Diabetes Prevention Program Outcomes Study

F02 ANNUAL VISIT INVENTORY

This form is completed for all participants at an in-clinic annual visit (01A, 02A, 03A, 04A, …).

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

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 — month / day / year — AVSTDT replaced with DAYSRAND

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

a. Blood Pressure Reading 1 (after sitting 5 minutes) — APSBP1 ___ / ___ APDBP1 mmHg

b. Blood Pressure Reading 2 (after waiting 30 seconds) — APSBP2 ___ / ___ APDBP2 mmHg

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.**

2. Supine Ankle/Arm Systolic Blood Pressure

If this is a 01A, 05A, or 10A visit, complete this section.
Right arm to be used unless left arm is ≥ 10 mmHg higher, in which case wait 30 seconds, repeat left arm pressure, and enter the repeat result as the first arm pressure reading.

a. Arm — APSSBP ___ MmHg — Right arm [1] Left arm [2] APSSBPA

b. Right dorsalis pedis — APADORR ___ MmHg

c. Right tibialis posterior — APAPOSR ___ MmHg

d. Left dorsalis pedis — APADORL ___ MmHg

e. Left tibialis posterior — APADOSL ___ MmHg

f. Arm (same arm as 2a) — APSSBPF ___ MmHg

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

Complete height at 01A, 05A and 11A visits only

3. Height	APHGHT1 ___ . ___ cm	APHGHT2 ___ . ___ cm	APHGHT3 ___ . ___ cm

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

D. Neuropathy Screening Instrument

1. Appearance and Condition of Both Feet

RIGHT APNORMR

a. Normal Yes [1] No [2]

IF NO, CHECK ALL THAT APPLY:

1. Deformities Yes [1] APDEFR
2. Dry skin, callus Yes [1] APSKINR
3. Infection Yes [1] APINFR
4. Fissure Yes [1] APFISSR
5. Other Yes [1] APOTHR

i. **If OTHER,** specify: APSPECR

LEFT APNORML

b. Normal Yes [1] No [2]

IF NO, CHECK ALL THAT APPLY:

1. Deformities Yes [1] APDEFL
2. Dry skin, callus Yes [1] APSKINL
3. Infection Yes [1] APINFL
4. Fissure Yes [1] APFISSL
5. Other Yes [1] APOTHL

i. **If OTHER,** specify: APSPECL

RIGHT

2. Ulceration — Present [1] Absent [2] APULCRR
3. Ankle Reflexes — Present [1] Present/ Reinforcement [2] Absent [3] APREFR
4. Vibration perception at great toe — Present (<10 sec) [1] Reduced (≥10 sec) [2] Absent [3] APTOER
5. 10gm filament (record number of applications detected) [ ][ ] applications out of 10 APNUMFILR

LEFT

6. Ulceration — Present [1] Absent [2] APULCRL
7. Ankle Reflexes — Present [1] Present/ Reinforcement [2] Absent [3] APREFL
8. Vibration perception at great toe — Present (<10 sec) [1] Reduced (≥10 sec) [2] Absent [3] APTOEL
9. 10gm filament (record number of applications detected) [ ][ ] applications out of 10 APNUMFILL

E. Diabetes Management

Complete this section for diabetics only.

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

If YES,

a. Number of units per day — [ ][ ][ ] units per day APUNITS

b. Type of insulin regimen — Infusion pump [1] Injection [2] APREGM

1. If injection, number of injections per day — [ ][ ] per day APINJCT

F. 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?
CHECK ALL THAT APPLY

a. Any acute life threatening event?..... [1] APACTT
b. Permanent or severe disability?..... [1] APDISA
c. Required or prolonged hospitalization?..... [1] APHOSP
d. Overdose of any medication?..... [1] APOVDO
e. Pregnancy resulting in congenital abnormality or birth defect? APCONG [1]
f. Required intervention or treatment to prevent serious adverse event?.... [1] APTSAE
g. Possible CVD event?..... [1] APPCVD
h. Renal failure?..... [1] APRENFL
i. Kidney transplant?..... [1] APKIDTRNS

If checked, complete E08 for each event.

j. Eye procedure? APRETINA [1] → Complete E09
k. Gastric reduction surgery? APGAS [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.

