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. In-person visit (1)
Phone visit (2)

6. What is the EDIC follow-up year? __ __

7. 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

1. a) 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 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 currently unemployed, or disabled check category corresponding to the type of occupation which the individual did or could do; also check the corresponding box marked "unemployed or retired, or disable.")

	Patient	Spouse	Guardian/Friend/ Significant Other
a) Professional, technical or similar worker	(1)	(1)	(1)
Manager, official, or proprietor	(2)	(2)	(2)
Craftsman, foreman, or similar worker	(3)	(3)	(3)
Clerical or similar worker	(4)	(4)	(4)
Sales Worker	(5)	(5)	(5)
Operative or similar worker	(6)	(6)	(6)
Service worker	(7)	(7)	(7)
Laborer	(8)	(8)	(8)
Farmer	(9)	(9)	(9)
Homemaker	(10)	(10)	(10)
Student	(11)	(11)	(11)
Other or unknown	(12)	(12)	(12)
b) Unemployed or retired	(1)	(1)	(1)
c) Disabled			
Diabetes related	(1)	(1)	(1)
Not related to diabetes	(1)	(1)	(1)

3. Education of patient and household providers
(Check highest level COMPLETED by each person for whom an occupation is given in B.2)

	Patient	Spouse	Guardian/Friend/ Significant Other
Graduate School	(1)	(1)	(1)
College graduate	(2)	(2)	(2)
Some college or trade school	(3)	(3)	(3)
Secondary school graduate	(4)	(4)	(4)
Some secondary school	(5)	(5)	(5)
Elementary school	(6)	(6)	(6)
None	(7)	(7)	(7)
Unknown	(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

9. a) 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) __ __

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)

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 judgment 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 insulin used by this patient: (Check all that apply)

Humalog	(1)	Lantus	(1)
NovoLog	(1)	Human 70/30	(1)
Apidra	(1)	Humalog 75/25	(1)
Inhaled insulin	(1)	Other _____	(1)
Human regular	(1)	Other _____	(1)
Human NPH	(1)	Other _____	(1)
Levemir	(1)	Other _____	(1)

2. What insulin regimen is currently being used by this patient? (Check all that apply)

insulin infusion pump (1)

three or more daily injections or inhalations (2)

one or two daily injections or inhalations (3)

other: _____ (4)

(describe the regimen in F.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 F.2, skip to F.4.

Total number of units per day: __ __ __

Number of Units Used	Breakfast	Lunch	Supper	Bedtime	Other
Humalog	__ __	__ __	__ __	__ __	__ __
NovoLog	__ __	__ __	__ __	__ __	__ __
Apidra	__ __	__ __	__ __	__ __	__ __
Inhaled ins.	__ __	__ __	__ __	__ __	__ __
Human regular	__ __	__ __	__ __	__ __	__ __
Human NPH	__ __	__ __	__ __	__ __	__ __
Levemir	__ __	__ __	__ __	__ __	__ __
Lantus	__ __	__ __	__ __	__ __	__ __
Human 70/30	__ __	__ __	__ __	__ __	__ __
Humalog 75/25	__ __	__ __	__ __	__ __	__ __
Other	__ __	__ __	__ __	__ __	__ __
Other	__ __	__ __	__ __	__ __	__ __

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 F.5.

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

ANSWER IF F.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 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: __ __

	No	Yes
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)
Illness	(5)
Other (please describe): _____	(6)

G. 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 Verification of DKA Form (Form 093)

2. Symptoms of hypoglycemia during the past three months

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? 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) 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 H.

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)

a) Hunger (1)
b) Rapid heart rate (1)
c) Anxiety (1)
d) Tremors (1)
e) Diaphoresis (sweating) (1)
f) Altered mental status (1)
g) Headache (1)
h) Other, specify: _____(1)
i) None (1)

H. VERIFICATION OF EVENTS

1. CARDIOVASCULAR EVENTS

Since the last evaluation, has the patient been told he/she has had any of 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)
e) Congestive heart failure	(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)
f) Other, specify: _____(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)
e) Other, specify: _____(1)
f) None of the above (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) Unknown (3)

ii) Was there a definite non-cardiac cause for the pain (i.e. induced by an accident)? (1) (2) (3)

If yes specify:_____

_____

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) (3)

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

If NO, skip to H.3.

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)

3. Since the last evaluation, has the patient experienced symptoms of CONGESTIVE HEART FAILURE? No Yes
If No, go to H.4. (1) (2)

No Yes
a) Paroxysmal Nocturnal Dyspnea (1) (2)

Attacks usually occurring at night in which the patient awakens suddenly, bolts upright from a recumbent position gasping for breath, wheezing, feeling anxious and as though he/she is suffocating. Attacks usually subside after sitting on the side of the bed with legs dependent for up to 30 minutes or longer.

