Participant ID	Nickname	Date of visit
		month day year

Diabetes Prevention Program Outcomes Study
F03 INTERIM VISIT INVENTORY

> This form is completed at follow-up visits for all participants when the Mid-year Visit Inventory (Form F01) and Annual Visit Inventory (Form F02) are not completed. Form F03 is used to document the following: SAEs and all CVD events, pregnancy, metformin management, arm blood pressure for hypertension management, or collection of CBL specimens for visits that are not mid-year or annual.

PART I / IDENTIFICATION

A. Participant Identification

1. Clinic number

2. Participant number

3. Nickname

4. Date of randomization
   month   day   year

5. Sex   Male ☐ 1   Female ☐ 2

6. Date of visit   JIVSTDT replaced with DAYSRAND
   month   day   year

7. Outcome visit   VISIT ▮▮▮▮▮▮▮▮▮ INT

8. Visit location   JIVISLOC   Clinic ☐ 1   Home ☐ 2   Phone ☐ 3
   Non-clinic medical facility ☐ 4

B. Reason for Interim Visit

> Complete the corresponding sections of this form for the reason(s) checked below. Part II, section D must be completed regardless of reason(s) for interim visit.

CHECK ALL THAT APPLY

1. Study metformin management... ☐ 1 JIMEDMG

2. Hypertension management.. ☐ 1 JIHYPMG

3. Pregnancy management.. ☐ 1 JIPRGMG

4. Serious adverse event and CVD management..................... ☐ 1 JISAEMG

5. Collection of specimen for CBL (e.g. OGTT)........................ ☐ 1 JISPEC
   → Complete CBL specimen transmittal form.

6. Repeat collection of outcome found to be deficient............ ☐ 1 JIOUT

7. Diabetes diagnosed by PCP.. ☐ 1 JIDBMG

8. Other... ☐ 1 JIOTH

JIFORMIN

Identification code of person reviewing completed form | Form entered in computer? ☐

Participant ID

Nickname

Date of visit

month   day   year

DPPOS **F03.7**
November 2009
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C. Blood Pressure

1. Seated Arm Blood Pressure

   Systolic   **Diastolic**

   a. Blood Pressure Reading 1
      (after sitting 5 minutes)

      JISBP1 ☐☐☐ / ☐☐☐ JIDBP1 mmHg

   b. Blood Pressure Reading 2
      (after waiting 30 seconds)

      JISBP2 ☐☐☐ / ☐☐☐ JIDBP2 mmHg

> **Inform participant and PCP via letter if**
> - The participant is NON-DIABETIC and if systolic BP $\geq$ 140 or diastolic BP $\geq$ 90 on the mean of 1a and 1b.
>   **OR**
> - The participant is DIABETIC and if systolic BP $\geq$ 130 or diastolic BP $\geq$ 80 on the mean of 1a and 1b.

PART II / HISTORY

> **This section must be completed for all participants.**

D. Events and Procedures

1. Since the last contact or visit, has the participant experienced any of the following?

   CHECK ALL THAT APPLY

   a. Any acute life threatening event?.. ☐1 JIACTT

   b. Permanent or severe disability?... ☐1 JIDISA

   c. Required or prolonged hospitalization?.. ☐1 JIHOSP

   d. Overdose of any medication?... ☐1 JIOVDO

   e. Pregnancy resulting in congenital abnormality or birth defect?.... JICONG ☐1

   f. Required intervention or treatment to prevent serious adverse event?.... ☐1 JITSAE

   g. Possible CVD event?... ☐1 JIPCVD

   h. Renal failure?.. ☐1 JIRENFL

   i. Kidney transplant?.. ☐1 JIKIDTRNS

   If checked, complete E08 for each event.

   j. Eye procedure?... JIRETINA ☐1 → Complete E09

   k. Gastric reduction surgery?................................ JIGAS ☐1 → Complete E11

> **If any of options a. – i. are checked, complete a separate E08 for each event. For multiple CVD events that may occur during the same hospitalization, complete an E08 for the first CVD diagnosis and report subsequent events (from the same hospitalization) on the same E08 form.**
>
> **If option j is checked, complete an E09 form. If option k is checked, complete an E11 form.**

Participant ID

Nickname

Date of visit

month   day   year

PART III/ MLS PARTICIPANT SECTION

> **Complete sections E and F for all MLS participants.**

E. Metformin Status

1. Has the participant taken any STUDY METFORMIN since the last visit? Yes [1] No [2] **JITAKMT**

> **IF YES, complete the F08 Metformin Safety & Adherence Form for this participant.**

F. Dispensing of Metformin

> **Complete the Metformin Safety Assessment Checklist for all participants receiving study metformin before metformin is dispensed.**

1. How many months of metformin was dispensed (0, 3, 6)?……………………………….. [ ] **JIDISP**

METFORMIN LABEL | Remove label from metformin before dispensing and affix here.

METFORMIN LABEL | Remove label from metformin before dispensing and affix here.