G. History

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

	Yes	No	
a. Skin rashes?	1	2	APRASH
b. Frequent stomach pains, bloating, nausea, diarrhea, or loss of appetite?	1	2	APSTOM
c. Unexplained weight loss?	1	2	APLOSSN
d. Increased thirst (drinking more liquids than usual)?	1	2	APTHRST
e. Urinating more often than usual?	1	2	APURINT
f. Infection requiring medical attention?	1	2	APINTMA
g. Sprains or fractures requiring medical attention?	1	2	APSPRN

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	APDIAB
b. High blood pressure?	1	2	APHYPER
c. Any lipid abnormality (high cholesterol, high triglycerides, etc.)?	1	2	APLIPID
d. Ulcer (stomach or duodenal), or intestinal bleeding?	1	2	APULCR
e. Hepatitis?	1	2	APHEPAT
f. Cancer?	1	2	APCNCR

If YES, complete an E12 Cancer Report form.

g. Gallstones, gallbladder disease, or gallbladder surgery?	1	2	APGALL
h. Gout?	1	2	APGOUT
i. Thyroid disease?	1	2	APTHYR
j. Transient ischemic attack (TIA)?	1	2	APTIA
k. Kidney disease?	1	2	APKIDNDI
l. Retinopathy?	1	2	APRETPTY

PART III/ MEDICAL HISTORY

H. 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] APPAIN

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

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? — Yes [1] No [2] APHURRY

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

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? — Yes [1] No [2] APSTILL

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

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] AP30MIN

I. 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] APNOFEEL

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? Yes [1] No [2] APPARL

   If YES,
   a. How long did the symptoms last?

   < 1 hour [1] APPARLT
   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] APBLUR

   If YES,
   a. How long did the symptoms last?

   < 1 hour [1] APBLURT
   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] APLUR

   If YES,
   a. How long did the symptoms last?

   < 1 hour [1] APLURT
   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] APDIZY

   If YES,
   a. How long did the symptoms last?

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

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

J. 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] APWK

   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 APBEER

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

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 APMIXD

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 APBINGE

If YES,

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

K. Smoking Status

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

If YES,

a. On average, how many cigarettes per day? ☐☐ APSDAY cigarettes per day

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)	APASPBABY ☐1 ☐2	APASPBABNO ☐☐.☐
b.	Regular-strength aspirin (325mg)	APASPREG ☐1 ☐2	APASPREGNO ☐☐.☐
c.	Extra -strength aspirin (500mg)	APASPEX ☐1 ☐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] No [2]
APNSAID

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)	APNSAIDIB [1] [2]	APIBDAY [ ][ ] days	APIBNO [ ][ ] pills
b.	Naproxen (e.g. Aleve, Anaprox, Naprosyn, Naprelan)	APNSAIDNA [1] [2]	APNADAY [ ][ ] days	APNANO [ ][ ] pills
c.	Other	APNSAIDOTH [1] [2]	APOTHDAY [ ][ ] days	APOTHNO [ ][ ] pills

3. If OTHER, specify: APNSAIDSP

M. 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)? APCHCD [ ][ ] time(s)

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

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

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

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) APCLOST [ ][ ]. [ ] day(s)

PART V/ MLS PARTICIPANT SECTION

Complete sections N and O for all MLS participants.

N. Metformin Status

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

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

O. 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)? ..... [ ] APDISP

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.

PART VI/ CONCOMITANT MEDICATIONS/NUTRITIONAL SUPPLEMENTS

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] AMRXDQ

If YES,

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

b. List medications below:

	AMDRUG1-30 Medicine Description	AMROUTE 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.

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? APMULTIV — Yes [1] No [2] AMMULTIV
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. AMSUP Has the participant taken any **non-prescription** oral supplements other than multivitamins at least once a week in the past 12 months? APSUPP — Yes [1] No [2] APTOTSUPP
   If YES, APSUPPMO

		APSUPPDSC **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?** APSUPPNO
AMOMEGA	a.	Omega 3 (fish oil)	1	2	AMOMEGAMO months	AMOMEGANO
AMVITA	b.	Vitamin A (not Beta-carotene)	1	2	AMVITAMO months	AMVITANO
AMVITB6	c.	Vitamin B6	1	2	AMVITB6MO months	AMVITB6NO
AMVITB12	d.	Vitamin B12	1	2	AMVITB12MO months	AMVITB12NO
AMVITC	e.	Vitamin C (with or without rose hips)	1	2	AMVITCMO months	AMVITCNO
AMVITD	f.	Vitamin D	1	2	AMVITDMO months	AMVITDNO
AMVITE	g.	Vitamin E	1	2	AMVITEMO months	AMVITENO
AMCAL	h.	Calcium	1	2	AMCALMO months	AMCALNO
AMCHRO	i.	Chromium	1	2	AMCHROMO months	AMCHRONO
AMFOL	j.	Folate (Folic Acid)	1	2	AMFOLMO months	AMFOLNO
AMIRON	k.	Iron	1	2	AMIRONMO months	AMIRONNO
AMMAG	l.	Magnesium	1	2	AMMAGMO months	AMMAGNO
AMPOT	m.	Potassium	1	2	AMPOTMO months	AMPOTNO
AMSEL	n.	Selenium	1	2	AMSELMO months	AMSELNO
AMZINC	o.	Zinc	1	2	AMZINCMO months	AMZINCNO