPH 64 (1) OBBPNPH

Beef/pork Lente 65 (1) OBBPLEN

2. a) What insulin regimen is currently being used by this patient? 66. OBINSREG

insulin infusion pump (1)

three or more daily injections (2)

one or two daily injections (3)

other: (4)

(describe the regimen in Question Number 4)

3. Please summarize this patient's usual insulin regimen here. (Refer to the previous day's insulin dosage only. However, if the previous day's dosage was atypical, use the most recent day that you would consider typical. Round off to the nearest whole unit.)

If you checked "other" in item #2, skip to item #4.

Total number of units per day: ___ 67. oBTOTUNT

Number of Units Used	Breakfast	Lunch	Supper	Bedtime	Other
Regular	68. oBREGBRK	69. oBREGLUN	70. oBREGSUP	71. oBREGBED	72. oBREGOTH
Semilente	73. oBSEMBRK	74. oBSEMLUN	75. oBSEMSUP	76. oBSEMBED	77. oBSEMOTH
NPH	78. oBNPHBRK	79. oBNPHLUN	80. oBNPHSUP	81. oBNPHBED	82. oBNPHOTH
Lente	83. oBLENBRK	84. oBNLENLUN	85. oBLENSUP	86. oBLENBED	87. oBLENOTH
Ultralente	88. oBULTBRK	89. oBULTLUN	90. oBULTSUP	91. oBULTBED	92. oBULTOTH
70/30	93. oB7030BRK	94. oB7030LU	95. oB7030SU	96. oB7030BE	97. oB7030OT

NOTE:

Lunch dose = all insulin given between breakfast and lunch
Supper dose = all insulin between lunch and supper
Snack dose = all insulin between supper and bedtime snack
Record 0 when a patient gives a prescribed mealtime dose which happened to be zero on the day recorded.
Leave the space blank if no dose was prescribed for a given time of day.

If a patient is on a pump, do not record basal here.

Meal insulin only refers to bolus doses. Capture basal in number 5 following.

4. If the insulin regimen used by this patient on a typical day cannot accurately be recorded on the table (question 3) please leave the table blank and describe the regimen here:

ANSWER IF #3 IS BLANK:
I am describing the insulin regimen here: 98. oBF4 Yes (1)

_____

_____

_____

5. COMPLETE ONLY FOR PATIENTS USING AN INSULIN INFUSION PUMP

Total number of UNITS BASAL insulin infused per day: 99. oBF5A ___

Total number of different BASAL RATES used per day: 100. oBF5B ___

Has the patient had any technical problems with the insulin infusion pump? 101. oBF5C No (1) Yes (2)

If YES, specify: _____

_____

6. COMPLETE THIS QUESTION ONLY FOR PATIENTS CURRENTLY ON ONE OR TWO DAILY INJECTIONS:

a) Have you or the patient's physician prescribed a change in the insulin regimen or dose since the last visit?

No (1) Yes (2)

If YES, please indicate the reason. 102.OBF6A ___

		No	Yes
Symptomatic polyuria/polydipsia/nocturia	103.OBF6A1	(1)	(2)
Unacceptable degree of hypoglycemia	104.OBF6A2	(1)	(2)
Recurrrent ketonuria	105.OBF6A3	(1)	(2)
Hemoglobin A1c above 13.0	106.OBF6A4	(1)	(2)
Pregnancy	107.OBF6A5	(1)	(2)
Other:	108.OBF6A6	(1)	(2)

Specify _____

Patient ID _____

7. COMPLETE FOR ALL PATIENTS:

How is this patient monitoring his/her diabetes?

	No	Yes	Uncertain
Self blood glucose monitoring 109. 0BF7A	(1)	(2)	(3)
If yes, frequency per day: 110. 0BF7B			__ __
Urine glucose monitoring 111. 0BF7C	(1)	(2)	(3)
If yes, frequency per day: 112. 0BF7D			__ __

G. TRANSFER TO INACTIVE STATUS

1. Since the last visit, has the patient been on inactive status at any time? (as defined in Chapter 5 in the Manual of Operations) 113. 0BG1 — No (1) Yes (2)

   a. If yes, is the patient currently on transfer to inactive status? 114. 0BG1A — No (1) Yes (2)

      (i) If NO, enter date of return to active status: 115. 0BG1A1 — Month __ Day __ Year __

      (ii) If this is a new transfer to inactive status, enter date of EDIC Form 144, Notification of Transfer to Inactive Status: 116. 0BG1A2 — Month __ Day __ Year __