No Yes
b) Orthopnea (1) (2)

Shortness of breath that develops rapidly in the recumbent position, even when the patient is awake. It is relieved or prevented by elevating the head and chest with two or more pillows or sitting in a chair.

No Yes
c) Dyspnea at rest (1) (2)

A severe form of shortness of breath or rapid breathing occurring at rest and not provoked by exercise or change in position.

No Yes
d) New York Heart Association Functional Classification III. (1) (2)
Marked limitation of physical activity caused by heart disease. Patients are comfortable at rest, but less than ordinary physical activity, for example walking one to two blocks on level surface or climbing one flight of stairs in normal conditions, causes fatigue, shortness of breath, palpitations or anginal pain.

4. 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.

5. 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.

6. INTERMITTENT CLAUDICATION (PERIPHERAL ISCHEMIA)

If patient does not have peripheral pain, check here and skip to H.7. (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? (1) (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 only one)

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

K. Were any cardiovascular 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)

7. 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 (e.g., depression)	(1)	(2)
e) Suicidal ideation	(1)	(2)
f) Suicide attempt	(1)	(2)
g) Criminal conduct	(1)	(2)
h) Psychiatric hospitalization or outpatient psychiatric treatment which included the use of tranquilizers such as phenothiazines	(1)	(2)
i) Other significant psychiatric condition?	(1)	(2)

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

8. MAJOR ACCIDENTS

Since the last evaluation, has the patient experienced any major accidents (e.g., auto accident, sports accident, on-the-job accident) that produced serious injury to the patient or to other persons whether or not hospitalization was required?	No	Yes
	(1)	(2)

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

I. 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) Pancreas Transplantation	(1)	(2)
8) Other, specify: _____	(1)	(2)

J. OPHTHALMIC COMPLICATIONS

Refer to the patient's experience since the last completed annual visit when answering section J.

	Right Eye No	Right Eye Yes	Left Eye No	Left Eye Yes
1. Has the patient had any changes in vision? If no in both eyes, skip to J.2.	(1)	(2)	(1)	(2)
a) Has the patient had blurred or reduced vision?	(1)	(2)	(1)	(2)
If YES, explain: _____				
b) Has the patient experienced floaters or flashing lights?	(1)	(2)	(1)	(2)
2. 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 J.3.

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 J FOR THE TIME SINCE THE LAST VISIT AND BEFORE ENUCLEATION. IF NO, LEAVE BLANK QUESTIONS 3-8 FOR THAT EYE.

	Right Eye No	Right Eye Yes	Left Eye No	Left Eye Yes
3. a,b) Has the patient had any ocular surgical procedure(s) since the last completed Annual Clinic Visit?	(1)	(2)	(1)	(2)

IF YES, IDENTIFY SURGICAL PROCEDURES IN THE FOLLOWING ITEMS FOR APPROPRIATE EYE(S). IF NO FOR BOTH EYES, PROCEED TO J.4.

	Right Eye No	Right Eye Yes	Left Eye No	Left Eye 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
4. a,b) Has the patient had any photocoagulation since the last completed Annual clinic visit?	(1)	(2)	(1)	(2)
If both eyes are NO, skip to J.5				
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)
5. a,b) Has the patient been diagnosed as having glaucoma in either eye since the last completed Annual Clinic Visit?	(1)	(2)	(1)	(2)
6. 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, then complete EDIC Form 004, Medication Form.				
7. a,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.				
R - _____				
L - _____				
	Right Eye No	Right Eye Yes	Left Eye No	Left Eye Yes
8. 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)
9. Has the patient had any other eye problems?	(1)	(2)	(1)	(2)
If YES, specify:				

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

K. NEUROLOGIC COMPLICATIONS

Has the patient experienced 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. Dizziness or lightheadedness (not associated with hypoglycemia)	(1)	(2)
4. Fainting (not associated with hypoglycemia)	(1)	(2)
5. Seizure (not associated with hypoglycemia)	(1)	(2)
6. Vomiting or bloating after meals	(1)	(2)
7. Have you been told you have gastroparesis?	(1)	(2)
a. If YES, has this been confirmed by diagnostic testing?	(1)	(2)
8. Recurrent constipation (fewer than 2 bowel movements/week OR less than 1 bowel movement/3 days)	(1)	(2)

	No	Yes
9. Persistent or recurrent diarrhea	(1)	(2)
10. Diarrhea with fecal incontinence	(1)	(2)
11. Urinary retention	(1)	(2)
12. Recurrent urinary incontinence (Check all that apply)	(1)	(2)
a) Stress incontinence	(1)	(2)
b) Urge incontinence	(1)	(2)
c) Mixed incontinence	(1)	(2)
d) Overflow incontinence	(1)	(2)
e) Functional incontinence	(1)	(2)

If the patient is female answer K.13; if male skip to K.14.

