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
   - Male [1]
   - Female [2]

   SEX

B. Visit Information

1. Date of visit ☐☐ ☐☐ ☐☐ QVSTDT replaced with DAYSRAND (month day year)
2. Week of visit ☐☐☐ QVSTWK
3. Type of visit
   - In Clinic [1]
   - Home Visit [2]

   QVSTVIS
4. Outcome visit ☐☐☐ VISIT
5. End of Study
   - Yes [1]
   - No [2]

   QVEOS

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 ☐☐☐☐ (first last) Form entered in computer? ☐

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 / PHYSICAL AND HISTORY

D. Anthropometrics - complete only at a Mid-year visit

1. Weight

a. First measurement ___.___ kg QPWGHT1

b. Second measurement ___.___ kg QPWGHT2

Record c. only if first 2 measurements are not within 0.2 kilogram (200 gm).

c. Third measurement ___.___ kg QPWGHT3

E. Blood Pressure - complete only at Mid-year visit

1. Seated Arm Blood Pressure

	Systolic	Diastolic	
a. Blood Pressure Reading 1 (after sitting 5 minutes)	QPSBP1 ___	QPDBP1 ___	mmHg
b. Blood Pressure Reading 2 (after waiting 30 seconds)	QPSBP2 ___	QPDBP2 ___	mmHg

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

Initials of data collector completing page 2 of this form (first, last)

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 [1] NO [2] QPAEQ

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

G. Pregnancy Questions

1. Does the participant have reproductive potential? YES [1] NO [2] 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 [1] NO [2] 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 (month day year) QPDOPT

4. Result of pregnancy test Positive [1] Negative [2] 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 [1] NO [2] QPLAN

If YES, coded metformin must be discontinued.

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?	1	2	QMTAKM

If YES,

	850 mg	1700 mg	
a. Daily dose of METFORMIN per protocol	1	2	QMDOSE

b. What is your best estimate of the participant's level of exposure to metformin per protocol? QMCOMM

- < 80% [1]
- ≥ 80% [2]
- did not return pill container [3]

c. For the most recent typical week, what is the participant's estimate of the number of days when the metformin pills were taken as prescribed by DPP staff? QMDAYSM

[ ] days

2. Dispensing of Medication

METFORMIN LABEL

Remove label from medication before dispensing and affix here. If not dispensed, check here [1] QMNOMET

I. Concomitant Medications

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

YES [1] NO [2] QMRXDQ

	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