Diabetes Prevention Program Outcomes Study

F06 NON-CLINIC VISIT INVENTORY

This form is completed for participants at scheduled Mid-year or Annual visits conducted outside the DPP-OS clinic (01M, 01A, 02M, 02A, ….). Refer to the MOO for a prioritized table of procedures to collect. Clinics can complete as many sections of this form as possible. Complete Part I-III for a mid-year visit; and the entire form for an annual visit.

Complete Part II only if visit is conducted at home or at a non-clinic medical facility where necessary equipment is available.

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. Outcome visit

01M	01A	02M	02A	03M	03A	04M	04A	05M	05A	06M	06A
07M	07A	08M	08A	09M	09A	10M	10A	11M	11A		

VISIT

7. Date of visit — month day year — KGVSTDT replaced with DAYSRAND
8. Visit Location
   - Home [1] — KGVISLOC
   - Phone [2]
   - Non-clinic medical facility [3]

Identification code of person reviewing completed form [ ][ ][ ] FORMIN

Form entered in computer? [ ]

Part II / PHYSICAL AND HISTORY

Complete Section B only if mercury sphygmomanometer is available and complete Section C.1. only if balance beam scale is available for weight collection. Complete Section C2 for annual visits only.

B. Blood Pressure

1. Seated Arm Blood Pressure

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

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

	Systolic		Diastolic	
KGSBP1	___	/	___ mmHg	KGDBP1
KGSBP2	___	/	___ mmHg	KGDBP2

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

C. Anthropometrics

- **For C.1 – Weight, record Measure 3 only if first 2 measurements are not within 0.2 Kilograms (200g).**
- **For C.2 – (Annual visits only) Waist Circumference record Measure 3 only if first 2 measurements are not within 0.5 cm.**

	Measure 1 KGWGHT1	**Measure 2** KGWGHT2	**Measure 3** KGWGHT3
1. Weight	___ . ___ kg	___ . ___ kg	___ . ___ kg
2. Waist Circumference	___ . ___ cm KGWSTC1	___ . ___ cm KGWSTC2	___ . ___ cm KGWSTC3

D. Concomitant Medications

1.Has the participant taken any **PRESCRIPTION** medications within the past 2 weeks (excluding study metformin)? Yes [1] No [2] KGRXDQ

If YES, list below:

	Medicine Description		Route
a.		KGRXDA	
b.		KGRXDB	
c.		KGRXDC	
d.		KGRXDD	
e.		KGRXDE	
f.		KGRXDF	
g.		KGRXDG	
h.		KGRXDH	
i.		KGRXDI	
j.		KGRXDJ	

E. Events

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]	KGACTT
b.	Permanent or severe disability?	[1]	KGDISA
c.	Required or prolonged hospitalization?	[1]	KGHOSP
d.	Overdose of any medication? KGOVDO	[1]	If checked, complete E08 for each event.
e.	Pregnancy resulting in congenital abnormality or birth defect?	[1]	KGCONG
f.	Required intervention or treatment to prevent serious adverse event?	[1]	KGTSAE
g.	Possible CVD event?	[1]	KGPCVD

If any of questions a. – g. are checked, complete a separate E08 for each event. For multiple CVD events that may occur during the same hospitalization: complete an E08 form for the first CVD diagnosis and report subsequent events (from the same hospitalization) on the same E08 form.

Part III/ MLS PARTICIPANT SECTION

Complete question F1 for all MLS participants. Complete the rest of section F if participant has taken study metformin since last visit.

F. Metformin Status

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

If NO, PROCEED to Section H.
If YES, CONTINUE with Section F.

a. Daily dose of METFORMIN per protocol

b. What is your best estimate of the participant's level of exposure to metformin per protocol? 850 mg [1] 1700 mg [2] KGDOSE

<80% [1] KGCOMPM

≥80% [2]

did not return pill container [3]

2. Since the last visit, has the participant had any problems taking his/her metformin pills as prescribed? Yes [1] No [2] KGPROB

If Yes to question 2, what are the main problems in taking pills as prescribed?

