Diabetes Prevention Program Outcomes Study

F02 ANNUAL VISIT INVENTORY

This Form is interviewer-administered for all participants at an in-clinic annual visit year 13 and on (13A, 14A, 15A …).

Form F02 records the following: anthropometrics, blood pressure, adverse events, study metformin status, concomitant medications, nutritional supplements, and diabetes monitoring.

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 — AVSTDT replaced with DAYSRAND — month / day / year

APFORMIN

Identification code of person reviewing completed form

Form entered in computer?

PART II / PHYSICAL AND HISTORY

Complete Part II for all participants.

B. Blood Pressure

1. Seated Arm Blood Pressure

		Systolic		Diastolic	
a. Blood Pressure Reading 1 (after sitting 5 minutes)	APSBP1	☐☐☐	/	☐☐☐	APDBP1 mmHg
b. Blood Pressure Reading 2 (after waiting 30 seconds)	APSBP2	☐☐☐	/	☐☐☐	APDBP2 mmHg

For participants without diabetes follow the JNCP guidelines and for participants with diabetes follow the ADA guidelines (refer 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.**
- **For C.3 – Height, record Measure 3 only if first 2 measurements are not within 0.5 cm.**

	Measure 1	Measure 2	Measure 3
1. Weight	APWGHT1 ☐☐☐ . ☐ kg	APWGHT2 ☐☐☐ . ☐ kg	APWGHT3 ☐☐☐ . ☐ kg

Complete waist circumference at 13A, 14A, 16A, and 18A visits only.

2. Waist Circumference	APWSTC1 ☐☐☐ . ☐ cm	APWSTC2 ☐☐☐ . ☐ cm	APWSTC3 ☐☐☐ . ☐ cm

Complete height at 15A and 18A visits only.

3. Height	APHGHT1 ☐☐☐ . ☐ cm	APHGHT2 ☐☐☐ . ☐ cm	APHGHT3 ☐☐☐ . ☐ cm

D. Events and Procedures

- **Query the participant for any events or procedures experienced since the last contact or visit.**
- **At the visit during which a participant is queried for eye, gastric reduction, renal failure, and kidney transplant procedures for the first time, ask the participant if s/he underwent any of these procedures since randomization in DPP.**
- **At subsequent visits, query for procedures done since the last contact or visit.**
- **Eye procedures to be queried are: laser/intravitreal treatment for diabetic retinopathy or diabetic macular edema, or other retinal procedures/surgeries.**
- **Gastric reduction surgeries include reversals of prior surgeries.**

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?........ APACTT ☐1

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

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

If marked, 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)? APINFTION ☐1
2. Fracture? APFRTURE ☐1
3. Joint replacement? APJTRPLMNT ☐1

d. Pregnancy resulting in congenital abnormality or birth defect? APCONG ☐1
e. Required intervention or treatment to prevent serious adverse event? APTSAE ☐1
f. Possible CVD event? APPCVD ☐1
g. Renal failure? APRENFL ☐1
h. Kidney transplant? APKIDTRNS ☐1

(d.–h.) If marked, complete E08 for each event.

i. Eye procedure? APRETINA ☐1 → Complete E09
j. Gastric reduction surgery? APGAS ☐1 → Complete E11
k. Cancer event? APCAN ☐1 → Complete E12

If any of options a.-h. are marked, 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 c.3 is marked, complete the E16 form.

If option I is marked, complete and E09 form. If option j is marked, complete an E11 form. If option k is marked, 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?	APSTOM	☐1	☐2
b. Unexplained weight loss?	APLOSSN	☐1	☐2
c. Sprains or fractures requiring medical attention?	APSPRN	☐1	☐2
d. A fall and landed on the floor, ground, OR has fallen and hit an object like a table or chair?	APFALL	☐1	☐2

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)?	APDIAB	1	2

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

		Yes	No
b. High blood pressure?	APHYPER	1	2
c. Any lipid abnormality (high cholesterol, high triglycerides, etc.)?	APLIPID	1	2
d. Dementia?	APDEMT	1	2
e. Alzheimer's disease?	APALZDS	1	2
f. Hearing loss?	APHEAR	1	2

PART III/MEDICAL HISTORY

F. 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 — APATHER

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 — APHIST

G. 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? APPAIN — Yes 1 — No 2

2. Have you had any pressure or heaviness in your chest? APPRES — Yes 1 — No 2

If Questions 1 AND 2 are NO, skip to section I. If either are YES, continue.

a. Do you get it when you walk uphill or hurry? APHURRY — Yes 1 — No 2

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

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

- Stop 1
- Slow down 2
- Continue at same pace 3

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

If YES,

1. How soon? APSOON — 10 min. or less [1] / More than 10 min. [2]

e. Where do you get this pain or discomfort:

1. Sternum (central chest)? APSTER — Yes [1] No [2]
2. Left anterior chest? APLCHST — Yes [1] No [2]
3. Left arm? APLARM — 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? AP30MIN — Yes [1] No [2]

H. 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? APNOFEEL — Yes [1] No [2]

If YES,

a. How long did the symptoms last? APNOFLT — < 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? APPARL — Yes [1] No [2]

If YES,

a. How long did the symptoms last? APPARLT — < 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? APBLUR — Yes [1] No [2]

If YES,

a. How long did the symptoms last? APBLURT — < 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] APLUR No [2]

If YES,

a. How long did the symptoms last? — APLURT
   - < 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] APDIZY No [2]

If YES,

a. How long did the symptoms last? — APDIZYT
   - < 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] APTIA No [2]

