Diabetes Prevention Program

ADVERSE EVENT REPORT

This form is to be completed if the participant has had any new symptoms, injuries, illness or side effects, or worsening of pre-existing conditions.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number ☐☐

2. Participant Identification Number (Complete a **OR** b)

   a. If before randomization, Screening number S☐☐☐☐☐

   b. If after randomization, Participant number ☐☐☐☐☐☐

3. Participant's initials ☐☐☐☐ (first last)

4. Participant's date of birth ☐☐ ☐☐ ☐☐ (month day year)

B. Visit Information

1. Date of visit ☐☐ ☐☐ ☐☐ (month day year)

2. Type of Visit
   - ☐ 1 Screening Step
   - ☐ 2 Standard Follow-up
   - ☐ 3 Major Follow-up
   - ☐ 4 Interim Follow-up

3. Week of visit (If Follow-up) ☐☐☐

C. Instructions for Form E01 Completion

Complete one or more Adverse Event's per visit. If an Adverse Event is serious, the Serious Adverse Event Form (E02) must also be completed.

Initials of person reviewing completed form ☐☐☐☐ (first last)

Form entered in computer? ☐

Participant's initials (first last) | Date of birth (month day year) | Date of visit (month day year)

D. Adverse Event(s) Summary

Event Number	Adverse Event (short description)	Classification Term	Onset Date	Date Resolved/ Continuing	Serious? 1 = YES* 2 = NO	Intervention: Relationship 1 = None 2 = Unlikely 3 = Possible 4 = Probable 5 = Definitely	Intervention: Suspended 1 = YES 2 = NO	Intervention: If YES, Which Intv? 1 = Metformin 3 = Diet 4 = Exercise
1.			month day year	month day year Continuing [1]				
2.			month day year	month day year Continuing [1]				
3.			month day year	month day year Continuing [1]				
4.			month day year	month day year Continuing [1]				
5.			month day year	month day year Continuing [1]				
6.			month day year	month day year Continuing [1]				

***** For each serious adverse event (SAE) complete the SAE Report (Form E02).

Participant's initials (first last) | Date of birth (month day year) | Date of visit (month day year)

D. Adverse Event(s) Summary

Event Number	Adverse Event (short description)	Classification Term	Onset Date	Date Resolved/ Continuing	Serious? 1 = YES* 2 = NO	Intervention: Relationship 1 = None 2 = Unlikely 3 = Possible 4 = Probable 5 = Definitely	Intervention: Suspended 1 = YES 2 = NO	Intervention: If YES, Which Intv? 1 = Metformin 3 = Diet 4 = Exercise
7.			month day year	month day year Continuing 1				
8.			month day year	month day year Continuing 1				
9.			month day year	month day year Continuing 1				
10.			month day year	month day year Continuing 1				
11.			month day year	month day year Continuing 1				
12.			month day year	month day year Continuing 1				

* For each serious adverse event (SAE) complete the SAE Report (Form E02).

Participant's initials (first last) | Date of birth (month day year) | Date of visit (month day year)

D. Adverse Event(s) Summary

Event Number	Adverse Event (short description)	Classification Term	Onset Date	Date Resolved/ Continuing	Serious? 1 = YES* 2 = NO	Intervention: Relationship 1 = None 2 = Unlikely 3 = Possible 4 = Probable 5 = Definitely	Intervention: Suspended 1 = YES 2 = NO	Intervention: If YES, Which Intv? 1 = Metformin 3 = Diet 4 = Exercise
13.			month day year	month day year Continuing 1				
14.			month day year	month day year Continuing 1				
15.			month day year	month day year Continuing 1				
16.			month day year	month day year Continuing 1				
17.			month day year	month day year Continuing 1				
18.			month day year	month day year Continuing 1				

* For each serious adverse event (SAE) complete the SAE Report (Form E02).

