EPIDEMIOLOGY OF DIABETES INTERVENTIONS 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

1. EDIC Clinic Number __ __

2. Patient ID Number __ __ __ __ __

3. Patient's Initials __ __ __

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

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.

   __ __ __ __ __ __
   Month Day Year

B. DEMOGRAPHIC AND GENERAL INFORMATION

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

- Never married (1)
- Married or remarried (2)
- Separated (3)
- Divorced (4)
- Widowed (5)

b) If married, how many times? ___

c) If married, remarried, separated, divorced or widowed, when did marital status change? __ __ __ __
   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.")

	Patient	Spouse	Mother	Father	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	(1)	(1)	(1)	(1)	(1)

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

	Patient	Spouse	Mother	Father	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)

C. SMOKING STATUS

1. During the past 12 months, has the patient ever smoked cigarettes or cigarillos? No (1) Yes (2)

   → Proceed to Question C.5

2. Does the patient currently smoke cigarettes or cigarillos? No (1) Yes (2)

   → Proceed to Question C.4

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

5. During the past 12 months, has the patient ever smoked pipes or cigars? No (1) Yes (2)

   → Proceed to Question C.9

6. Does the patient currently smoke pipes or cigars? No (1) Yes (2)

   → Proceed to Question C.8

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

9a) During the past 12 months has the patient lived in a residence where there were individuals who smoked? No (1) Yes (2)

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

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)

Hours Minutes

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, golf without power cart)

Hours Minutes

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)

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)

Hours Minutes

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)

Human regular	(1)	Pork Regular	(1)
Human NPH	(1)	Pork NPH	(1)
Human Lente	(1)	Pork Lente	(1)
Human Ultralente	(1)		
Human 70/30	(1)		
HumaLog	(1)		
Beef/pork Regular	(1)		
Beef/pork NPH	(1)		
Beef/pork Lente	(1)		

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

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: __ __ __

Number of Units Used	Breakfast	Lunch	Supper	Bedtime	Other
Regular	__ __	__ __	__ __	__ __	__ __
NPH	__ __	__ __	__ __	__ __	__ __
Lente	__ __	__ __	__ __	__ __	__ __
Ultralente	__ __	__ __	__ __	__ __	__ __
70/30	__ __	__ __	__ __	__ __	__ __
HumaLog	__ __	__ __	__ __	__ __	__ __

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		wwen 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: Yes
I am describing the insulin regimen here: (1)

_____

_____

_____

Total Number of Units per day: __ __ __

5. COMPLETE ONLY FOR PATIENTS USING AN INSULIN INFUSION PUMP

Total number of different BASAL RATES used per day: __ __

Total number of UNITS BASAL insulin infused per day: __ __

	No	Yes
Has the patient had any technical problems with the insulin infusion pump?	(1)	(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	Yes	Uncertain
	(1)	(2)	(3)

If YES, please indicate the reason.

Symptomatic polyuria/polydipsia/ nocturia	(1)	(2)	(3)
Unacceptable degree of hypoglycemia	(1)	(2)	(3)
Recurrrent ketonuria	(1)	(2)	(3)
Hemoglobin A1c above 13.0	(1)	(2)	(3)
Pregnancy	(1)	(2)	(3)
Other:	(1)	(2)	(3)

Specify _____

7. COMPLETE FOR ALL PATIENTS:

a) How is this patient monitoring his/her diabetes?

	No	Yes	Uncertain
Self blood glucose monitoring	(1)	(2)	(3)
If yes, frequency per day:			__ __
Urine glucose monitoring	(1)	(2)	(3)
If yes, frequency per day:			__ __

(IF FREQUENCY OF MONITORING IS LESS THAN ONCE PER DAY, PLEASE CODE 00)

b) Does the patient adjust usual insulin regimen?	(1)	(2)

If yes, is the insulin adjustment based on any of the following? (Check all that apply):

Glucose monitoring	(1)
Food intake	(2)
Exercise	(3)
Hypoglycemia	(4)
Prescribed algorithm (i.e., target BS at certain time of day)	(5)
Other (please describe): _____	(6)

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) — No (1) Yes (2)

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

      (i) If NO, enter date of return to active status: __ __ __ __ __ __ (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: __ __ __ __ __ __ (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? — No (1) Yes (2)

   If YES, indicate which assessments:

   _____

   _____

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

I. DIABETES CONTROL - ANSWER FOR ALL PATIENTS

1. Symptoms of hyperglycemia

   a) How many times did the patient experience DKA during the past three months? __ __

   (As defined in Chapter 11 of the Manual of Operations)

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

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

   If YES, specify symptoms and frequency:

