

A. IDENTIFYING INFORMATION

la) Was a refraction performed

for both eyes?

EPIDEMIOLOGY OF DIABETES INTERVENTIONS AND COMPLICATIONS

Ophthalmic Examination and Visual Acuity

Patients are to undergo eye examinations at the 8th, 12th, and 16th anniversary post-DCCT randomization. The ophthalmic follow-up visits should be scheduled to correspond with other regularly scheduled visits whenever possible. Visual acuity is measured and stereo fundus photographs are taken in the course of each eye examination. The following procedures are also required: measurement of intraocular pressure, slit-lamp examination, ophthalmoscopy. Chapter 18 of the Manual of Operations should be consulted for procedures to follow in completing these examinations. The original of this form is to be completed at each scheduled eye examination and sent to the Data Coordinating Center; a copy of the form should be kept in the clinic's files.

No Yes

(1) (2)

	1. EDIC Clinic Number
	2. Patient ID Number
	3. Patient's Initials
	4. Date of examination Month Day Year
	5. EDIC year
B.	DISTANCE SUBJECTIVE REFRACTION
	Use any visual acuity chart other than ETDRS Visual Acuity Chart 1 or 2.
	IF A SUBJECTIVE REFRACTION CANNOT BE PERFORMED IN ONE OR BOTH EYES AT FOUR METERS BECAUSE OF POOR ACUITY, ATTEMPT THE REFRACTION AT ONE METER. IF A ONE METER REFRACTION IS POSSIBLE, SUBTRACT +0.75 SPHERE FROM THE REFRACTION USED AT ONE METER, AND ENTER THIS RESULT IN QUESTION 2.

IF YES, PROCEED TO QUESTION 2.

IF NO, ANSWER THE FOLLOWING ITEMS AND LEAVE BLANK
THE RESPONSE TO QUESTION 2 FOR EYE(S) NOT REFRACTED.

Sı	pecify reason:		ight No	E		!		Left No	Ey	
b,c)	Poor visual acuity	(1)	(2)		(1)	(2)
d, e)	<pre>Eye(s) enucleated*</pre>	(1)	(2)		(1)	(2)
f,g)	Other (specify below)	(1)	(2)		(1)	(2)
	R -							-		
	r -									

^{*}LEAVE BLANK ALL RESPONSES TO QUESTIONS B-2 THROUGH F-7 FOR ENUCLEATED EYE(S).

2. Corrective lenses obtained by subjective refraction for distance:

IF A SUBJECTIVE REFRACTION WAS NOT PERFORMED AT FOUR OR ONE METERS, ENTER THE DISTANCE SUBJECTIVE REFRACTION FROM EITHER THE BASELINE OPHTHALMIC EXAMINATION OR THE LAST OPHTHALMIC EXAMINATION, WHICHEVER IS MORE RECENT. INDICATE WHETHER PLUS OR MINUS SPHERES OR CYLINDERS WERE USED BY CIRCLING THE APPROPRIATE SIGNS. IF SPHERE, CYLINDER, AND AXIS ARE ALL ZERO, RECORD A CHECK MARK () IN THE APPROPRIATE SPACE BELOW:

a,b)	Sphere	Right Eye + 	Left Eye +
c,d)	Cylinder	<u>-</u>	+
e,f)	Axis		
g,h)	Sphere, cy and axis a		1 (1
		pia greater than one or both eyes?	No Yes (1) (2)

C. VISUAL ACUITY MEASUREMENTS

Use ETDRS Visual Acuity CHART 1 for the RIGHT EYE and CHART 2 for the LEFT EYE.

1. What is the distance between the patient and the chart (record in meters to nearest 1/10 meter)?

Meters

2. Letters correct at four meters distance:

CIRCLE EACH LETTER THE PATIENT IDENTIFIES CORRECTLY AND WRITE THE TOTAL CORRECT FOR EACH ROW IN COLUMN AT RIGHT. EACH ROW TOTAL MUST BE ENTERED.