H. MODIFICATIONS OF FOLLOW-UP SCHEDULE FOR ENDPOINT ASSESSMENTS

(See Manual of Operations Chapter 13)

1. Since the last visit, has the patient been on a modified follow-up schedule at any time? 117. 0BH1 — No (1) Yes (2)

   If YES, indicate which assessments:

   _____

   _____

2. Is the patient currently on a modified follow-up schedule? 118. 0BH2 — No (1) Yes (2)

I. DIABETES CONTROL - ANSWER FOR ALL PATIENTS

1a) Has the patient completed any quarterly telephone interviews (Form 003) since the last annual visit? 119. 0BI1A — No (1) Yes (2)

b) If yes, when was the last quarterly telephone interview held? 120. 0BI1B — Month __ Day __ Year __

> All of the questions in the rest of Section I refer to the patient's experience since the date of the last quarterly telephone interview (Question I.1.b. above). If the patient had no telephone interviews, then refer to the patient's experience since the last annual visit.

2. Symptoms of hyperglycemia

a) How many times did the patient experience DKA? (As defined in Chapter 11 of the Manual of Operations) 121. 0BI2A __ __

> *If the patient has had DKA, complete the the Verification of DKA Form (Form 093)*

b) Has the patient experienced other symptoms of hyperglycemia? 122. 0BI2B — No (1) Yes (2)

If YES, specify: _____

_____

3. How many days has the patient had moderate or large ketonuria? (If none, enter 00 and proceed to Question I.4) 123. 0BI3 __ __

If unknown, check here New 124. 0BI3A (1)

How many of these were . . .

a) explained by change in routine? 125. 0BI3A __ __

b) due to illness? 126. 0BI3B __ __

c) due to medical equipment failure? 127. 0BI3C __ __

d) spontaneous or unexplained? 128. 0BI3D __ __

P13

Patient ID _____

4. Symptoms of hypoglycemia <u>since last visit or phone contact</u>

a) Number of hospitalizations for hypoglycemia. (Hospitalization implies overnight admission to the hospital; an emergency ward visit that did not result in hospitalization does not apply.) 129.0BI4A ___

If the patient has been hospitalized for hypoglycemia, complete the Notification and Further Details of Hypoglycemic Event (Form 042) if not previously completed for this hospitalization.

b) How many times did the patient experience hypoglycemia of such severity that the patient . . .

(i) lost consciousness without seizure 130. 0BI4B1 ___

(ii) lost consciousness with seizure 131. 0BI4B2 ___

c) How many times did the patient experience hypoglycemia of such severity . . .

(i) that the patient required professional medical assistance, including placement of an IV or an intravenous injection of glucose? 132.0BI4C1 ___

(ii) as to require the assistance of another person, such as the administration of glucagon, but did not require any of the assistance described in (i)? 133.0BI4C2 ___

(iii) as to require the assistance of another person but did not require any of the help described in (i) or (ii)? 134.0BI4C3 ___

d) Complete only if severe hypoglycemia which the patient could not treat himself/herself has occurred:

(i) How many times has the patient received glucagon? 135.0BI4D1 ___

(ii) How many times has the patient received IV glucose to treat hypoglycemia? 136.0BI4D2 ___

(iii) Did any episodes result in injury to the patient or others? 137.0BI4D3 No (1) Yes (2)

If YES, specify: _____

_____

If the patient has experienced severe hypoglycemia which he/she could not treat himself/herself, please complete Notification and Further Details of Hypoglycemic Event (Form 042) for any episodes for which this has not previously been done.

e) Since the last annual visit, has the patient had recurrent (more than one) hypoglycemic episodes resulting in cerebral impairment (e.g., coma, severe confusion, seizure, loss of consciousness) of such severity that he/she was unable to help himself/herself before the development of warning symptoms of hypoglycemia (e.g., adrenergic symptoms or sweating)? No (1) Yes (2)

f) Since the last annual visit, has the patient had recurrent (more than one) hypoglycemic episodes resulting in cerebral impairment (e.g., confusion, lethargy, bizarre behavior, etc.) that the patient recognized and was able to treat himself/herself, but occurred before the development of warning symptoms of hypoglycemia (.e.g, adrenergic symptoms or sweating)? 138.0BI4E No (1) Yes (2)

139.0BI4F

g) How many times in the past seven days did the patient experience hypoglycemia which was mild enough for the patient to treat himself/herself? 140.0BI4G ___

h) If the patient has experienced hypoglycemia in the past seven days which was mild enough for the patient to treat himself/herself, answer Items (i) through (iii) below.