CHECK ALL THAT APPLY

a. Forgets to take pills in general..... [1] KGFORG

b. Forgets to take evening dose..... [1] KGEVEN

c. Inconvenient to take pills as prescribed..... [1] KGINCON

d. GI reaction to pills..... [1] KGIRCT

e. Disruption of regular routine..... [1] KGDISRP

f. Hospitalization/New illness/Medical reason..... [1] KGMEDC

g. Lack of motivation..... [1] KGMOTV

h. Lost/misplaced pills..... [1] KGLOST

i. Other (specify): _____ KGOTHSP _____ [1] KGOTHER

3. **If YES** to question 2, what plan or strategy will the participant use to deal with this problem?

CHECK ONE MAIN STRATEGY

Will continue current plan..... [1] KGSTRAT

New time routine..... [2]

New strategy/routine..... [3]

New reminder device..... [4]

Change type and/or frequency of DPP-OS staff communication... [5]

Does NOT want to deal with the problem..... [6]

Other (specify): _____ KGSTSPEC [7]

If option 1 (will continue current plan) is selected,

CHECK ALL THAT APPLY

i. time routine (e.g. time of day, meal time) [1] KGTIME

ii. strategy routine (e.g. takes with other pills; medication in a convenient place) [1] KGSTRRO

iii. reminder device (e.g. pill box, calendar) [1] KGRMND

iv. other [1] KGOTHRS

G. Pregnancy Questions

Complete this question for all MLS women who are actively taking study metformin.

1. Does the participant have reproductive potential? Yes [1] No [2] KGPREM

If YES, review menstrual history, confirm use and form of contraception and CONTINUE.

a. Date of last menstrual period ____ ____ ____ KGDOLM
month day year

i. Menstrual period more than one week late? Yes [1] No [2] KG1WK

If 1.a.i is YES, a pregnancy test must be performed.

If NO, skip to question 1. b.

a.) Date of pregnancy test ____ ____ ____ KGDOPT
month day year

b.) Result of pregnancy test Positive [1] Negative [2] KGPREG

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

b. Does the participant plan on becoming pregnant within the next 6 months? Yes [1] No [2] KGPLAN

If YES, study metformin must be discontinued.

H. 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)? ..... [ ] KGDISP

METFORMIN LABEL

Remove label from metformin before dispensing and affix here.

METFORMIN LABEL

Remove label from metformin before dispensing and affix here.

IF metformin is NOT dispensed for reasons other than a previously reported permanent condition, a Metformin Discontinuation Form (Form F07) must be completed.

IF THIS IS A MID-YEAR VISIT, STOP. FORM IS COMPLETE. IF THIS IS AN ANNUAL VISIT, CONTINUE.

I. Complete Blood Count

If the MLS participant is actively taking study metformin, RECORD THE CBC RESULTS.

1. Hemoglobin [ ][ ].[ ] g/dL KGHGLOB
2. Hematocrit [ ][ ].[ ] % KGHCRIT
3. Platelet Count [ ][ ][ ] X10/ml KGPLATE

Part IV/ ANNUAL ASSESSMENTS

Complete Section J for each annual visit. This section should be completed after the Neuropathy Questionnaire has been completed (Form Q15).

J. Neuropathy Screening Instrument

1. Appearance and Condition of Both Feet

RIGHT KGNORMR

a. Normal Yes [1] No [2]

IF NO, CHECK ALL THAT APPLY:

i. Deformities Yes [1] KGDEFR

ii. Dry skin, callus Yes [1] KGSKINR

iii. Infection Yes [1] KGINFR

iv. Fissure Yes [1] KGFISSR

v. Other, Yes [1] KGOTHR

Specify: _____

LEFT KGNORML

b. Normal Yes [1] No [2]