13. Female sexual dysfunction	(1)	(2)
14. Impotence	(1)	(2)
15. 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)
16. Other neurologic problem?	(1)	(2)

If YES, specify: _____

_____

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

L. 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) Cutaneous (non-infusion site) or mucocutaneous (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.

	No	Yes
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:

a) Had any surgical procedures requiring inpatient hospitalization?	(1)	(2)

If YES, specify: _____

_____

Since the last evaluation, has the patient:

b) Had any outpatient procedures?	(1)	(2)

If YES, specify: _____

_____

3. Since the last evaluation, has the patient been diagnosed with an autoimmune endocrine disease? (If YES, specify below) — No (1) Yes (2)

a) Addison's Disease (1) (2)
b) Ulcerative Colitis (1) (2)
c) Crohn's Disease (1) (2)
d) Systemic Lupus Erythematosus (1) (2)
e) Rheumatoid Arthritis (1) (2)
f) Multiple Sclerosis (1) (2)
g) Celiac Sprue (1) (2)
h) Grave's Disease (Hyperthyroid) (1) (2)
i) Hashimoto's Disease (Hypothyroid) (1) (2)
j) Pernicious Anemia (1) (2)
k) Vitiligo (1) (2)
l) Alopecia (1) (2)
m) Other, specify: _____ (1) (2)

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

M. FEMALE/REPRODUCTIVE

(SKIP TO SECTION N IF THE PATIENT IS MALE)

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

If NO, skip to Question M.2.

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

c) Specify treatment: _____

_____

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

If NO, skip to Question M.3.

b) Enter start date of last menstrual period:

__ __ __ __ __ __
Month Day Year

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

If NO, skip to Question M.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 visit has the patient had any changes to the conditions listed below?

	No	Yes	NA
a) Nodules in breast	(1)	(2)	(3)
b) Breast cancer	(1)	(2)	(3)
c) Breast discharge	(1)	(2)	(3)
d) Irregular menses	(1)	(2)	(3)
e) Dysmenorrhea	(1)	(2)	(3)

5. Other significant gynecologic condition? — No (1) Yes (2)
If YES, specify: _____

_____

	No	Yes
6. Has the patient ever used oral contraceptives?	(1)	(2)
7. Does the patient use any other form of birth control?	(1)	(2)

If YES, specify: _____

_____

	No	Yes	Uncertain
8. a) Have the patient's menstrual periods ceased? (≥ 1 year without menses)	(1)	(2)	(3)
b) If YES, is this considered to be permanent?	(1)	(2)	(3)
i) If YES for both a) and b) in any of the previous years, check here and skip to M.8.f.		(2)	

c) At what age did the periods cease? _____

d) For what reason?

Naturally	(1)
Due to radiation	(2)
Due to surgery	(3)
Due to use of oral contraceptives or Depo-provera or norplant	(4)

	No	Yes
e) If due to surgery: were BOTH ovaries removed	(1)	(2)
was only ONE ovary removed	(1)	(2)
was ONLY the uterus removed	(1)	(2)
f) After menstrual periods ceased, were female hormones taken?	(1)	(2)

g) If YES, for how long? _____

If patient is currently taking hormones, please complete EDIC Form 004, Medication Form.

N. CANCER

1. Historical Information
IF HISTORICAL INFORMATION HAS PREVIOUSLY BEEN FILLED OUT, CHECK HERE AND SKIP TO N.2. **(1)**

a. Has the patient EVER been diagnosed as having cancer? No (1) Yes (2)
If NO, skip to section O.