Otherwise, skip to Section J.

(i) Did mild hypoglycemia occur: 141.0BI4H1

While the patient was awake (1)

While the patient was asleep (2)

Both (3)

(ii) What was the usual reason for the mild hypoglycemia? (CHECK ALL THAT APPLY)

Missed meal or snack 142.0BI4H2A (1)

Decreased food intake at meal or snack 143.0BI4H2B (1)

Increased exercise level 144.0BI4H2C (1)

Too much insulin taken 145.0BI4H2D (1)

Lack of early warning signs of low blood glucose 146.0BI4H2E (1)

Other; specify: _____ 147.0BI4H2F (1)

_____

Unexplained 148.0BI4H2G (1)

(iii) What symptoms does the patient have with mild hypoglycemia? (CHECK ALL THAT APPLY)

Adrenergic warning symptoms 149.0BI4H3A (1)

Diaphoresis (sweating) 150.0BI4H3B (1)

Altered mental status 151.0BI4H3C (1)

Other 152.0BI4H3D (1)

None 153.0BI4H3E (1)

J. VERIFICATION OF EVENTS

1. CARDIOVASCULAR EVENTS

Since the last evaluation, has the patient suffered any of the following or experienced any signs or symptoms consistent with the following? (As defined in Chapter 11 of the Manual of Operations)

		No	Yes
a) Myocardial infarction	154.0BJ1A	(1)	(2)
b) Angina Pectoris	155.0BJ1B	(1)	(2)
c) Coronary artery disease	156.0BJ1C	(1)	(2)
d) Arrhythmia	157.0BJ1D	(1)	(2)
e) Chest pain or chest discomfort	158.0BJ1E	(1)	(2)

If YES to any of above, then complete EDIC Form 090, Verification of Cardiovascular Event.

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2. CEREBROVASCULAR EVENTS

Since the last evaluation, has the patient suffered any of the following or experienced any signs or symptoms consistent with the following? (As defined in Chapter 11 of the Manual of Operations)

		No	Yes
a) Cerebrovascular accident (CVA)	159 oBJ2A	(1)	(2)
b) Transient ischemic attack (TIA)	160 oBJ2B	(1)	(2)

If YES to any of above, then complete EDIC Form 091, Verification of Cerebrovascular Event.

3. PERIPHERAL VASCULAR EVENTS

Since the last evaluation, has the patient suffered any of the following or experienced any signs or symptoms consistent with the following? (As defined in Chapter 11 of the Manual of Operations)

		No	Yes
a) Peripheral ischemia (claudication)	161 oBJ3A	(1)	(2)
b) Amputation (surgical or traumatic)	162 oBJ3B	(1)	(2)
c) Lower extremity ulcer	163 oBJ3C	(1)	(2)
d) Other arterial events (specify below)		(1)	(2)

specify: _____ 164 oBJ3D

If YES to any of above, then complete EDIC Form 092, Verification of Peripheral Vascular Event.

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4. PSYCHIATRIC EVENTS

Since the last evaluation, has the patient experienced any of the following?

		No	Yes
a) Nervousness or anxiety	oBJ4A 165	(1)	(2)
b) Unreasonable fears	166 oBJ4B	(1)	(2)
c) Eating disturbance	167 oBJ4C	(1)	(2)
d) Affective disorder	168 oBJ4D	(1)	(2)
e) Suicide attempt	169 oBJ4E	(1)	(2)
f) Criminal conduct	170 oBJ4F	(1)	(2)
g) Psychiatric hospitalization or outpatient psychiatric treatment which included the use of tranquilizers such as phenothiazines	171 oBJ4G	(1)	(2)
h) Other significant psychiatric condition?	172 oBJ4H	(1)	(2)

If YES to any of the above, then complete EDIC Form 094, Verification of Psychiatric Event.

5. MAJOR ACCIDENTS

New

Since the last evaulation, has the patient experienced any major accidents (e.g., auto accident, sports accident, on-the-job accident) oBJ5 173

No	Yes
(1)	(2)

If YES to above, then complete EDIC Form 095, Verification of Major Accident.

K. **RENAL COMPLICATIONS**

Prior to the development of nephrotic-range proteinuria, few if any clinical signs or symptoms of progressive glomerulosclerosis are manifested.

Since the last evaluation, has the patient experienced any of the following?

