Diabetes Prevention Program

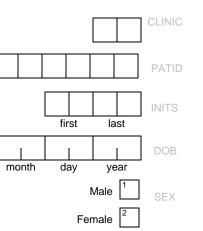
STANDARD FOLLOW-UP VISIT INVENTORY

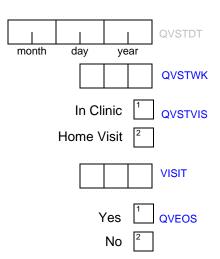
This form is completed at all quarterly follow-up visits, except for annual (i.e., Major) follow-up visits (End-month 3, 6, 9, 15. . .).

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

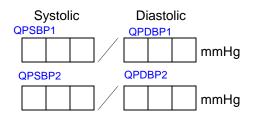
last

		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
		/lid-year visit (End- Blood Pressure.	month 6, 1	8, 30,	42, 54, 66), com	plete sec	tion D	- Anthropon	netrics	and
Part II /	'PH`	YSICAL AND HIST	ORY								
D. <u>Ant</u>	hrop	ometrics - comple	te only at a	a Mid-y	ear visit						
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 initi	ials Date of	birth	Date	of visit		DPI	P FORM F01.2
		firet							Page 3 of 5
		first last	month	day year	mon	ith day	year		-
F.	. <u>Ad</u>	verse Events							
	1.	During the inter	val since the las	t visit, has the	participant		YES	NO	
		had any new sy	mptoms, injurie	s, illness or side	•		1	2	QPAEQ
		worsening of pr	e-existing condi	tions?					
١f	YES	, an Adverse Eve	ent Report (Form	EO1) MUST b	e completed.				
G.	<u>Pre</u>	gnancy Question	<u>15</u>						
	1.	Does the partic	ipant have repro	ductive notenti	əl?		YES	NO 2	QPPREM
		Does the partie	ipant nave repre						Grinten
		YES, Review mer			nd form of cor	ntraception a	and CONTI	NUE.	
	lf I	NO, SKIP to Part	III - Medications	3.					
	2.	Date of last me	nstrual period						QPDOLM
						month	n day	year	
			ant is assigned						
		If particip	ant is assigned	to intensive life	style treatmer	nt, answer 2	.b.		
							YES	NO	
		a. Menstrual p	period more than	n one week late	?		1	2	QP1WK
		h Marada al a			. 0		1	2	QP2WK
		b. Menstrual p	period more thar	i two weeks lat	9?				
			If 2.a or 2.b. is Y	'ES a pregnan	cy test must h	e performe	4		
			If NO, skip to qu		by tost must b	e performed			
		L							
	3.	Date of pregnar	ncy test						QPDOPT
						month	n day	year	
	4.	Result of pregn	ancy test				Posit	ive	QPREG
							Negat	ive ²	QFREG
		If POSITIVE,	coded metformi	n must be disc	ontinued and	complete a	Pregnancy		
		Confirmation R	Report (Form E0	4). Skip to Sec	tion H.				
							YES	NO	
	5.	Does the partic	ipant plan on be	coming pregna	nt within the n	ext 3 month	ns?	2	QPLAN
			If YES, co	ded metformin	must be disc	ontinued.			

F [Participant's initials	Date of birth	Date of visit	year	DPP FORM F01.2 November, 1999 Page 4 of 5
<u>Part III /</u>	MEDICATIONS				
	Complete	Section H if assigned the ph	armacological		
H. <u>Cod</u>	led Medication			YES	NO
1.	Has the participant ta	ken any coded METFORMI	N since the last visit?	1	2 QMTAKM
	If YES, a. Daily dose of ME	TFORMIN per protocol	850 mg 1	1700 mg	QMDOSE
	-	t estimate of the participant's ormin per protocol?	< 8 ¹ ≥ 8 ¹	0% ²	QMCOMM
			did not return pill contai	ner ³	
	estimate of the nu	nt typical week, what is the p <u>mber of days</u> when the metf scribed by DPP staff?	•		QMDAYSM days
2.	Dispensing of Medica	tion			
		METF	ORMIN LABEL		

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

Participa	ant's initials	Date of birth			Date of visit			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