Diabetes Prevention Program

SERIOUS ADVERSE EVENT REPORT

The initial Serious Adverse Event Report (E02) and the corresponding Adverse Event Report (E01) should be FAXED to the Coordinating Center IMMEDIATELY at (301) 881-8752.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number ☐☐

2. Participant Identification Number (Complete a **OR** b)

   a. If before randomization, Screening number S☐☐☐☐☐☐

   b. If after randomization, Participant number ☐☐☐☐☐☐

3. Participant's initials ☐☐☐☐ (first last)

4. Participant's date of birth ☐☐ ☐☐ ☐☐ (month day year)

B. Report Identification

1. Date of report ☐☐ ☐☐ ☐☐ (month day year)

2. Date of onset of serious adverse event ☐☐ ☐☐ ☐☐ (month day year)

3. Type of report
   - [1] Initial
   - [2] Follow-up

4. Type of visit
   - [1] In Clinic / Home Visit
   - [2] Unattended

C. Instructions for Form E02 Completion

This form is to be completed if the participant has had a Serious Adverse Event (SAE) recorded on the Adverse Event Report (E01).

Initials of person reviewing completed form ☐☐☐☐ (first last) Form entered in computer? ☐

Signature of P.I. _____ Date: _____

Part II / ADVERSE EVENT DESCRIPTION

D. General Classification

1. Event Number (from Form E01; column 1) ☐☐

   a. Classification term from Form E01: ☐

2. Did the adverse experience result in: *(check all that apply)*

   a. Required or prolonged hospitalization . . . . . ☐ 1

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

   c. Death . . . . . ☐ 1

If Death checked, CONTINUE. If Death not checked, SKIP to Question 3.

   i. Date of death ☐☐☐ (month, day, year)

   ii. Probable cause of death

---

3. Was the adverse experience: *(check all that apply)*

   a. Congenital anomaly . . . . . ☐ 1

   b. Cancer . . . . . ☐ 1

   c. Life-threatening . . . . . ☐ 1

   d. Due to an overdose . . . . . ☐ 1

   e. Treatment to prevent a serious event . . . . . ☐ 1

E. Event Information

Complete question E1 if assigned the pharmacological treatment.
Skip to question E2 for troglitazone and lifestyle participants.

1. Was the participant on coded metformin at the time of the adverse experience? YES [1] NO [2]

   If YES, CONTINUE.
   If NO, SKIP to Question E.2.

   a. Was the coded metformin interrupted or stopped as a result of the event? YES [1] NO [2]

      If YES, CONTINUE.
      If NO, SKIP to Question E.2.

      i. Was the adverse experience reversible when the coded metformin was withdrawn? YES [1] NO [2]

      ii. Was the coded metformin re-started? YES [1] NO [2]

      If YES, CONTINUE.
      If NO, SKIP to Question E.2.

      a) How long was the participant off coded metformin? [ ][ ]
      [1] days
      [2] weeks
      [3] months

      b) Did the symptoms recur? YES [1] NO [2]

2. Describe the adverse event in detail: (i.e. issues leading up to event, procedures or test completed, date stopped intervention if applicable, etc.)

3. Duration of adverse experience
   <1day [1]
   1day - 1week [2]
   >1week [3]

4. Treatment administered for the adverse event:

check all that apply

a. Out-patient - changes in medications . . . . . [1]

b. Out-patient - procedure . . . . . [1]

c. Hospitalization . . . . . [1]

i. Total length of stay ____ days

d. Skilled nursing facility . . . . . [1]

i. Total length of stay ____ days

e. Out-patient rehabilitation . . . . . [1]

i. Total days ____ days

f. In-patient rehabilitation . . . . . [1]

i. Total days ____ days

5. During the adverse event was insulin therapy used? YES [1] NO [2]

If YES,
a. Is insulin therapy continuing? YES [1] NO [2]

6. Outcome

recovered, no residual effect [1]
residual effect, no treatment [2]
residual effect, being treated [3]
persistent, no treatment [4]
persistent, being treated [5]
death [6]

F. Conclusion

1. Additional comments: (i.e. note if former troglitazone participant, whether or not they have experienced this problem before, any follow-up plans, etc.)