IF NO, CHECK ALL THAT APPLY:

i. Deformities Yes [1] KGDEFL

ii. Dry skin, callus Yes [1] KGSKINL

iii. Infection Yes [1] KGINFL

iv. Fissure Yes [1] KGFISSL

v. Other, Yes [1] KGOTHL

Specify: _____

RIGHT

2. Ulceration — Present [1] Absent [2] KGULCRR

3. Ankle Reflexes — Present [1] Present/ Reinforcement [2] Absent [3] KGREFR

4. Vibration perception at great toe — Present (<10 sec) [1] Reduced (≥10 sec) [2] Absent [3] KGTOER

5. 10gm filament (record number of applications detected) — Present (≥ 8) [1] Reduced (1-7) [2] Absent (0) [3] KGFILR

LEFT

6. Ulceration — Present [1] Absent [2] KGULCRL

7. Ankle Reflexes — Present [1] Present/ Reinforcement [2] Absent [3] KGREFL

8. Vibration perception at great toe — Present (<10 sec) [1] Reduced (≥10 sec) [2] Absent [3] KGTOEL

9. 10gm filament (record number of applications detected) — Present (≥ 8) [1] Reduced (1-7) [2] Absent (0) [3] KGFILL

K. History

1. Since the last annual visit, did the participant experience any of the following?

	Yes	No	
a. Skin rashes?	1	2	KGRASH
b. Frequent stomach pains, bloating, nausea, diarrhea, or loss of appetite?	1	2	KGSTOM
c. Unexplained weight loss?	1	2	KGLOSSN
d. Increased thirst (drinking more liquids than usual)?	1	2	KGTHRST
e. Urinating more often than usual?	1	2	KGURINT
f. Infection requiring medical attention?	1	2	KGINTMA
g. Sprains or fractures requiring medical attention?	1	2	KGSPRN

2. Did a health care provider (outside the DPPOS) diagnose the participant with a new onset of the following since the last annual visit?

	Yes	No	
a. Diabetes (sugar in blood or urine)?	1	2	KGDIAB
b. High blood pressure?	1	2	KGHYPER
c. Any lipid abnormality (high cholesterol, high triglycerides, etc.)?	1	2	KGLIPID
d. Ulcer (stomach or duodenal), or intestinal bleeding?	1	2	KGULCR
e. Hepatitis?	1	2	KGHEPAT
f. Cancer?	1	2	KGCNCR
g. Gallstones, gallbladder disease, or gallbladder surgery?	1	2	KGGALL
h. Gout?	1	2	KGGOUT
i. Thyroid disease?	1	2	KGTHYR
j. Transient ischemic attack (TIA)?	1	2	KGTIA

L. Diabetes Management

Complete for diabetics only.

1. If diabetic, is participant taking insulin? Yes [1] No [2] KGINSUL

IF YES,

a. Number of units per day [ ][ ][ ] units per day KGUNITS

b. Type of insulin regimen

Infusion pump [1] KGREGM

Injection [2]

i. If injection, number of injections per day [ ][ ] per day KGINJCT

Part V/ MEDICAL HISTORY

M. Interval Cardiovascular History

Ask the participant to think about the last 12 months when answering the following questions:

1. Have you had any pain or discomfort in your chest? Yes [1] No [2] KGPAIN

2. Have you had any pressure or heaviness in your chest? Yes [1] No [2] KGPRES

If Questions 1 AND 2 are NO, skip to Section M. If either are Yes, continue.

a. Do you get it when you walk uphill or hurry? Yes [1] No [2] KGHURRY

b. Do you get it when you walk at an ordinary pace on the level? Yes [1] No [2] KGLEVEL

c. When you get it in your chest, what do you do?

Stop [1]

Slow down [2] KGDO

Continue at same pace [3]

d. Does it go away when you stand still? Yes [1] No [2] KGSTILL

IF YES,

i. How soon?