REMEMBER: THE PATIENT STARTS AT THE TOP READING SLOWLY AND GETS ONLY ONE CHANCE AT EACH LETTER. PUSH THE PATIENT UNTIL HE/SHE CLEARLY DEMONSTRATES HE/SHE CANNOT READ OR GUESS LETTERS CORRECTLY.

RIGHT EYE - CHART 1

Acuity Equivalent	Cha	rt	1 1	ett	ers	Number Correct
20/200	N	С	K	z	0	
20/160	R	Н	S	D	K	
20/125	D	0	V	Н	R	
20/100	С	Z	R	Н	s	
20/80	0	N	Н	R	С	
20/63	D	K	S	N	v	-
20/50	Z	S	0	K	N	
20/40	С	K	D	N	R	
20/32	S	R	Z	K	D	
20/25	Н	z	0	V	С	
20/20	N	V	D	0	K	
20/16	V	Н	С	N	0	
20/13	S	V	Н	С	Z	
20/10	0	Z	D	V	Н	

a) Total number correct at four meters

NOTE: DO NOT CHANGE TO CHART 2 UNTIL YOU HAVE CHANGED THE COVER TO THE PATIENT'S RIGHT EYE.

LEFT EYE - CHART 2

	acuity nivalent	Chai	rt 2	2 10	ette	ers	Number Correct
2	20/200	D	s	R	K	N	
2	20/160	С	K	Z	0	Н	
2	20/125	0	N	R	K	D	
2	20/100	K	Z	V	D	С	
2	20/80	V	S	Н	Z	0	
2	20/63	Н	D	K	С	R	
2	20/50	С	S	R	Н	N	
2	20/40	S	V	Z	D	K	
2	20/32	N	С	v	0	Z	
2	20/25	R	Н	S	D	V	
:	20/20	S	N	R	0	Н	
:	20/16	0	D	Н	K	R	
:	20/13	Z	K	С	S	N	
:	20/10	С	R	Н	D	V	

b) Total number correct at four meters

IF THE TOTAL NUMBER OF LETTERS READ CORRECTLY IS GREATER THAN OR EQUAL TO 20 IN EACH EYE, PROCEED TO SECTION D.

IF TOTAL NUMBER OF LETTERS READ CORRECTLY WITH EITHER EYE IS LESS THAN 20, MOVE THE PATIENT TO A DISTANCE OF ONE METER FROM THE CHART AND TEST THE ACUITY AT THIS DISTANCE IN EACH EYE WITH LESS THAN 20 LETTERS CORRECT. ANSWER QUESTIONS 3 AND

- 3. Letters correct at one meter distance:
- a) Will the right eye be tested? No Yes (1) (2)

IF NO, PROCEED TO QUESTION 4.
PRIOR TO ACTUAL TESTING AT ONE METER, A +0.75
SPHERE SHOULD BE ADDED TO THE DISTANCE CORRECTION
IN THE TRIAL FRAME.

CIRCLE EACH LETTER THE PATIENT IDENTIFIES CORRECTLY AND WRITE THE TOTAL CORRECT FOR EACH ROW IN COLUMN AT RIGHT. EACH ROW TOTAL MUST BE ENTERED.

RIGHT EYE - CHART 1

Acuity Equivalent	Cha	rt	1 1	ett	ers	Number Correct
5/200	N	С	K	Z	0	-
5/160	R	Н	S	D	K	
5/125	D	0	V	H	R	
10/200	C	Z	R	H	S	
10/160	0	N	H	R	С	
10/125	D	K	S	N	V	
20/200	Z	S	0	K	N	***************************************
20/160	C	K	D	N	R	
20/125	S	R	Z	K	D	
20/100	Н	Z	0	V	C	
20/80	N	V	D	0	K	
20/63	V	Н	С	N	0	
20/50	S	V	Н	С	Z	
20/40	0	Z	D	V	Н	

- b) Total number correct at one meter:
- c) If total number correct at one meter is zero, were count fingers, No Yes hand motion, or light perception present? (1) (2)

4a) Will the left eye be tested? No Yes (1) (2)

IF NO, PROCEED TO SECTION D.
PRIOR TO ACTUAL TESTING AT ONE METER, A +0.75
SPHERE SHOULD BE ADDED TO THE DISTANCE CORRECTION
IN THE TRIAL FRAME.