		No	Yes
New 1) Cystitis	174 oBK1	(1)	(2)
New 2) Pyelonephritis	175 oBK2	(1)	(2)
New 3) Uncontrollable hypertension	176 oBK3	(1)	(2)
4) Edema (of renal etiology only)	177 oBK4	(1)	(2)
New 5) Dialysis	178 oBK5	(1)	(2)
New 6) Renal Transplantation	179 oBK6	(1)	(2)
7) Other, specify: _____	180 oBK7	(1)	(2)

L. OPHTHALMIC COMPLICATIONS

Refer to the patient's experience since the last completed annual visit when answering Section L.

	Right Eye No	Right Eye Yes	Left Eye No	Left Eye Yes
003-p15 1. Has the patient had blurred or reduced vision?	181 OBL1AR (1)	(2)	(1)	(2) OBL1AL 182
If YES, explain: _____				
003p=15 2. Has the patient experienced floaters or flashing lights?	183 OBL2AR (1)	(2)	(1)	(2) OBL2AL 184
FORM 27 p=1 3a,b) Is the eye enucleated?	185 OBL3AR (1)	(2)	(1)	(2) OBL3BL 186
IF YES FOR EITHER EYE, ANSWER THE FOLLOWING ITEM FOR THE APPROPRIATE EYE(S). IF NO FOR BOTH EYES, PROCEED TO QUESTION 4.				
c,d) Has enucleation occurred since the last completed Annual Clinic Visit?	187 OBL3CR (1)	(2)	(1)	(2) OBL3DL 188
IF YES FOR EITHER EYE, COMPLETE THE REMAINDER OF SECTION L FOR THE TIME SINCE THE LAST VISIT AND BEFORE ENUCLEATION. IF NO, LEAVE BLANK QUESTIONS 4-9 FOR THAT EYE, I.E., EYE ENUCLEATED BEFORE LAST VISIT.				
4a,b) Has the patient had any ocular surgical procedure(s) since the last completed Annual Clinic Visit? FORM 27 - page 2	Right Eye No	Right Eye Yes	Left Eye No	Left Eye Yes
FORM 27 p=2	189 OBL4AR (1)	(2)	(1)	(2) OBL4BL 190
IF YES, IDENTIFY SURGICAL PROCEDURES IN THE FOLLOWING ITEMS FOR APPROPRIATE EYE(S). IF NO FOR BOTH EYES, PROCEED TO QUESTION 5.				
c,d) External plastic surgery	191 OBL4CR (1)	(2)	(1)	(2) OBL4DL 192
e,f) Extraocular muscle surgery	193 OBL4ER (1)	(2)	(1)	(2) OBL4FL 194
√g,h) Corneal transplant	195 OBL4GR (1)	(2)	(1)	(2) OBL4HL 196
i,j) Other corneal surgery	197 OBL4IR (1)	(2)	(1)	(2) OBL4JL 198
k,l) Filtering surgery, cyclocryotherapy, or other operative procedure to lower intraocular pressure	199 OBL4KR (1)	(2)	(1)	(2) OBL4LL 200
m,n) Cataract extraction	201 OBL4MR (1)	(2)	(1)	(2) OBL4NL 202
o,p) Vitrectomy	203 OBL4OR (1)	(2)	(1)	(2) OBL4PL 204
q,r) Retinal detachment surgery	205 OBL4QR (1)	(2)	(1)	(2) OBL4RL 206

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		Right Eye No	Right Eye Yes	Left Eye No	Left Eye Yes
s,t)	Other surgery (specify below) [207 OBL4SR]	(1)	(2)	(1)	(2) [OBL4TL 208]

R - ____________________

L - ____________________

		Right Eye No	Right Eye Yes	Left Eye No	Left Eye Yes
5a,b)	Has the patient had any photocoagulation since the last completed Annual Clinic Visit? [209 OBL5AR]	(1)	(2)	(1)	(2) [OBL5BL 210]

If both eyes are NO, go to Question 6

(new)

		Right Eye No	Right Eye Yes	Left Eye No	Left Eye Yes
c,d)	Has the patient had scatter treatment(given for retinopathy)? [211 OBL5CR]	(1)	(2)	(1)	(2) [OBL5DL 212]
e,f)	Has the patient had focal treatment (given for macular edema)? [213 OBL5ER]	(1)	(2)	(1)	(2) [OBL5FL 214]
g,h)	Has the patient had other treatment (for non-diabetic retinopathy)? [OBL5GR 215]	(1)	(2)	(1)	(2) [OBL5HL 216]
6a,b)	Has the patient been diagnosed as having glaucoma in either eye since the last completed Annual Clinic Visit? [217 OBL6AR]	(1)	(2)	(1)	(2) [OBL6BL 218]
7a,b)	Has the patient used any ocular medications which require a prescription since the last completed Annual Clinic Visit? [219 OBL7AR]	(1)	(2)	(1)	(2) [OBL7BL 220]

IF YES, COMPLETE EDIC FORM 004, MEDICATION FORM IF NO, PROCEED TO QUESTION 8.