b. Specify diagnosis date: __ __ / __ __ / __ __
Month / Day / Year

c. Indicate the type of cancer (Check all that apply)	Diagnosis	Metastasized	Treatment Types (Check all that apply) Surgery	Chemotherapy	Radiation	Other	Currently in Remission
		No Yes	No Yes	No Yes	No Yes	No Yes	No Yes
1) Bone, blood, and lymphatic cancer (leukemia, Hodgkin's disease, sarcoma)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
2) Breast cancer	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
3) Digestive cancer (colorectal, liver, gallbladder, pancreatic, stomach)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
4) Head and neck cancer (oral, throat, thyroid)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
5) Prostate cancer	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
6) Reproductive cancer (ovarian, testicular, cervical, endometrial)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
7) Skin cancer, melanoma	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
8) Thoracic cancer (esophageal, lung)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
9) Urinary cancer (bladder, kidney)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
10) Other, specify: _____	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)

d. If "Other" treatment type was indicated, please describe treatment: _____

_____

2. Since the last evaluation, has the patient been diagnosed as having cancer? No (1) Yes (2)

   a. If YES, specify diagnosis date: __ __ Month __ __ Year

3. Since the last evaluation, has the patient had a change in status with a previously diagnosed cancer? (1) (2)

If NO to both questions 2 and 3, skip to section O.

4. Indicate the type of cancer (Check all that apply)	Diagnosis	Status Change	Metastasized	Treatment Types (Check all that apply) Surgery	Chemotherapy	Radiation	Other	Currently in Remission
			No Yes	No Yes	No Yes	No Yes	No Yes	No Yes
1) Bone, blood, and lymphatic cancer (leukemia, Hodgkin's disease, sarcoma)	(1)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
2) Breast cancer	(1)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
3) Digestive cancer (colorectal, liver, gallbladder, pancreatic, stomach)	(1)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
4) Head and neck cancer (oral, throat, thyroid)	(1)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
5) Prostate cancer	(1)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
6) Reproductive cancer (ovarian, testicular, cervical, endometrial)	(1)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
7) Skin cancer, melanoma	(1)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
8) Thoracic cancer (esophageal, lung)	(1)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
9) Urinary cancer (bladder, kidney)	(1)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)
10) Other, specify: _____	(1)	(1)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)	(1)(2)

5. If "Other" treatment type was indicated, please describe treatment: _____

_____

O. 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.

P. PHYSICAL EXAMINATION (A PHYSICAL EXAMINATION SHOULD BE PERFORMED).

If phone interview, check here and skip to section Q. (1)

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. 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: ___ ___ ___.___

If pregnant skip to P.6.

3. Natural Waist Circumference (cm)

Is lipohypertropy present? No (1) Yes (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: ___ ___ ___.___

4. Iliac Waist Circumference (cm)

Is lipohypertropy present? No (1) Yes (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. Hip Circumference (cm)

Is lipohypertropy present? No (1) Yes (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. Pulse (bpm) __ __ __

7. Sitting blood pressure (Right arm preferred at level of heart) The measurement should begin after 5 minutes of rest. A 2-minute rest should be given between the first and second measurements. The blood pressure measurement will be determined by the average of first and second measurements. If right arm is unavailable, use left.

First measurement		BP Cuff Size Reg.	Lg.
a) systolic (mm Hg)	__ __ __	(1)	(2)
b) diastolic (mm Hg)	__ __ __	(1)	(2)

Second measurement		BP Cuff Size Reg.	Lg.
c) systolic (mm Hg)	__ __ __	(1)	(2)
d) diastolic (mm Hg)	__ __ __	(1)	(2)

e) 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 (1) Yes (2)

f) Is the current systolic or diastolic blood pressure so high as to indicate hypertension as ≥ 130 systolic or or ≥ 80 diastolic? No (1) Yes (2)

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

	Right	Left	BP Cuff Size Reg.	Lg.
a) Brachial	_ _ _	_ _ _	(1)	(2)
b) Dorsalis pedis	_ _ _	_ _ _	(1)	(2)
c) Posterior tibial	_ _ _	_ _ _	(1)	(2)

d) If any of the above have not been measured, check here & specify reason: _____ (1)

9. Cardiovascular Examination

	No	Yes	Not Done
Were any abnormalities present on the cardio-vascular exam?	(1)	(2)	(3)

If yes, Specify: _____

10. Extremities and Skin Examinations

	No	Yes	Not Done
Were any abnormalities present on the skin exam?	(1)	(2)	(3)

	RIGHT SIDE Absent	Present	LEFT SIDE Absent	Present
Ulceration	(1)	(2)	(1)	(2)
Gangrene	(1)	(2)	(1)	(2)
Necrobiosis	(1)	(2)	(1)	(2)
Deformity	(1)	(2)	(1)	(2)

If PRESENT, specify: _____

11. Injection sites (INCLUDING CATHETER INFUSION SITES):

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

12. Feet:

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

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

Specify:_____

_____

14. Is there anything new in their medical history that has not been captured on this form? No (1) Yes (2)

Specify:_____

_____

Q. 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. Have you had contact with this patient more than once per month? No (1) Yes (2)

4. 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 or email (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)