   _____

   _____

2. How many days has the patient had moderate or large ketonuria during the past three months? __ __

   (If none, enter 00 and proceed to Question I.3)

   If unknown, check here (1)

   How many of these were . . .

   a) explained by change in routine? __ __

   b) due to illness? __ __

   c) due to medical equipment failure? __ __

   d) spontaneous or unexplained? __ __

3. Symptoms of hypoglycemia <u>during the past three months</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 __ __

   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 __ __

      (ii) lost consciousness with seizure __ __

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? — —

(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)? — —

(iii) as to require the assistance of another person but did not require any of the help described in (I) or (ii)? — —

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? — —

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

(iii) Did any episodes result in injury to the patient or others? Yes (1) No (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 Hypogly-cemic Event (Form 042) for any episodes for which this has not previously been done.*

e) During the past three months, 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) During the past three months, 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)?

No (1) Yes (2)

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?

— —

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:

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 (1)

Decreased food intake at meal or snack (1)

Delayed meal or snack (1)

Increased exercise level (1)

Too much insulin taken (1)

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

Other; specify: _____ (1)

_____

Unexplained (1)

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

Adrenergic warning symptoms	(1)
Diaphoresis (sweating)	(1)
Altered mental status	(1)
Other	(1)
None	(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	(1)	(2)
b) Angina Pectoris	(1)	(2)
c) Coronary artery disease	(1)	(2)
d) Arrhythmia	(1)	(2)

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

2. **CHEST PAIN**

(If no pain, check here and skip to 2.c) **(1)**

a.i) Has the patient complained of pain in the Check all that apply)

a) left anterior chest	(1)
b) left arm	(1)
c) jaw	(1)
d) sternum upper or middle	(1)
e) sternum lower	(1)

ii) Did the pain also involve (Check all that apply)

a) the back	(1)
b) the shoulder	(1)
c) the right arm	(1)
d) the abdomen on one or both sides	(1)

b.i) If yes to any of the above, did the pain last for a duration of more than 20 minutes? No (1) Yes (2)

ii) Was there a definite non-cardiac cause for the pain (i.e.induced by an accident)? (1) (2)

iii) Were additional doses of nitrates or calcium channel blockers self-administered without obtaining relief of the pain? (before medical care was sought) (1) (2)

c. Has the patient ever had any feeling of pressure or heaviness in the chest? No (1) Yes (2)

If NO, skip to 2.e.

d. If the patient has pain or discomfort (pressure, heaviness) in the chest:

i) Does the patient get this walking up hill or hurrying? (1) (2)

ii) Does the patient get this pain when walking at an ordinary pace on a level surface? (1) (2)

iii) When the patient gets this pain, what does he/she do?

Stop (1)

Slow down (2)

Continue at the same pace (3)

iv) What happens to the pain when standing still?

Relieved (1)

Not relieved (2)

v) If relieved when standing still, how soon does the pain go away?

10 minutes or less (1)

More than 10 minutes (2)

e. Were any diagnostic tests performed on this patient? No (1) Yes (2)

If yes, what tests were performed and what were the results?

		Result: Positive	Negative	?
Test 1		(1)	(2)	(3)
Test 2		(1)	(2)	(3)
Test 3		(1)	(2)	(3)
Test 4		(1)	(2)	(3)
Test 5		(1)	(2)	(3)

3. 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)	(1)	(2)
b) Transient ischemic attack (TIA)	(1)	(2)

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

4. 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) Amputation (surgical or traumatic)	(1)	(2)
b) Lower extremity ulcer	(1)	(2)
c) Other arterial events (specify below)	(1)	(2)

specify: _____

_____

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

5. **INTERMITTENT CLAUDICATION (PERIPHERAL ISCHEMIA)**

If patient does not have peripheral pain, check here and skip to Section 6. (1)

a. Does the patient get pain in either leg when walking? No (1) Yes (2)

b. Does this pain ever begin when standing still or sitting? (1) (2)

c. In what part of the leg does the pain occur?

	Buttock	Thigh	Calf
Right	(1)	(2)	(3)
Left	(1)	(2)	(3)

d. Does the patient have pain when walking uphill or hurrying? No (1) Yes (2)

e. Does the patient have pain when walking at an ordinary pace on a level surface? (1) (2)

f. Does the pain ever disappear while the patient is walking? (1) (2)

g. What does the patient do if he/she gets this pain when walking?

Stop (1)

Slow down (2)

Continue at the same pace (3)

h. What happens to the pain if the patient stands still?

Relieved	(1)
Not relieved	(2)

i. If the pain is relieved by standing still, how soon does relief occur?