		Right Eye No	Right Eye Yes	Left Eye No	Left Eye Yes
8a,b)	Has the patient received any other ocular treatments administered by a physician since the last completed Annual Clinic Visit? [OBL8AR 221]	(1)	(2)	(1)	(2) [OBL8BL 222]

IF YES, INDICATE IN THE FOLLOWING ITEMS ALL SUCH TREATMENTS. IF NO, PROCEED TO QUESTION 9.

		No	Yes	No	Yes
c,d)	Retrobulbar steroids [223 OBL8CR]	(1)	(2)	(1)	(2) [OBL8DL 224]
e,f)	Retrobulbar alcohol [225 OBL8ER]	(1)	(2)	(1)	(2) [OBL8FL 226]
g,h)	Other (specify below) [227 OBL8GR]	(1)	(2)	(1)	(2) [OBL8HL 228]

____

____

	Right Eye No	Right Eye Yes	Left Eye No	Left Eye Yes
the patient describe symptoms which you believe to be caused itreous hemorrhage since the last completed Annual Clinic Visit? [229 OBL9AR]	(1)	(2)	(1)	(2) [OBL9BL 230]
the patient had any other eye problems? [231 OBL10AR]	(1)	(2)	(1)	(2) [OBL10BL 232]

ES, specify: ____________________

the patient be referred to an ophthalmologist for any physical itions noticed during this exam? No (1) Yes (2) [OBL11 233]

p=15

M. NEUROLOGIC COMPLICATIONS

Has the patient had any of the following since the last completed annual visit?

		No	Yes
1. Paresthesias (pain or numbness) in hands or feet	234 OBM1	(1)	(2)
(i) If the patient has pain, is he/she taking medication for the pain?	OBM11 235	(1)	(2)
2. Unexplained muscle weakness	236 OBM2	(1)	(2)
3. Vomiting or bloating after meals	237 OBM3	(1)	(2)
4. Bouts of persistent or recurrent diarrhea	238 OBM4	(1)	(2)
5. Urinary retention	239 OBM5	(1)	(2)
6. Dizziness or lightheadedness (not associated with hypoglycemia)	240 OBM6	(1)	(2)
7. Fainting (not associated with hypoglycemia)	241 OBM7	(1)	(2)
8. Seizure (not due to hypoglycemia)	242 OBM8	(1)	(2)

If YES, complete EDIC Form 004, Medication Form

If the patient is male answer M.9; if female go to M.10.

		No	Yes
9. Impotence	243 OBM9	(1)	(2)
10. Has the patient developed symptoms compatible with a focal neuropathy (described as sudden onset, asymmetrical and self-limited, i.e., cranial mononeuropathy, proximal motor neuropathy, truncal neuropathy)?	244 OBM10	(1)	(2)
11. Other neurologic problem ?	245 OBM11	(1)	(2)

If YES, specify: _____

_____

12. Will the patient be referred to a neurologist for any physical conditions noticed during this exam?	246 OBM12	(1)	(2)

p=16

N. INFECTIONS, MAJOR SURGERY, MINOR OUTPATIENT SURGERY, ENDOCRINOLOGICAL, OR SKIN COMPLICATIONS

1. INFECTIONS

Has the patient had any of the following since the last evaluation? (As defined in Chapter 11 of the Manual of Operations)

		No	Yes
a) Urinary tract infection (e.g., cystitis, pyelonephritis, perinephric abscess)	247 OBN1A	(1)	(2)
b) Upper or lower respiratory tract infection	248 OBN1B	(1)	(2)
c) Gastroenteritis with fever	249 OBN1C	(1)	(2)
d) Cutaneous (non-infusion site) or mucocutaneous (e.g., Candida vulvo-vaginitis, furunculosis, dental abscess) infection	250 OBN1D	(1)	(2)

If YES, specify: _____

_____

e) Post-operative or deep wound infection	251 OBN1E	(1)	(2)
f) Gangrene	252 OBN1F	(1)	(2)
g) Other infections not specifically defined in the Manual of Operations (i.e., mononucleosis, epididymitis, measles, chicken pox)	253 OBN1G	(1)	(2)