CIRCLE EACH LETTER THE PATIENT IDENTIFIES
CORRECTLY AND WRITE THE TOTAL CORRECT FOR EACH ROW
IN COLUMN AT RIGHT. EACH ROW TOTAL MUST BE
ENTERED.

LEFT EYE - CHART 2

Acuity Equivalent	Cha	rt	2 1	ett	ers	Number Correct
5/200	D	S	R	K	N	
5/160	С	K	Z	0	Н	
5/125	0	N	R	K	D	
10/200	K	Z	v	D	С	
10/160	v	S	Н	Z	0	
10/125	Н	D	K	С	R	
20/200	С	S	R	Н	N	
20/160	S	V	Z	D	K	
20/125	N	С	V	0	Z	
20/100	R	Н	S	D	v	
20/80	S	N	R	0	Н	
20/63	0	D	Н	K	R	
20/50	Z	K	С	s	N	
20/40	С	R	Н	D	v	

- b) Total number correct at one meter:
- c) If total number correct at one meter is zero, were count fingers, hand motion, or light perception present?

No Yes

(1) (2)

D. INTRAOCULAR PRESSURE

Use Goldmann applanation tonometry		
	Right Eye	Left Eye
<pre>1a,b) Intraocular pressure:</pre>	mm Hg	mm Hg
SLIT-LAMP EXAMINATION		
	Right Eye No Yes	Left Eye No Yes
<pre>1a,b) Is the lens missing?</pre>	(1) (2)	(1) (2)
2a,b) Is there evidence of definite iris neovascularization?	(1) (2)	(1) (2)
IF YES, GONIOSCOPY SHOULD BE PERFORMED AND THE FOLLOWING ITEM SHOULD BE ANSWERED FOR THAT EYE.		
c,d) Is there evidence of angle neovascularization?	(1) (2)	(1) (2)
NOTE: BECAUSE GONIOSCOPY MAY INTERFERE WITH CORNEAL CLARITY AND AFFECT THE ABILITY TO TAKE ADEQUATE QUALITY PHOTOGRAPHS, IT IS RECOMMENDED THAT THE PATIENT RETURN FOR A SEPARATE VISIT IF POSSIBLE, OR THAT GONIOSCOPY BE DEFERRED UNTIL AFTER PUPILLARY DILATION AND FUNDUS PHOTOGRAPHY.		
OPHTHALMOSCOPIC EXAMINATION		
1a,b) Was the ophthalmoscopic examination of the fundus satisfactory?	Right Eye	Left Eye
Yes	(1)	(1)
Not entirely satisfactory, but performed	(2)	(2)
Examination could not be performed	(3)	(3)

IF YES FOR BOTH EYES, PROCEED TO QUESTION 2.

IF NOT ENTIRELY SATISFACTORY FOR EITHER EYE OR IF
EXAMINATION WAS NOT PERFORMED FOR EITHER EYE, ANSWER
THE FOLLOWING ITEM FOR APPROPRIATE EYE.

Specify the main reason the fundus examination was unsatisfactory or could not be performed (CHECK ONLY ONE)	Right Eye	Left Eye
Patient refused	(1)	(1)
Vitreous opacity	(2)	(2)
Vitreous hemmorrhage	(3)	(3)
Lens opacity	(4)	(4)
Corneal opacity secondary to neovascular glaucoma	(5)	(5)
Other corneal opacity	(6)	(6)
Posterior synechia prevent dilation of pupil	(7)	(7)
Other (SPECIFY IN THE SPACE PROVIDED)	(8)	(8)
R -		
L		

IF OPHTHALMOSCOPIC EXAMINATION COULD NOT BE PERFORMED FOR EITHER EYE (I.E., IF QUESTION 1 IS ANSWERED "NOT PERFORMED" FOR BOTH EYES), SKIP QUESTIONS 2 AND 3.

