

## 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 CLINIC
2. Participant number PATID
3. Participant's initials INITS  

first		last	
4. Participant's date of birth DOB  

month	day	year
5. Participant's sex SEX  

Male	1	
Female	2	

#### B. Visit Information

1. Date of visit QVSTDT  

month	day	year
2. Week of visit QVSTWK
3. Type of visit QVSTVIS  

In Clinic	1	
Home Visit	2	
4. Outcome visit VISIT
5. End of Study QVEOS  

Yes	1	
No	2	

#### 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.

Initials of person reviewing completed form     Form entered in computer?

first                  last



Participant's initials

first		last	

Date of birth

month	day	year

Date of visit

month	day	year

F. Adverse 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

NO

QPAEQ

If YES, an Adverse Event Report (Form EO1) MUST be completed.

G. Pregnancy Questions

1. Does the participant have reproductive potential?

YES

NO

QPPREM

If YES, Review menstrual diary and confirm use and form of contraception and CONTINUE.  
If NO, SKIP to Part III - Medications.

2. Date of last menstrual period

month	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

NO

QP1WK

- b. Menstrual period more than two weeks late?

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

month	day	year

QPDOPT

4. Result of pregnancy test

Positive

Negative

QPREG

If POSITIVE, coded metformin must be discontinued and complete a Pregnancy Confirmation Report (Form E04). Skip to Section H.

5. Does the participant plan on becoming pregnant within the next 3 months?

YES

NO

QPLAN

If YES, coded metformin must be discontinued.

Participant's initials

first		last	

Date of birth

month	day	year

Date of visit

month	day	year

Part III / MEDICATIONS

Complete Section H if assigned the pharmacological

H. Coded Medication

- |  | YES  | NO                                  |                 |
|--|--|-------------------------------------|-----------------|
| 1. Has the participant taken any coded METFORMIN since the last visit?   | <input type="checkbox"/>                               | <input type="checkbox"/>            | QMTAKM          |
| If YES,  |  |                                     |                 |
| a. Daily dose of METFORMIN per protocol  | 850 mg<br><input type="checkbox"/>                     | 1700 mg<br><input type="checkbox"/> | QMDOSE          |
| b. What is your best estimate of the participant's level of exposure to metformin per protocol?  | < 80% <input type="checkbox"/>                         | ≥ 80% <input type="checkbox"/>      | QMCOMM          |
|  | did not return pill container <input type="checkbox"/> |                                     |                 |
| c. For the most recent typical week, what is the participant's estimate of the <u>number of days</u> when the metformin pills were taken as prescribed by DPP staff? | <input type="checkbox"/>                               |                                     | QMDAYSM<br>days |

2. Dispensing of Medication

METFORMIN LABEL

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

Participant's initials

first		last	

Date of birth

month	day	year	

Date of visit

month	day	year	

I. Concomitant Medications

1. Is the participant currently taking any PRESCRIPTION medications other than the coded metformin?

YES

NO

QMRXDQ

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

		.	
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g/dL

QLHGLOB

2. Hematocrit

		.	
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%

QLHCRT

3. Platelet Count

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x10<sup>3</sup>/ml

QLPLATE