If YES, specify: _____

_____

ANSWER THE FOLLOWING ONLY FOR PATIENTS WHO USE AN INDWELLING NEEDLE OR CATHETER FOR INSULIN ADMINISTRATION.

h) Has the patient had infection at the insertion site (e.g., >1.5 cm erythema and purulence)?	254 OBN1H	(1)	(2)

New

2. Since the last evaluation, has the patient had MAJOR SURGERY 255 OBN2 — No (1) Yes (2)

If YES, specify: _____

_____

P=16 3. Since the last evaluation, has the patient had MINOR OUTPATIENT SURGERY OR INCIDENTAL TRAUMA (e.g., simple fracture, uncomplicated laceration). 256 OBN3 — No (1) Yes (2)

If YES, specify: _____

_____

4. Since the last evaluation, has the patient had an ENDOCRINE EVENT (e.g., hypothroidism, Grave's disease, Cushing's disease) 257 OBN4 — No (1) Yes (2)

If YES, specify: _____

_____

5. SKIN

a) Since the last evaluation, has the patient experienced any of the following? — No Yes

Eruptive xanthoma	258 OBN5A1	(1)	(2)
Xanthelasma	259 OBN5A2	(1)	(2)
Necrobiosis	260 OBN5A3	(1)	(2)
Shin spot (diabetic dermopathy)	OBN5A4	(1)	(2)

b) Other significant skin condition? 261 (1) (2)

If YES, specify: 262 OBN5B _____

_____

If YES to any of the items in N.1 through N.5 and the patient was prescribed medications for this condition, then complete EDIC Form 004, Medication Form.

P=13

O. FEMALE/REPRODUCTIVE

(SKIP TO SECTION P IF THE PATIENT IS MALE)

Refer to the patient's experience since the last annual visit when answering Section O.

1a) Has the patient had any vaginal itching or discharge 263 OB01A — No (1) Yes (2)

Proceed to Question O.2.A

b) Was the patient treated for this? 264 OB01B — No (1) Yes (2)

c) Specify treatment: _____

_____

2a) Does the patient menstruate? OB02A — No (1) Yes (2)

Proceed to Question O.3 265

b) Enter date of start of last menstrual period:

266 OB02B

Month Day Year

c) Was the last menstrual period more than five weeks ago? 267 OB02C — No (1) Yes (2)

Proceed to Question O.3

d) Was a pregnancy test performed? 268 OB02D — No (1) Yes (2)

If no, why not? _____

_____

e) Is the patient currently pregnant? 269 OB02E — No (1) Yes (2)

3. Has the patient completed or terminated a pregnancy since the last annual visit? — No (1) Yes (2)

270 OB03

If YES, complete EDIC Form 005, Details of Pregnancy and Outcome.

New

P=17 4. Since the last annual visit, has the patient had any of the following?

		No	Yes
a) Nodules in breast	271 OB04A	(1)	(2)
b) Breast cancer	272 OB04B	(1)	(2)
c) Breast discharge	273 OB04C	(1)	(2)
d) Irregular menses	274 OB04D	(1)	(2)
e) Dysmenorrhea	275 OB04E	(1)	(2)
f) Vaginitis	276 OB04F	(1)	(2)

5. Other significant gynecologic condition? 277 OB05 (1) (2)

If YES, specify: _____

_____

P=18 6. Has the patient ever used oral contraceptives? 278 OB06 No (1) Yes (2)

a) Is the patient currently using oral contraceptives? 279 OB06A (1) (2)

If YES, complete EDIC Form 004 Medication Form.

7. Does the patient use any other form of birth control? 280 OB07 (1) (2)

If YES, specify: _____

_____

8. Since the last annual visit, has the patient experienced any difficulties with sexual function? 281 OB08 (1) (2)

P. MEDICATIONS

Refer to the patient's experience since the last annual visit when answering Section P.