IF THE FUNDUS OF EITHER EYE IS EXAMINED, QUESTIONS 2-7 SHOULD BE ANSWERED FOR THAT EYE.

2a,b) Which statement best describes the clarity of the lens in each eye? (CHECK ONLY ONE)

	lens in each eye? (CHECK ONLY ONE)		
		Right Eye	Left Eye
	No lens opacity or some lens opacity but not sufficient to expect reduced visual acuity	(1)	(1)
	Lens opacity sufficient to reduce visual acuity but not to less than 20/100	(2)	(2)
	Lens opacity sufficient to reduce visual acuity to less than 20/100	(3)	(3)
3a,b)	Are vitreous or preretinal hemorrhage present in any areas of the fundus?	No Yes (1) (2)	No Yes (1) (2)
	IF YES, ANSWER THE FOLLOWING ITEM FOR THAT EYE IF NO, PROCEED TO QUESTION 4.		

creur I	, <u> </u>	EDIC E	OLM 030.3, rage / OL 3
c,d)	Does hemorrhage obscure one or more disc areas of retina?	Right Eye No Yes (1) (2)	Left Eye No Yes (1) (2)
	IF YES, ANSWER THE FOLLOWING ITEMS FOR THAT EYE.		
	Indicate areas in which vitreous or preretinal hemorrhage obscures one or more disc areas of retina:	 Right Eye	Left Eye
e,f)	Within seven standard fields	(1)	(1)
g,h)	Outside seven standard fields but posterior to vortex ampullae	(1)	(1)
i,j)	Anterior to vortex ampullae	(1)	(1)
		Right Eye	Left Eye
4a,b)	Are new vessels present on or within one disc diameter of the optic nerve head (NVD)?	No Yes Quest. (1) (2) (3)	No Yes Quest. (1) (2) (3)
	IF YES, ANSWER THE FOLLOWING ITEM FOR THAT EYE. IF NO, PROCEED TO QUESTION 5.		
c,d)	Are the vessels greater than or equal to DRS Standard Photo 10A?	No Yes (1) (2)	No Yes (1) (2)
5a,b)	Are new vessels elsewhere present?	No Yes Quest. (1) (2) (3)	No Yes Quest.
	IF YES, ANSWER THE FOLLOWING ITEMS FOR THAT EYE. IF NO, PROCEED TO QUESTION 6.		
c,d)	Are there new vessels within the seven standard fields?	No Yes (1) (2)	No Yes (1) (2)
e,f)	Are there new vessels outside the seven standard fields?	(1) (2)	(1) (2)
g,h)	Are the new vessels greater than or equal to 1/2 DA in size in any 30 degree field?	(1) (2)	(1) (2)
6a,b)	Is there retinal thickening within one disc diameter of the center of the macula, i.e., within a circle two disc diameters in diameter centered on the macula?	Right Eye No Yes Quest. (1) (2) (3)	Left Eye No Yes Quest. (1) (2) (3)
	IF YES OR QUESTIONABLE, ANSWER THE FOLLOWING ITEMS FOR THAT EYE. IF NO, PROCEED TO QUESTION 7.		
c, d)	Is the center of the macular involved?	(1) (2) (3)	(1) (2) (3)
e,f)	Are cystoid changes present?	(1) (2) (3)	(1) (2) (3)

			sion, etc.?	
F YES,	DESCRIBE	E:		

Type or print name of Ophthalmologist performing eye examination:	Certification Numbers (if any)
Type or print name of individual performing visual acuity examination:	
Type or print name of Study Coordinator or other person who reviewed the form for completeness:	