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

I. Drinking Status

1. During the past 12 months, have you consumed an average of at least one alcoholic beverage per week? — Yes [1] APWK 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? — APBEER 12 oz Bottles

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

c. How many 1.5 oz. shots of hard liquor or mixed drinks did you consume during the past 7 days? — APMIXD 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] APBINGE No [2]

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

J. Smoking Status

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

If YES,

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

K. 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)? [ ][ ][ ][ ] mins AP7DAY

L. Anti-inflammatory Medication Status

1. During an average week, how often do you take one or more aspirin tablets regardless of dosage? APASPIR
   - 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)	1 APASPBABY	2	[ ][ ] . [ ] APASPBABNO
b.	Regular-strength aspirin (325mg)	1 APASPREG	2	[ ][ ] . [ ] APASPREGNO
c.	Extra-strength aspirin (500mg)	1 APASPEX	2	[ ][ ] . [ ] APASPEXNO

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] APNSAID No [2]

	Type of NSAID	Do 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) APNSAIDIB	1	2	APIBDAY [ ][ ] days	[ ][ ] pills APIBNO

b.	Naproxen (e.g. Aleve, Anaprox, Naprosyn, Naprelan) APNSAIDNA	1	2	APNADAY days	pills APNANO
c.	Other APNSAIDOTH	1	2	APOTHDAY days	pills APOTHNO
	3. If OTHER, specify:	APNSAIDSP			

M. Diabetes Management

Complete this section for participants with diabetes only.

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

If YES,

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

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

If number of insulin formulations is greater than zero,

a. Type of insulin regimen? APREGM
Injection 1
Infusion pump 2

APINSFORM APINSUNT APINSTM APINSTDD

	Insulin formulation description APINSDES	Form	If injection (option 1), i. Number of units per injection (inj)?	If Injection (option 1), ii. Number of times per day?	If Infusion pump (option 2), iii. Average total daily dose
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
7.			units/inj	times/day	units
8.			units/inj	times/day	units

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)? ☐☐ times(s) APCHCD

   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?) ☐☐ times(s) APELECTCOM

   c. had a regularly scheduled out-patient visit(s)? ☐☐ times(s) APCOPV

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

   e. had an emergency room visit(s)? ☐☐ times(s) APCERV

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) APCDYLOST

PART V / MLS PARTICIPANT SECTION

Complete sections O and P for all MLS participants

O. Metformin Status

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

If YES, complete the F08 Metformin Safety & Adherence Form for this participant.

P. 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)?.. ☐ APDISP

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 VI / CONCOMITANT MEDICATIONS / NUTRITIONAL SUPPLEMENTS / CANCER SCREENINGS

Complete this section for all participants.

Q. Concomitant Medications

AMRXDQ

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

If YES,

a. Total number of medications taken (including any medications listed on additional sheets) AMTOTMEDS

b. List all medications without metformin below:

	Medicine Description AMDRUG1-30	Form AMROUTE
1.		
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 AMDESMET	Form AMRUTMET	Total metformin daily dose AMDSEMET
1.			mg/day
2.			mg/day
3.			mg/day

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 S3. 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? AMMULTIV — Yes [1] No [2]

2. Has the participant received any Vitamin B12 shots in the past 12 months? AMB12SHOT — Yes [1] No [2]

If YES,

a. Number of shots received in the past 12 months — AMSHOTNO [ ][ ] shots

3. Has the participant taken any **non-prescription** oral supplements other than multivitamins at least once a week in the past 12 months? AMSUP — 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?	
AMOMEGA	a. Omega 3 (fish oil)	1	2	[ ][ ] months	AMOMEGAMO
AMVITA	b. Vitamin A (not Beta-carotene)	1	2	[ ][ ] months	AMVITAMO
AMVITB6	c. Vitamin B6	1	2	[ ][ ] months	AMVITB6MO
AMVITB12	d. Vitamin B12	1	2	[ ][ ] months	AMVITB12MO
AMVITC	e. Vitamin C (with or without rose hips)	1	2	[ ][ ] months	AMVITCMO
AMVITD	f. Vitamin D	1	2	[ ][ ] months	AMVITDMO
AMVITE	g. Vitamin E	1	2	[ ][ ] months	AMVITEMO
AMCAL	h. Calcium	1	2	[ ][ ] months	AMCALMO
AMCHRO	i. Chromium	1	2	[ ][ ] months	AMCHROMO
AMFOL	j. Folate (Folic Acid)	1	2	[ ][ ] months	AMFOLMO
AMIRON	k. Iron	1	2	[ ][ ] months	AMIRONMO
AMMAG	l. Magnesium	1	2	[ ][ ] months	AMMAGMO

AMPOT	m.	Potassium	1	2	months AMPOTMO
AMSEL	n.	Selenium	1	2	months AMSELMO
AMZINC	o.	Zinc	1	2	months AMZINCMO

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	APPAP	1	2	3	4	APPAPMO	APPAPYR
2. Mammogram	APMAM	1	2	3	4	APMAMMO	APMAMYR
3. Breast biopsy	APBRST	1	2	3	4	APBRSTMO	APBRSTYR

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)	APPSA	1	2	3	4	APPSAMO	APPSAYR
5. Prostate biopsy	APPROST	1	2	3	4	APPROSTMO	APPROSTYR

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	APFOBT	1	2	3	4	APFOBTMO	APFOBTYR
7. Sigmoidoscopy	APSIG	1	2	3	4	APSIGMO	APSIGYR
8. Colonoscopy	APCOL	1	2	3	4	APCOLMO	APCOLYR
9. Other cancer screening test	APOTHTST	1	2	3	4	APSCRMO	APSCRYR

If YES, specify: APCOTHSP