10 min. or less [1]

More than 10 min. [2] KGSOON

e. Where do you get this pain or discomfort:

i. Sternum (central chest)? Yes [1] No [2] KGSTER

ii. Left anterior chest? Yes [1] No [2] KGLCHST

iii. Left arm? Yes [1] No [2] KGLARM

f. Have you ever had a severe pain across the front of your chest lasting for half an hour or more? Yes [1] No [2] KG30MIN

N. Stroke / TIA

1. During the past 12 months, have you had any sudden feeling of numbness, tingling, or loss of feeling in either arm, hand, leg, foot, or face? Yes [1] No [2] KGNOFEEL

IF YES,
a. How long did the symptoms last? KGNOFLT

< 1 hour [1]
1-24 hour (s) [2]
> 24 hours [3]

2. During the past 12 months, have you had any sudden attacks of paralysis, or loss of use of either arm, hand, leg, or foot? Yes [1] No [2] KGPARL

IF YES,
a. How long did the symptoms last? KGPARLT

< 1 hour [1]
1-24 hour (s) [2]
> 24 hours [3]

3. During the past 12 months, have you had any sudden loss of eyesight or blurring of vision for a short period of time? Yes [1] No [2] KGBLUR

IF YES,
a. How long did the symptoms last? KGBLURT

< 1 hour [1]
1-24 hour (s) [2]
> 24 hours [3]

4. During the past 12 months, have you had any sudden attacks of changes in speech, loss of speech or inability to say words for more than two minutes? — Yes [1] No [2] KGLUR

   IF YES,
   a. How long did the symptoms last? — < 1 hour [1] KGLURT; 1-24 hour (s) [2]; > 24 hours [3]

5. During the past 12 months, have you had any spells of dizziness, difficulty in walking, lightheadedness or loss of balance? — Yes [1] No [2] KGDIZY

   IF YES,
   a. How long did the symptoms last? — < 1 hour [1] KGDIZYT; 1-24 hour (s) [2]; > 24 hours [3]

Part VI / INTERVAL DRINKING, SMOKING, ASPIRIN, & ROUTINE CARE HISTORY

O. Drinking Status

1. During the past 12 months, have you consumed an average of at least one alcoholic beverage per week? — Yes [1] No [2] KGWK

   IF YES, for the most recent normal (i.e., usual) week:

   a. How many 12 oz. bottles of beer did you consume during the past 7 days? — [ ][ ] 12 oz Bottles KGBEER

   b. How many 4 oz. glasses of wine did you consume during the past 7 days? — [ ][ ] 4 oz Glasses KGWINE

   c. How many 1.5 oz. shots of hard liquor or mixed drinks did you consume during the past 7 days? — [ ][ ] 1.5 oz Shots KGMIXD

2. During the past 12 months, have you ever consumed 7 or more alcoholic beverages (including mixed drinks, shots, beer, and/or wine) within a 24-hour period? — Yes [1] No [2] KGBINGE

   IF YES,
   a. About how often is this (that you have had 7 or more drinks within a 24-hour period)? — No answer [1] KGBTIME; Rare or less than once a month [2]; 1-3 times per month [3]; Once a week or more [4]

P. Smoking Status

1. During the past 30 days, have you smoked any cigarettes? Yes [1] No [2] KGSMOK

   IF YES,

   a. On average, how many cigarettes per day? [ ][ ] KGSDAY cigarettes per day

Q. Aspirin Status

1. During an average week, how often do you take one or more aspirin tablets regardless of dosage? KGASPIR

   - Never [1]
   - Less than 1 day per week [2]
   - 1 or 2 days per week [3]
   - 3 to 4 days per week (includes every other day) [4]
   - 5 or 6 days per week [5]
   - Every day [6]

R. Routine Medical Care

1. During the past 3 months, how many times have you, outside the DPPOS: (none = 0)

   a. called a health care provider (for a specific issue/concern)? [ ][ ] time(s) KGCHCD

   b. had a regularly scheduled out-patient visit(s)? [ ][ ] time(s) KGCOPV

   c. had urgent care visit(s) (i.e. doctor's office, clinic; not to emergency room)? [ ][ ] time(s) KGUCV

   d. had an emergency room visit(s)? [ ][ ] time(s) KGCERV

2. During the past 3 months, how many days have you lost from school, work, or household activities due to illness or injury or medical care including visits related to the DPPOS? (round to nearest half day) [ ][ ] . [ ] day(s) KGCLOST