P=19 1. Has the patient used or is he/she currently using any prescription drug on a regular basis other than insulin? 282 OBP1 No (1) Yes (2)

If Yes, complete EDIC Form 004, Medication Form _____

2. Has the patient used any over-the-counter drugs? 283 OBP2 No (1) Yes (2)

If Yes, complete EDIC Form 004, Medication Form _____

3. Does the patient use vitamin supplements on a regular basis? 284 OBP3 No (1) Yes (2)

If Yes, complete EDIC Form 004, Medication Form _____

Q. PHYSICAL EXAMINATION (A COMPLETE PHYSICAL EXAMINATION SHOULD BE PERFORMED)

F114.3 P=1 1. Weight (kg)

a. First measurement: 285 OBQ1A ___ ___ ___.___

b. Second measurement: 286 OBQ1B ___ ___ ___.___

Record (c) and (d) only if first 2 measurements are not within 0.2 kilograms (200 gm).

c. Third measurement: OBQ1C 287 ___ ___ ___.___

d. Fourth measurement: OBQ1D 288 ___ ___ ___.___

F003 P=20 2. What is the patient's desired weight (kg)? OBQ2 289 ___ ___ ___.___

F114 P=2 3. Height (cm)

a. First measurement: OBQ3A 290 ___ ___ ___.___

b. Second measurement: OBQ3B 291 ___ ___ ___.___

Record (c) and (d) only if first 2 measurements are not within 1.0 cm (10.0 mm)

c. Third measurement: OBQ3C 292 ___ ___ ___.___

d. Fourth measurement: OBQ3D 293 ___ ___ ___.___

Patient ID _____

1143 p=1

4. Waist Circumference (cm) -- Natural

		NO	YES
Is lipohypertropy present? 294. OBQ41		(1)	(2)
Is lipoatrophy present? 295. OBQ42		(1)	(2)
a. First measurement:	OBQ4A ___ ___ ___.___		
b. Second measurement: 296.	OBQ4B ___ ___ ___.___		

Record (c) and (d) only if first 2 measurements are not within 0.5 cm.

c. Third measurement:	OBQ4C 298 ___ ___ ___.___
d. Fourth measurement:	OBQ4D 299 ___ ___.___

5. Iliac Waist Circumference (cm)

		NO	YES
Is lipohypertropy present? 300	OBQ51	(1)	(2)
Is lipoatrophy present? 301	OBQ52	(1)	(2)
a. First measurement:	OBQ5A 302 ___ ___.___		
b. Second measurement:	OBQ5B 303 ___ ___.___		

Record (c) and (d) only if first 2 measurements are not within 0.5 cm.

c. Third measurement:	OBQ5C 304 ___ ___.___
d. Fourth measurement:	OBQ5D 305 ___ ___.___

6. Hip Circumference (cm)

		NO	YES
Is lipohypertropy present? 306	OBQ61	(1)	(2)
Is lipoatrophy present? 307.	OBQ62	(1)	(2)
a. First measurement: /	OBQ6A 308 ___ ___.___		
b. Second measurement:	OBQ6B 309 ___ ___.___		

Record (c) and (d) only if first 2 measurements are not within 0.5 cm.

c. Third measurement:	OBQ6C 310 ___ ___.___
d. Fourth measurement:	OBQ6D 311 ___ ___.___

p=20

7. Pulse (bpm) 312 OBPULSE ___ ___ ___

8. Sitting blood pressure (RIGHT ARM)

a) Systolic (mm Hg) 313 OBSYSTR ___ ___ ___

b) Diastolic (mm Hg) 314 OBDIASR ___ ___ ___

c) Has hypertension been previously documented by the DCCT/EDIC? OBHYPDOC

No	Yes
(1)	(2)

SKIP TO QUESTION Q.9 | 315 _____

d) Is the current systolic or diastolic blood pressure so high as to indicate hypertension as defined in Chapter 11 of the Manual of Operations i.e. ≥ 140 systolic or ≥ 90 diastolic?

No	Yes
(1)	(2)

9. Doppler Arm/Leg Systolic Blood Pressure Results (collected supine, while resting) 316 OBHIBLP

	Right	Left
a) Brachial	317 OBQ9AR ___ ___ ___	OBQ9AL 318 ___ ___ ___
b) Dorsalis pedis	319 OBQ9BR ___ ___ ___	320 OBQ9BL ___ ___ ___
c) Posterior tibial	321 OBQ9CR ___ ___ ___	322 OBQ9CL ___ ___ ___

10. General Examination

a) Examine the patient for abnormalities of the following sites.

		Normal	Abnormal
Ears, Nose and Throat	323 OBENT	(1)	(2)
Thyroid	324 OBTHYRD	(1)	(2)
Lungs	325 OBLUNGS	(1)	(2)
Breasts	326 OBBREAST	(1)	(2)
Abdomen	327 OBABDOM	(1)	(2)

		Absent	Present
i) Hepatomegaly	328 OBHEPATO	(1)	(2)

ii) If present, how large (span)? OBSPAN ___ ___ cm 329

		Normal	Abnormal	Not Done
Lymphatic system	330. OBLYMPH	(1)	(2)	
Rectum	331. OBRECTUM	(1)	(2)	(3)
Pelvis	332. OBPELVIS	(1)	(2)	(3)
Genitalia	333. OBGENIT	(1)	(2)	(3)

11. Cardiovascular Examination

a) Examine the patient for the following cardiac abnormalities.