Not applicable	(1)
10 minutes or less	(2)
More than 10 minutes	(3)

j. Since first experiencing the pain, has the patient noticed a change in its severity? (Check one):

Increased	(1)
Decreased	(2)
Unchanged	(3)

k. Were any diagnostic tests performed on this patient? No (1) Yes (2)

If yes, what tests were performed and what were the results?

		Result: Positive	Negative	Equivocal
Test 1	_____	(1)	(2)	(3)
Test 2	_____	(1)	(2)	(3)
Test 3	_____	(1)	(2)	(3)
Test 4	_____	(1)	(2)	(3)
Test 5	_____	(1)	(2)	(3)

6. PSYCHIATRIC EVENTS

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

	No	Yes
a) Nervousness or anxiety	(1)	(2)
b) Unreasonable fears	(1)	(2)
c) Eating disturbance	(1)	(2)
d) Affective disorder	(1)	(2)
e) Suicide attempt	(1)	(2)
f) Criminal conduct	(1)	(2)
g) Psychiatric hospitalization or outpatient psychiatric treatment which included the use of tran quilizers such as phenothiazines	No (1)	Yes (2)
h) Other significant psychiatric condition?	(1)	(2)

If YES to c-h, then complete EDIC Form 094, Verification of Psychiatric Event.

7. MAJOR ACCIDENTS

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

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
1) Cystitis	(1)	(2)
2) Pyelonephritis	(1)	(2)
3) Uncontrollable hypertension	(1)	(2)
4) Edema (of renal etiology only)	(1)	(2)
5) Dialysis	(1)	(2)
6) Renal Transplantation	(1)	(2)
7) Other, specify: _____	(1)	(2)

L. OPHTHALMIC COMPLICATIONS

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

		Right Eye No (1)	Right Eye Yes (2)	Left Eye No (1)	Left Eye Yes (2)
1.	Has the patient had blurred or reduced vision?	(1)	(2)	(1)	(2)
	If YES, explain: _____				
2.	Has the patient experienced floaters or flashing lights?	No (1)	Yes (2)	No (1)	Yes (2)
3.a,b)	Is the eye enucleated?	(1)	(2)	(1)	(2)
	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?	(1)	(2)	(1)	(2)
	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.				
		Right Eye		Left Eye	
4.a,b)	Has the patient had any ocular surgical procedure(s) since the last completed Annual Clinic Visit?	No (1)	Yes (2)	No (1)	Yes (2)
	IF YES, IDENTIFY SURGICAL PROCEDURES IN THE FOLLOWING ITEMS FOR APPROPRIATE EYE(S).IF NO FOR BOTH EYES, PROCEED TO QUESTION 5.				
		Right Eye		Left Eye	
		No	Yes	No	Yes
c,d)	Corneal transplant	(1)	(2)	(1)	(2)
e,f)	Other corneal surgery	(1)	(2)	(1)	(2)
g,h)	Filtering surgery, cyclocryotherapy, or other operative procedure to lower intraocular pressure	(1)	(2)	(1)	(2)
i,j)	Cataract extraction	(1)	(2)	(1)	(2)
k,l)	Vitrectomy	(1)	(2)	(1)	(2)
m,n)	Retinal detachment surgery	(1)	(2)	(1)	(2)
o,p)	Other surgery (specify below)	(1)	(2)	(1)	(2)

R - _____

L - _____

		Right Eye No	Right Eye Yes	Left Eye No	Left Eye Yes
5.a,b)	Has the patient had any photocoagulation since the last completed Annual clinic visit?	(1)	(2)	(1)	(2)
	If both eyes are NO go to Question 6				
c,d)	Has the patient had scatter treatment (given for retinopathy)?	(1)	(2)	(1)	(2)
e,f)	Has the patient had focal treatment (given for macular edema)	(1)	(2)	(1)	(2)
g,h)	Has the patient had other treatment (for non-diabetic retinopathy)?	(1)	(2)	(1)	(2)
6 a,b)	Has the patient been diagnosed as having glaucoma in either eye since the last completed Annual Clinic Visit?	(1)	(2)	(1)	(2)
7 a,b)	Has the patient used any ocular medications which require a prescription since the last completed Annual Clinic Visit?	(1)	2)	(1)	(2)
	IF YES, COMPLETE EDIC FORM 004, MEDICATION FORM. IF NO, PROCEED TO QUESTION 9				
8a,b)	Has the patient received any other ocular treatments administered by a physician since the last completed Annual Clinic Visit?	(1)	(2)	(1)	(2)
	IF YES, SPECIFY BELOW . IF NO, PROCEED TO QUESTION 9.				
	R - _____				
	L - _____				
		Right Eye No	**Right Eye** Yes	**Left Eye** No	**Left Eye** Yes
9.a,b)	Does the patient describe symptoms which you believe to be caused by vitreous hemorrhage since the last completed Annual Clinic Visit?	(1)	(2)	(1)	(2)
10.	Has the patient had any other eye problems?	(1)	(2)	(1)	(2)
	If YES, specify: _____				

		No	Yes
11.	Will the patient be referred to an ophthalmologist for any physical conditions noticed during this exam?	(1)	(2)

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	(1)	(2)
(i) If the patient has pain, is he/she taking medication for the pain?	(1)	(2)
If YES, complete EDIC Form 004, Medication Form		
2. Unexplained muscle weakness	(1)	(2)
3. Vomiting or bloating after meals	(1)	(2)
4. Bouts of persistent or recurrent diarrhea	(1)	(2)
5. Diarrhea with fecal incontinence	(1)	(2)
6. Urinary retention	(1)	(2)
7. Dizziness or lightheadedness (not associated with hypoglycemia)	(1)	(2)
8. Fainting (not associated with hypoglycemia)	(1)	(2)
9. Seizure (not due to hypoglycemia)	(1)	(2)

If the patient is male answer M.10; if female go to M.11.

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

If YES, specify: _____

_____

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

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)

a) Cutaneous (non-infusion site) or muocutaneous (e.g., Candida vulvo-vaginitis, furunculosis, dental abscess) infection	(1)	(2)

If YES, specify: _____

_____

b) Post-operative or deep wound infection	(1)	(2)
c) Gangrene	(1)	(2)
d) Mononucleosis, epididymitis, measles, chicken pox	(1)	(2)

If YES, specify: _____

_____

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

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

2. Since the last evaluation, has the patient had MAJOR SURGERY	(1)	(2)

If YES, specify: _____

_____

3. Since the last evaluation, has the patient had an autoimmune ENDOCRINE EVENT?	(1)	(2)

If YES, specify:

a) Hypothydroidism	(1)	(2)
b) Adrenal insufficiency	(1)	(2)
c) Pernicious Anemia	(1)	(2)
d) Premature Ovarian Failure	(1)	(2)

If YES to any of the items in N.1 through N.3 and the patient was prescribed medications for this condition, then complete EDIC Form 004, Medication Form.

O. FEMALE/REPRODUCTIVE

(SKIP TO SECTION P IF THE PATIENT IS MALE)

1a) Has the patient had any vaginal itching or discharge	(1)	(2)

Proceed to Question O.2.A	

b) Was the patient treated for this?	(1)	(2)

c) Specify treatment: _____

_____

2a) Does the patient menstruate?	(1)	(2)

Proceed to Question O.3	

b) Enter date of start of last menstrual period:

__ __ __ __ __ __
Month Day Year

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

| Proceed to Question 0.3 | |

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

If no, why not? _____

_____

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

If yes, estimated date of conception:

__ __ Month __ __ Day __ __ Year

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

If yes, estimated date of conception:

__ __ Month __ __ Day __ __ Year

Date of termination of pregnancy:

__ __ Month __ __ Day __ __ Year

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

	No	Yes
a) Nodules in breast	(1)	(2)
b) Breast cancer	(1)	(2)
c) Breast discharge	(1)	(2)
d) Irregular menses	(1)	(2)
e) Dysmenorrhea	(1)	(2)

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

If YES, specify: _____

_____

6. Has the patient ever used oral contraceptives? No (1) Yes (2)

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

If YES, specify: _____

_____

P. MEDICATIONS

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

If Yes, complete EDIC Form 004, Medication Form	__

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

If Yes, complete EDIC Form 004, Medication Form	__

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

If Yes, complete EDIC Form 004, Medication Form	__

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

1. Weight (kg)

a. First measurement: ___ ___ ___.___

b. Second measurement: ___ ___ ___.___

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

c. Third measurement: ___ ___ ___.___

d. Fourth measurement: ___ ___ ___.___

2. What is the patient's desired weight (kg)? ___ ___ ___.___

3. Height (cm)

a. First measurement: ___ ___ ___.___

b. Second measurement: ___ ___ ___.___

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

c. Third measurement: ___ ___ ___.___

d. Fourth measurement: ___ ___ ___.___

4. Natural Waist Circumference (cm)

	NO	YES
Is lipohypertropy present?	(1)	(2)
Is lipoatrophy present?	(1)	(2)

a. First measurement: ___ ___ ___.___

b. Second measurement: ___ ___ ___.___

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

c. Third measurement: ___ ___ ___.___

d. Fourth measurement: ___ ___ ___.___

5. Iliac Waist Circumference (cm)

	NO	YES
Is lipohypertropy present?	(1)	(2)
Is lipoatrophy present?	(1)	(2)

