Diabetes Prevention Program Outcomes Study

F06 ANNUAL NON-CLINIC VISIT INVENTORY

This form is completed at Annual visits conducted outside the DPPOS clinic year 13 and on (13A, 14A…). 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 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

If 'Phone' (option 2) is selected, SKIP to PART III/EVENTS AND HISTORY.

Identification code of person reviewing completed form

Form entered in computer?

PART II / PHYSICAL

Complete Section B only if aneroid sphygmomanometer is available. Complete Section C.1. only if balance beam or digital scale is available for weight collection.

B. Blood Pressure

1. Seated Arm Blood Pressure

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

For participants without diabetes follow the JNCP guidelines and for participants with diabetes follow the ADA guidelines (referred to in Chapter 6 of the Manual of Operations) to determine if a blood pressure letter needs to be sent to the participant and their PCP.

C. Anthropometrics

- **For C.1 – Weight, record Measure 3 only if first 2 measurements are not within 0.2 Kilograms (200g).**
- **For C.2 – Waist Circumference record Measure 3 only if first 2 measurements are not within 0.5 cm. Complete waist circumference at 13A, 14A, and 16A visits only.**

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

PART III / EVENTS AND HISTORY

D. Events and Procedures

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

MARK WITH AN 'X' ALL THAT APPLY

a. Any acute life threatening event?..... 1
b. Permanent or severe disability?..... 1
c. Required or prolonged hospitalization?..... 1

If checked, complete E08 for each event.

If 'Required or prolonged hospitalization' is selected, mark any events that caused or occurred during the hospitalization.

1. Infection (including nosocomial)?..... 1
2. Fracture?..... 1

d. Pregnancy resulting in congenital abnormality or birth defect?..... 1 → Complete E08

e. Required intervention or treatment to prevent serious adverse event?.... 1
f. Possible CVD event?..... 1
g. Renal failure?..... 1
h. Kidney transplant?..... 1

If checked, complete E08 for each event.

i. Joint replacement?..... 1 → Complete E16
j. Eye procedure?..... 1 → Complete E09
k. Gastric reduction surgery?..... 1 → Complete E11
l. Cancer event?..... 1 → Complete E12

If any of options a. – h. 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 c.1 is marked complete the E14 form. If option c.2 is marked complete the E15 form.

If option i is checked, complete an E16 form. If option j is checked, complete an E09 form. If option k is checked, complete an E11 form. If option l is checked, complete an E12 form.

E. History

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

	Yes	No	
a. Frequent stomach pains, bloating, nausea, diarrhea, or loss of appetite? ...	1	2	KGSTOM
b. Unexplained weight loss?	1	2	KGLOSSN
c. Sprains or fractures requiring medical attention?	1	2	KGSPRN
d. A fall and landed on the floor, ground, OR has fallen and hit an object like a table or chair?	1	2	KGFALL

If YES, complete an R25 Falls Report.

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

If YES, complete an E10 Outside PCP Diabetes Diagnosis Event Report form.

b. High blood pressure?	1	2	KGHYPER
c. Any lipid abnormality (high cholesterol, high triglycerides, etc.)?.....	1	2	KGLIPID
d. Dementia?.....	1	2	KGDEMT
e. Alzheimer's disease?.....	1	2	KGALZDS
f. Hearing loss?	1	2	KGHEAR

PART IV/ MLS PARTICIPANT SECTION

Complete sections F and G for all MLS participants.

F. 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.

G. Dispensing of Metformin

Complete the Metformin Safety and Adherence Checklist for all participants receiving study metformin before metformin is dispensed.

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

METFORMIN LABELS:

Remove label from metformin before dispensing and affix here.	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.

PART V/ MEDICAL HISTORY

H. CHD Status

Complete this section at 14A, 16A, and 18A visits only.

1. Does the participant have atherosclerotic vascular disease including coronary disease, cerebrovascular disease, or peripheral vascular disease? (NOTE: abnormal ABI does not define PVD in the absence of signs or symptoms) Yes [1] No [2] KGATHER

2. Family history of premature CHD (any event or CVD procedure before age 55 in father or other first-degree male relative, or before age 65 in mother or other first-degree female relative) Yes [1] No [2] KGHIST

I. 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? KGPAIN Yes [1] No [2]

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

If Questions 1 AND 2 are NO, skip to section J. If either are Yes, continue.

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

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

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? KGSTILL Yes [1] No [2]

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)? KGSTER Yes [1] No [2]
2. Left anterior chest? KGLCHST Yes [1] No [2]
3. Left arm? KGLARM Yes [1] No [2]

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

J. 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? KGNOFEEL Yes [1] No [2]

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

6. Since your last annual visit has your doctor diagnosed you with a new onset of Transient ischemic attack (TIA)? Yes [1] No [2] KGTIA

PART VI / INTERVAL DRINKING, SMOKING, ANTI-INFLAMMATORY MEDICATION, & ROUTINE CARE HISTORY

K. Drinking Status

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

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? KGBEER 12 oz Bottles

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

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

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 KGBINGE No 2

a. About how often is this (that you have had 7 or more drinks within a 24-hour period)? KGBTIME

No answer 1
Rare or less than once a month 2
1-3 times per month 3
Once a week or more 4