		Regular	Irregular
Rhythm	334. OBRHYTHM	(1)	(2)

		Normal	Abnormal
Venous Pressure	335. OBVENPRS	(1)	(2)

		Absent	Present
Cardiomegaly	336. OBMEGALY	(1)	(2)
S3 Gallop	337. OBS3GALP	(1)	(2)
S4 Gallop	338. OBS4GALP	(1)	(2)
Systolic Ejection Murmur	339. OBSMURMR	(1)	(2)
Diastolic Murmur	340. OBDMURMR	(1)	(2)
Other Murmur:	341. OBOMURMR	(1)	(2)

If PRESENT, specify: _____

Rub	342. OBRUB	(1)	(2)
Other Cardiac Abnormality:		(1)	(2)

If PRESENT, specify: 343. OBCARDAB _____

12. Peripheral Pulse Examination

a) Indicate the grade of the peripheral pulses using the following scale for the right and left pulse.

		RIGHT SIDE			LEFT SIDE		
		Normal	Diminished	Absent	Normal	Diminished	Absent
OBP12A1R	344 Carotid	(1)	(2)	(3)	(1)	(2)	(3)
OBP12A2R	346 Brachial	(1)	(2)	(3)	(1)	(2)	(3)
OBP12A3R	348 Radial	(1)	(2)	(3)	(1)	(2)	(3)
OBP12A4R	350 Femoral	(1)	(2)	(3)	(1)	(2)	(3)
OBP12A5R	352 Popliteal	(1)	(2)	(3)	(1)	(2)	(3)
OBP12A6R	354 Posterior Tibial	(1)	(2)	(3)	(1)	(2)	(3)
	Dorsalis Pedis	(1)	(2)	(3)	(1)	(2)	(3)

OBP12A1L 345 OBP12A2L 347 OBP12A3L 349 OBP12A4L 351 OBP12A5L 353 OBP12A6L 355 OBP12A7R 356 OBP12A7L 357

b) Indicate the presence or absence of bruits.

		RIGHT		LEFT	
		Absent	Present	Absent	Present
OBP12B1R	358 Femoral	(1)	(2)	(1)	(2)
OBP12B2R	360 Carotid	(1)	(2)	(1)	(2)
OBP12B3R	362 Other:	(1)	(2)	(1)	(2)

OBP12B1L 359 OBP12B2L 361 OBP12B3L 363

If PRESENT, specify: _____

13. Extremities and Skin Examinations

		RIGHT SIDE Absent	RIGHT SIDE Present	LEFT SIDE Absent	LEFT SIDE Present
oBP13AR 364	Ulceration	(1)	(2)	oBP13AL 365 (1)	(2)
oBP13BR 366	Skin discoloration	(1)	(2)	oBP13BL 367 (1)	(2)
oBP13CR 368	Gangrene	(1)	(2)	oBP13CL 369 (1)	(2)
oBP13DR 370	Charcot joint	(1)	(2)	oBP13DL 371 (1)	(2)
oBP13ER 372	Deformity	(1)	(2)	oBP13EL 373 (1)	(2)

If PRESENT, specify: _____

14. Injection sites (INCLUDING CATHETER SITES):

		Absent	Present
a) Lipoatrophy	374. oBP14A	(1)	(2)
b) Lipohypertrophy	375. oBP14B	(1)	(2)
c) Inflammation	376. oBP14C	(1)	(2)

15. Feet:

		Absent	Present
a) Ulcers	377. oBP15A	(1)	(2)
b) Infection	378. oBP15B	(1)	(2)
c) Abnormal toenails	379. oBP15C	(1)	(2)
d) Other _____	380. oBP15D	(1)	(2)

16. Were any other abnormalities noted on physical examination? 381. oBP16 No (1) Yes (2)

Specify: _____

Name of persons responsible for information on this form:

	Certification Number	
382.	CERTIF1 ___ ___ - ___ ___	(Study Coordinator, Nurse)
(new) 383.	CERTIF2 ___ ___ - ___ ___	(Principal Investigator, Physician)

384. WEEKNO