a. First measurement: ___ ___ ___.___

b. Second measurement: ___ ___ ___.___

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

c. Third measurement: ___ ___ ___.___

d. Fourth measurement: ___ ___ ___.___

6. Hip Circumference (cm)

	NO	YES
Is lipohypertropy present?	(1)	(2)
Is lipoatrophy present?	(1)	(2)

a. First measurement: ___ ___ ___.___

b. Second measurement: ___ ___ ___.___

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

c. Third measurement: ___ ___ ___.___

d. Fourth measurement: ___ ___ ___.___

7. Pulse (bpm) ___ ___ ___

8. Sitting blood pressure (RIGHT ARM)

a) Systolic (mm Hg) ___ ___ ___

b) Diastolic (mm Hg) ___ ___ ___

	No	Yes
c) Has hypertension been previously documented by the DCCT/EDIC?	(1)	(2)

SKIP TO QUESTION Q.9	_____

	No	Yes
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?	(1)	(2)

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

	Right	Left
a) Brachial	___ ___ ___	___ ___ ___
b) Dorsalis pedis	___ ___ ___	___ ___ ___
c) Posterior tibial	___ ___ ___	___ ___ ___

10. Cardiovascular Examination

a) Examine the patient for the following cardiac abnormalities.

	Regular	Irregular
Rhythm	(1)	(2)
	Normal	Abnormal
Venous Pressure	(1)	(2)
	Absent	Present
Cardiomegaly	(1)	(2)
S3 Gallop	(1)	(2)
S4 Gallop	(1)	(2)
Systolic Ejection Murmur	(1)	(2)
Diastolic Murmur	(1)	(2)
Other Murmur:	(1)	(2)

If PRESENT, specify: _____

Rub	(1)	(2)
Other Cardiac Abnormality:	(1)	(2)

If PRESENT, specify: _____

11. 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
Carotid	(1)	(2)	(3)	(1)	(2)	(3)
Brachial	(1)	(2)	(3)	(1)	(2)	(3)
Radial	(1)	(2)	(3)	(1)	(2)	(3)
Femoral	(1)	(2)	(3)	(1)	(2)	(3)
Popliteal	(1)	(2)	(3)	(1)	(2)	(3)
Posterior Tibial	(1)	(2)	(3)	(1)	(2)	(3)
Dorsalis Pedis	(1)	(2)	(3)	(1)	(2)	(3)

b) Indicate the presence or absence of bruits.

	RIGHT		LEFT	
	Absent	Present	Absent	Present
Femoral	(1)	(2)	(1)	(2)
Carotid	(1)	(2)	(1)	(2)
Other:	(1)	(2)	(1)	(2)

If PRESENT, specify: _____

12. Extremities and Skin Examinations

	RIGHT SIDE Absent	RIGHT SIDE Present	LEFT SIDE Absent	LEFT SIDE Present
Ulceration	(1)	(2)	(1)	(2)
Gangrene	(1)	(2)	(1)	(2)
Necrobiosis	(1)	(2))	(1)	(2)
Xanthelasma	(1)	(2)	(1)	(2)
Eruptive Xanthoma	(1)	(2)	(1)	(2)
Charcot joint	(1)	(2)	(1)	(2)
Deformity	(1)	(2)	(1)	(2)

If PRESENT, specify: _____

_____

13. Injection sites (INCLUDING CATHETER SITES):

	Absent	Present
a) Lipoatrophy	(1)	(2)
b) Lipohypertrophy	(1)	(2)
c) Inflammation	(1)	(2)

14. Feet:

	Absent	Present
a) Ulcers	(1)	(2)
b) Infection	(1)	(2)
c) Abnormal toenails	(1)	(2)
d) Other _____	(1)	(2)

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

Specify: _____

_____

R. CONTACT WITH PATIENT BETWEEN ANNUAL VISITS

1. Have you had any contact the patient in any way since the last annual visit? (i.e., phone calls, in person, cards, letters, etc.) No (1) Yes (2)

If YES, answer the following:

2. How many times did you have contact with the patient?

___ ___
# of times

3. What forms of contact occurred? (Check all that apply)

a) Telephone call (1)

b) Talked to patient in person (1)

c) Sent card or letter (1)

d) Sent newsletter or university publication (1)

e) Other, specify: _____ (1)

_____

Name of persons responsible for information on this form: Certification Number

_____ __ __ - __ __ (Study Coordinator, Nurse)

_____ __ __ - __ __ (Principal Investigator, Physician)