L. Smoking Status

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

If YES,

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

M. Physical Activity Status

1. Over the past seven days, how many total minutes did you participate in activities that were at least moderate in intensity (like a brisk walk)? KG7DAY mins

N. 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 electronic communication other than a phone call (i.e. email, text, online portal message) with a health care provider (for a specific issue/concern)? ☐☐ time(s) KGELECTCOM

   c. had a regularly scheduled out-patient visit(s)? ☐☐ time(s) KGCOPV

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

   e. 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 services received **not** including visits related to the DPPOS? **Do not include any time that you are taking off for this visit today**. (round to nearest half day) ☐☐.☐ day(s) KGCDYLOST

O. 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)	1	2	☐☐.☐
		KGASPEX		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 in the past 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:				

P. Diabetes Management

Complete this section for participants with diabetes only.

1. During the **past month**, did you routinely monitor your blood glucose? Yes [1] No [2] KGMNTBG

If YES,

a. On average, how many days per week did you monitor your blood glucose? KGMNTWK ___ day(s)/week

b. On days that you monitored your blood glucose, on average, how many times per day did you monitor your blood glucose? KGMNTDY ___ time(s)/day

2. Total number of insulin formulations taken in the past 2 weeks KGINSNO ___

If number of insulin formulations is greater than zero,

a. Type of insulin regimen? KGREGM Injection [1] Infusion pump [2]

	KGINSDRUG KGINSFORM **Insulin formulation description**	**Form**	KGINSUNT **If Injection (option 1), i. Number of units per injection (inj)?**	KGINSTM **If Injection (option 1), ii. Number of times per day?**	**If Infusion pump (option 2), iii. Average total daily dose** KGINSTDD
1.			___ units/inj	___ times/day	___ units
2.			___ units/inj	___ times/day	___ units
3.			___ units/inj	___ times/day	___ units
4.			___ units/inj	___ times/day	___ units
5.			___ units/inj	___ times/day	___ units
6.			___ units/inj	___ times/day	___ units

PART VII / CONCOMITANT MEDICATIONS

Complete this section for all participants.

Q. 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 all medications without metformin below:

	Medicine Description	Form
1.	KGDRUG	
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		

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

   c. List all medications that include metformin below(list the total daily dose of metformin only):

	Medicine Description	Form	Total metformin daily dose
1.	KGDESMET		mg/day
2.			mg/day
3.			mg/day

PART VIII/ NUTRITIONAL SUPPLEMENTS AND CANCER SCREENINGS

R. 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 R3. Multivitamins should exclude B-Complex and instead the relevant B-vitamins should be included in the specific supplement list in Question R3.

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 KGSHOTNO [ ] shots
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?	
KGOMEGA	a.	Omega 3 (fish oil)	1	2	[ ] months	KGOMEGAMO
KGVITA	b.	Vitamin A (not Beta-carotene)	1	2	[ ] months	KGVITAMO
KGVITB6	c.	Vitamin B6	1	2	[ ] months	KGVITB6MO
KGVITB12	d.	Vitamin B12	1	2	[ ] months	KGVITB12MO
KGVITC	e.	Vitamin C (with or without rose hips)	1	2	[ ] months	KGVITCMO
KGVITD	f.	Vitamin D	1	2	[ ] months	KGVITDMO
KGVITE	g.	Vitamin E	1	2	[ ] months	KGVITEMO
KGCAL	h.	Calcium	1	2	[ ] months	KGCALMO
KGCHRO	i.	Chromium	1	2	[ ] months	KGCHROMO
KGFOL	j.	Folate (Folic Acid)	1	2	[ ] months	KGFOLMO
KGIRON	k.	Iron	1	2	[ ] months	KGIRONMO
KGMAG	l.	Magnesium	1	2	[ ] months	KGMAGMO
KGPOT	m.	Potassium	1	2	[ ] months	KGPOTMO
KGSEL	n.	Selenium	1	2	[ ] months	KGSELMO
KGZINC	o.	Zinc	1	2	[ ] months	KGZINCMO

S. Cancer Screening Assessment

Screening questions should be completed for any cancer screening test(s) the participant has had in the past year.

Complete questions 1-3 for female participants only.

Type of test	Have you had this test in the past year? Yes	No	Don't know	N/A	If YES, a. Date of last test or biopsy (month/year)
1. Pap smear KGPAP	1	2	3	4	
2. Mammogram KGMAM	1	2	3	4	
3. Breast biopsy KGBRST	1	2	3	4	

Complete questions 4-5 for male participants only.

Type of test	Have you had this test in the past year? Yes	No	Don't know	N/A	If YES, a. Date of last test or biopsy (month/year)
4. A blood test for prostate cancer, prostate specific antigen (PSA) KGPSA	1	2	3	4	
5. Prostate biopsy KGPROST	1	2	3	4	

Complete questions 6-9 for all participants.

Type of test	Have you had this test in the past year? Yes	No	Don't know	N/A	If YES, a. Date of last test or biopsy (month/year)
6. Fecal occult blood test KGFOBT	1	2	3	4	
7. Sigmoidoscopy KGSIG	1	2	3	4	
8. Colonoscopy KGCOL	1	2	3	4	
9. Other cancer screening test KGOTHTST	1	2	3	4	

If YES, specify: