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 DPPOS 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 Parts I-III and VII 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 — VISIT
7. Date of visit — KGVSTDT replaced with DAYSRAND (month / day / year)
8. Visit Location — KGVISLOC
   - Home [1]
   - Phone [2]
   - Non-clinic medical facility [3]

KGFORMIN

Identification code of person reviewing completed form

Form entered in computer?

PART II / PHYSICAL AND HISTORY

Complete Section B only if aneroid 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

		Systolic		Diastolic	
a. Blood Pressure Reading 1 (after sitting 5 minutes)	KGSBP1	☐☐☐	/	☐☐☐ mmHg	KGDBP1
b. Blood Pressure Reading 2 (after waiting 30 seconds)	KGSBP2	☐☐☐	/	☐☐☐ mmHg	KGDBP2

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.**

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

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

b. Permanent or severe disability?.. ☐ 1

c. Required or prolonged hospitalization?.. ☐ 1

d. Overdose of any medication?.. ☐ 1

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

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

g. Possible CVD event?.. ☐ 1

h. Renal failure?.. ☐ 1

i. Kidney transplant?.. ☐ 1

If checked, complete E08 for each event.

j. Eye procedure?.. ☐1 → Complete E09

k. Gastric reduction surgery?.. ☐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.

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 KGTAKM

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)? .... ☐ 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, SKIP TO PART VII (CONCOMITANT MEDICATIONS). IF THIS IS AN ANNUAL VISIT, CONTINUE.

Part IV/ ANNUAL ASSESSMENTS

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

G. Neuropathy Screening Instrument

1. Appearance and Condition of Both Feet

RIGHT

a. Normal KGNORMR Yes 1 No 2

IF NO, CHECK ALL THAT APPLY:

1. Deformities KGDEFR Yes 1
2. Dry skin, callus KGSKINR Yes 1
3. Infection KGINFR Yes 1
4. Fissure KGFISSR Yes 1
5. Other, KGOTHR Yes 1
   i. **If OTHER,** specify: KGSPECR

LEFT

b. Normal KGNORML Yes 1 No 2

IF NO, CHECK ALL THAT APPLY:

1. Deformities KGDEFL Yes 1
2. Dry skin, callus KGSKINL Yes 1
3. Infection KGINFL Yes 1
4. Fissure KGFISSL Yes 1
5. Other, KGOTHL Yes 1
   i. **If OTHER,** specify: KGSPECL

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) — ☐☐ applications out of 10 KGNUMFILR

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) — ☐☐ applications out of 10 KGNUMFILL

H. 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

If YES, complete an E12 Cancer Report form.

	Yes	No	
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
k. Kidney disease?	1	2	KGKIDNDI
l. Retinopathy?	1	2	KGRETPTY

I. 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]

   1. If injection, number of injections per day ___ per day KGINJCT

PART V/ MEDICAL HISTORY

J. 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 K. 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? KGDO
   - Stop [1]
   - Slow down [2]
   - Continue at same pace [3]

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

   1. How soon? KGSOON
      - 10 min. or less [1]
      - More than 10 min. [2]

e. Where do you get this pain or discomfort:

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

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

3. 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

K. 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? KGLURT
< 1 hour [1]
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, ANTI-INFLAMMATORY MEDICATION, & ROUTINE CARE HISTORY

L. 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]

M. 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

N. Anti-inflammatory Medication 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

If you take aspirin (options 2-6),

	Type of aspirin	Do you take this type of aspirin? Yes / No	If YES, 1. On days you use aspirin, what is the total number of pills you take?
a.	Baby-strength aspirin (81mg)	KGASPBABY 1 2	KGASPBABNO __ __ . __
b.	Regular-strength aspirin (325mg)	KGASPREG 1 2	KGASPREGNO __ __ . __
c.	Extra -strength aspirin (500mg)	KGASPEX 1 2	KGASPEXNO __ __ . __

2. Has the participant taken a non- prescription non-steroidal anti-inflammatory drug (NSAID) other than aspirin in the past month? (Many pain relievers are NSAIDs, including ibuprofen, Advil, Motrin, and Aleve)

