Diabetes Prevention Program

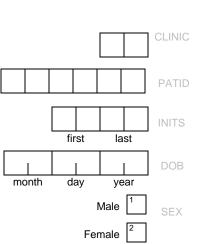
STANDARD FOLLOW-UP VISIT INVENTORY

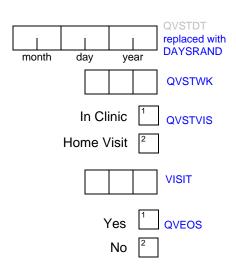
This form is completed at all quarterly follow-up visits, except for annual (i.e., Major) follow-up visits (End-month 3, 6, 9, 15. . .).

Form F01 records the following: weight, blood pressure, pregnancy information, coded and concomitant medication, and local CBC results.

Part I / IDENTIFICATION

- A. Participant Identification
 - 1. Clinic number
 - 2. Participant number
 - 3. Participant's initials
 - 4. Participant's date of birth
 - 5. Participant's sex
- B. Visit Information
 - 1. Date of visit
 - 2. Week of visit
 - 3. Type of visit
 - 4. Outcome visit
 - 5. End of Study





C. Instructions for Form F01 Completion

If this is a Mid-year visit (End-month 6, 18, 30, 42, 54, 66) the data collector completes sections D - Anthropometrics and E - Blood Pressure. If this is not a Mid-year visit, SKIP to Section F - Adverse Events and complete Part III - Medications. If this is the End-month 6 Mid-year visit and the participant was assigned to the pharmacological treatment, complete Part IV - Local Laboratory Results.

first

Initials	of person	reviewing	completed	form
	0. 00.00.			

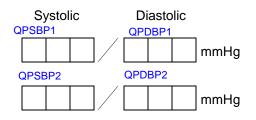
last

		ricipant's initials	Date of b	irth day	year		Date of v	isit day	year	-	PP FORM F01.2 November, 1999 Page 2 of 5
If this is a Mid-year visit (End-month 6, 18, 30, 42, 54, 66), complete section D - Anthropometrics and section E - Blood Pressure.											
Part II /	'PH`	YSICAL AND HIST	ORY								
D. <u>Ant</u>											
1.	We	ight									
	a.	First measuremer	nt							kg	QPWGHT1
	b.	Second measurer	ment							kg	QPWGHT2
		Record c. only if f	irst 2 meas	sureme	ents are no	ot withi	n 0.2 kilo	gram (200 gm).		
	C.	Third measureme	ent							kg	QPWGHT3

- E. Blood Pressure complete only at Mid-year visit
 - 1. Seated Arm Blood Pressure

D.

- a. Blood Pressure Reading 1 (after sitting 5 minutes)
- b. Blood Pressure Reading 2 (after waiting 30 seconds)



Hypertension management aims at maintaining blood pressure < 140/90 mmHg.

Initials of data collector	completing page	2 of this fo	rm
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first	last

		Participant's initials Date of birth Date of visit		PP FORM F01.2 November, 1999 Page 3 of 5
F.	<u>Ad</u>	verse Events		
	1.	During the interval since the last visit, has the participant had any new symptoms, injuries, illness or side effects, or worsening of pre-existing conditions?	YES NC	QPAEQ
١f	YES,	an Adverse Event Report (Form EO1) MUST be completed.		
G.	Pre	gnancy Questions		
0.	<u></u>	grandy <u>queetere</u>	YES NC)
	1.	Does the participant have reproductive potential?		QPPREM
		YES, Review menstrual diary and confirm use and form of contraception and NO, SKIP to Part III - Medications.	CONTINUE.	
	2.	Date of last menstrual period	day year	QPDOLM
		If participant is assigned to pharmacologic treatment, answer 2.a. If participant is assigned to intensive lifestyle treatment, answer 2.b.		
		a. Menstrual period more than one week late?	YES NC	QP1WK
		b. Menstrual period more than two weeks late?	1 2	QP2WK
		If 2.a or 2.b. is YES, a pregnancy test must be performed. If NO, skip to question G.5.		
	3.	Date of pregnancy test	day year	QPDOPT
	4.	Result of pregnancy test	Positive ¹ Negative ²	QPREG
		If POSITIVE, coded metformin must be discontinued and complete a Pre- Confirmation Report (Form E04). Skip to Section H.	gnancy	
	5.	Does the participant plan on becoming pregnant within the next 3 months?	YES NC) QPLAN

If YES, coded metformin must be discontinued.

P	articipant's initials Date of birth	Date of vis	sit day year	DPP FORM F01.2 November, 1999 Page 4 of 5
<u>Part III / N</u>	MEDICATIONS			
	Complete Section H if assigned	d the pharmacological		
H. <u>Code</u>	ed Medication		YES	NO
1.	Has the participant taken any coded MET	FORMIN since the last	t visit?	2 QMTAKM
	If YES, a. Daily dose of METFORMIN per proto	col	850 mg 1700 mg	QMDOSE
	b. What is your best estimate of the par exposure to metformin per protocol?		< 80% ¹ ≥ 80% ²	QMCOMM
		did not return p	bill container ³	
с	For the most recent typical week, wha estimate of the <u>number of days</u> when were taken as prescribed by DPP staf	the metformin pills		QMDAYSM days
2. [Dispensing of Medication			
	Pamoyo labal f	METFORMIN LABEL		

ĩ	·····
	Remove label from medication before dispensing and
	affix here. If not dispensed, check here a QMNOMET
-	· · · · · · · · · · · · · · · · · · ·

Participa	ant's initials	Date of b	irth		_	Date of v	/isit		DPP FORM F01.2
first	last	month	day	year		month	day	year	November, 1999 Page 5 of 5

YES

1

NO

2 QMRXDQ

I. Concomitant Medications

1.	Is the participant currently taking any PRESCRIPTION
	medications other than the coded metformin?
	If YES, list below:

	Medicine Description	Route
a.	QMRXDA	
b.	QMRXDB	
C.	QMRXDC	
d.	QMRXDD	
e.	QMRXDE	
f.	QMRXDF	
g.	QMRXDG	
h.	QMRXDH	
i.	QMRXDI	
j.	QMRXDJ	

Diuretic agents, beta blockers, and fluoxetine > 20 mg/day (or equivalent dose of SSRI) are discouraged.

Part IV / LOCAL LABORATORY RESULTS

If this is the End-month 6 Mid-year visit and the participant was assigned to the pharmacological treatment, RECORD THE CBC RESULTS. If not, STOP.

J. Complete Blood Count	
1. Hemoglobin	g/dL QLHGLOB
2. Hematocrit	QLHCRIT
3. Platelet Count	x10³/ml QLPLATE