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, pregnancy information, study metformin, concomitant medications, diabetes monitoring and local CBC results.

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 — 01A 02A 03A 04A 05A 06A 07A 08A 09A 10A 11A VISIT
7. Date of visit — month day year AVSTDT replaced with DAYSRAND

Identification code of person reviewing completed form FORMIN

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 ___	/	___	mmHg APDBP1
b.	Blood Pressure Reading 2 (after waiting 30 seconds)	APSBP2 ___	/	___	mmHg APDBP2

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 or 05A 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	___ . ___ kg APWSTC1	___ . ___ kg APWSTC2	___ . ___ kg APWSTC3
2. Waist Circumference	___ . ___ cm	___ . ___ cm	___ . ___ cm

Complete height at 01A and 05A visits only

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

D. 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, list below:

	Medicine Description		Route
a.		AMRXDAM	
b.		AMRXDBM	
c.		AMRXDCM	
d.		AMRXDDM	
e.		AMRXDEM	
f.		AMRXDFM	
g.		AMRXDGM	
h.		AMRXDHM	
i.		AMRXDIM	
j.		AMRXDJM	

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 [ ][ ][ ] APUNITS
units per day

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

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

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

F. Neuropathy Screening Instrument

1. Appearance and Condition of Both Feet

	RIGHT APNORMR	LEFT APNORML
a./b. Normal	Yes [1] No [2]	Yes [1] No [2]
IF NO, CHECK ALL THAT APPLY:		
i. Deformities	Yes [1] APDEFR	Yes [1] APDEFL
ii. Dry skin, callus	Yes [1] APSKINR	Yes [1] APSKINL
iii. Infection	Yes [1] APINFR	Yes [1] APINFL
iv. Fissure	Yes [1] APFISSR	Yes [1] APFISSL
v. Other,	Yes [1] APOTHR	Yes [1] APOTHL
Specify:	APSPECR	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) — Present (≥ 8) [1] Reduced (1-7) [2] Absent (0) [3] APFILR

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) — Present (≥ 8) [1] Reduced (1-7) [2] Absent (0) [3] APFILL

G. 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] APACTT

b. Permanent or severe disability? ..... [1] APDISA

c. Required or prolonged hospitalization? ..... [1] APHOSP

d. Overdose of any medication? ..... APOVDO [1]

e. Pregnancy resulting in congenital abnormality or birth defect?..... [1] APCONG

f. Required intervention or treatment to prevent serious adverse event? ..... [1] APTSAE

g. Possible CVD event? ..... [1] APPCVD

If checked, complete E08 for each event.

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.

H. 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

		Yes	No	
e.	Hepatitis?	1	2	APHEPAT
f.	Cancer?	1	2	APCNCR
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

Part III/ MEDICAL HISTORY

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? — 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 J. 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,

i. How soon? — APSOON
- 10 min. or less 1
- More than 10 min. 2

e. Where do you get this pain or discomfort:

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

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

iii. 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

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? 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? 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? Yes [1] No [2] APBLUR

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] No [2] APLUR

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

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

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

Part IV / INTERVAL DRINKING, SMOKING, ASPIRIN, & 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?

   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)?

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

L. 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? [ ][ ] cigarettes per day APSDAY

M. Aspirin 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]

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) APCHCD
   b. had a regularly scheduled out-patient visit(s)? [ ][ ] time(s) APCOPV
   c. had urgent care visit(s) (i.e. doctor's office, clinic; not to emergency room)? [ ][ ] time(s) APUCV
   d. had an emergency room visit(s)? [ ][ ] time(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 care including visits related to the DPPOS? (round to nearest half day) [ ][ ] . [ ] day(s) APCLOST

Part V/ MLS PARTICIPANT SECTION

Complete question O.1 for all MLS participants. Complete the rest of section O if participant has taken study metformin since last visit. IF NOT MLS, STOP; FORM IS COMPLETE.

O. Metformin Status

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

If NO, PROCEED to Section R.
If YES, CONTINUE with Section O.

   a. Daily dose of METFORMIN per protocol 850 mg [1] 1700 mg [2] AMDOSE
   b. What is your best estimate of the participant's level of exposure to metformin per protocol? AMCOMPM
      - <80% [1]
      - ≥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] APPROB

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] APFORG
b. Forgets to take evening dose..... [1] APEVEN
c. Inconvenient to take pills as prescribed..... [1] APINCON
d. GI reaction to pills..... [1] APGIRCT
e. Disruption of regular routine..... [1] APDISRP
f. Hospitalization/new illness/medical reason..... [1] APMEDC
g. Lack of motivation..... [1] APMOTV
h. Lost/misplaced pills..... [1] APLOST
i. Other (specify): APOTHSP [1] APOTHER

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] APSTRAT
New time routine..... [2]
New strategy/routine..... [3]
New reminder device..... [4]
Change type and/or frequency of DPPOS staff communication... [5]
Does NOT want to deal with the problem..... [6]
Other (specify): APSTSPEC [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] APTIME
ii. strategy routine (e.g. takes with other pills; medication in a convenient place) [1] APSTRRO
iii. reminder device (e.g. pill box, calendar) [1] APRMND
iv. other [1] APOTHRS

P. 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] APREM

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

a. Date of last menstrual period [ ][ ][ ][ ][ ][ ] month day year APDOLM

i. Menstrual period more than one week late? Yes [1] No [2] AP1WK

If 1.a.i is YES, a pregnancy test must be performed.
If NO, skip to question 1. b.

a.) Date of pregnancy test [ ][ ][ ][ ][ ][ ] month day year APDOPT

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

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

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

If YES, study metformin must be discontinued.

Q. Complete Blood Count

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

1. Hemoglobin [ ][ ].[ ] g/dL ALHGLOB
2. Hematocrit [ ][ ].[ ] % ALHCRIT
3. Platelet Count [ ][ ][ ] X10/ml ALPLATE

R. 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.