Yes [1] No [2] KGNSAID

If YES,

	Type of NSAID	**Did you take this NSAID?** Yes No	**If YES, 1. On average how many days per month?**	**2. On days you use the NSAID, what is the total number of pills you take?**
a.	Ibuprofen (e.g. Advil, Motrin, Nuprin)	KGNSAIDIB [1] [2]	KGIBDAY [ ][ ] days	KGIBNO [ ][ ] pills
b.	Naproxen (e.g. Aleve, Anaprox, Naprosyn, Naprelan)	KGNSAIDNA [1] [2]	KGNADAY [ ][ ] days	KGNANO [ ][ ] pills
c.	Other	KGNSAIDOTH [1] [2]	KGOTHDAY [ ][ ] days	KGOTHNO [ ][ ] pills
	3. If OTHER, specify:	KGNSAIDSP		

O. 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

PART VII / CONCOMITANT MEDICATIONS

Complete this section for all participants.

P. 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,

   a. Total number of medications taken (including any medications listed on supplemental sheets)   [|]   KGTOTMEDS

   b. List medications below: KGDRUG1-30

	Medicine Description	Route
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		

Specify additional medications by appending the CONMED supplemental sheet to this form as needed.

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

Q. Nutritional Supplements

Multivitamins are identified by the word multivitamin in the bottle label or if the number of active ingredients are 5 or more. If there are fewer than 5 active ingredients in a supplement, include them in Question Q3. Multivitamins should exclude B-Complex and instead the relevant B-vitamins should be included in the specific supplement list in Question Q3.

1. Has the participant taken any **non-prescription** oral multivitamins at least once a week in the past 12 months? KGMULTIV — Yes [1] No [2]
2. Has the participant received any Vitamin B12 shots in the past 12 months? KGB12SHOT — Yes [1] No [2]

   If YES,

   a. Number of shots received in the past 12 months [ ][ ] shots KGSHOTNO
3. Has the participant taken any **non-prescription** oral supplements other than multivitamins at least once a week in the past 12 months? KGSUP — Yes [1] No [2]

   If YES,

		Type of supplement	Did the participant take this supplement? Yes	No	If YES, 1. Number of months used in the past 12 months?	2. Average number of doses per week?
KGOMEGA	a.	Omega 3 (fish oil)	1	2	KGOMEGAMO [ ][ ] months	KGOMEGANO [ ][ ]
KGVITA	b.	Vitamin A (not Beta-carotene)	1	2	KGVITAMO [ ][ ] months	KGVITANO [ ][ ]
KGVITB6	c.	Vitamin B6	1	2	KGVITB6MO [ ][ ] months	KGVITB6NO [ ][ ]
KGVITB12	d.	Vitamin B12	1	2	KGVITB12MO [ ][ ] months	KGVITB12NO [ ][ ]
KGVITC	e.	Vitamin C (with or without rose hips)	1	2	KGVITCMO [ ][ ] months	KGVITCNO [ ][ ]
KGVITD	f.	Vitamin D	1	2	KGVITDMO [ ][ ] months	KGVITDNO [ ][ ]
KGVITE	g.	Vitamin E	1	2	KGVITEMO [ ][ ] months	KGVITENO [ ][ ]
KGCAL	h.	Calcium	1	2	KGCALMO [ ][ ] months	KGCALNO [ ][ ]
KGCHRO	i.	Chromium	1	2	KGCHROMO [ ][ ] months	KGCHRONO [ ][ ]
KGFOL	j.	Folate (Folic Acid)	1	2	KGFOLMO [ ][ ] months	KGFOLNO [ ][ ]
KGIRON	k.	Iron	1	2	KGIRONMO [ ][ ] months	KGIRONNO [ ][ ]
KGMAG	l.	Magnesium	1	2	KGMAGMO [ ][ ] months	KGMAGNO [ ][ ]
KGPOT	m.	Potassium	1	2	KGPOTMO [ ][ ] months	KGPOTNO [ ][ ]
KGSEL	n.	Selenium	1	2	KGSELMO [ ][ ] months	KGSELNO [ ][ ]
KGZINC	o.	Zinc	1	2	KGZINCMO [ ][ ] months	KGZINCNO [ ][ ]