_____

_____

_____

Diabetes Prevention Program

PREGNANCY CONFIRMATION REPORT

This form is to be completed if the participant has had a positive pregnancy test.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number [ ][ ] CLINIC
2. Participant number [ ][ ][ ][ ][ ][ ] PATID
3. Participant's initials [ ][ ][ ][ ] INITS (first last)
4. Participant's date of birth [ ][ ] [ ][ ] [ ][ ] DOB (month day year)

B. Report Identification

1. Date of report [ ][ ] [ ][ ] [ ][ ] DORPTDT (month day year)

C. Instructions for Form E04 Completion

Complete all sections of Form E04 if the participant is assigned to pharmacological treatment. If the participant is assigned to Intensive Lifestyle Intervention, complete up to and including question D.3.

Initials of person reviewing completed form [ ][ ][ ][ ] (first last) Form entered in computer? [ ]

D. Pre-natal

1. Date of positive pregnancy test (month day year) — DOTSTDT replaced with DAYSPREG

2. Estimated date of delivery (month day year) — DOEDD replaced with DAYEDD

3. Name/Address/Phone of Obstetric care provider:

_____

_____

_____

_____

If participant is assigned to pharmacological treatment, continue.

4. Was this a planned pregnancy? YES [1] NO [2] — DOPLAN

If YES,

a. Was coded metformin discontinued prior to conception? YES [1] NO [2] — DODISA

b. Metformin stop date (month day year) — DODISCA replaced with DAYSMETS_PRIOR

NOTE; THESE VARIABLES ALSO INCLUDE TROGLITAZONE

If NO,

c. Has coded metformin been discontinued? YES [1] NO [2] — DODISB

d. Metformin stop date (month day year) — DODISCB replaced with DAYSMETS_AFTER

5. Does participant wish to continue pregnancy? YES [1] NO [2] — DOCONT

6. Was coded metformin unmasked? [1] [2] — DOBLIND

Diabetes Prevention Program

PREGNANCY OUTCOME REPORT

This form is to be completed when the participant's pregnancy has ended.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number ☐☐ CLINIC
2. Participant number ☐☐☐☐☐☐ PATID
3. Participant's initials ☐☐☐☐ INITS (first last)
4. Participant's date of birth ☐☐ / ☐☐ / ☐☐ DOB (month day year)
5. Participant's sex Male [1] Female [2] SEX

B. Report Identification

1. Date of report ☐☐ / ☐☐ / ☐☐ DURPTDT (month day year)
2. Date of positive pregnancy test ☐☐ / ☐☐ / ☐☐ DPOSDT replaced with DAYSPREG (month day year)

C. Instructions for Form E05 Completion

Complete all sections of Form E05.

Initials of person reviewing completed form ☐☐☐☐ (first last) Form entered in computer? ☐

D. Pregnancy Outcome

1. Voluntary termination — month day year — DUTRMDT replaced with DAYSVOLUNTARY
2. Miscarriage — month day year — DUMSCDT replaced with DAYSMISCARRIAGE
3. Delivery date — month day year — DUDELDT replaced with DAYSDELIVERY

a. Infant's sex — Male [1] Female [2] — DUINSEX

b. Infant's weight percentile — [ ] % — DUWGHT

c. Were there any anomalies? — YES [1] NO [2] — DUANOM

If YES, complete Adverse Event Forms E01 & E02

d. Did the participant have GDM during gestation? — YES [1] NO [2] — DUGDM

e. Did the participant receive insulin during gestation? — [1] [2] — DUINSGT

E. Post-pregnancy

1. Is the participant breast feeding? — YES [1] NO [2] — DUFEED

a. Date resumed intervention after breast feeding — month day year — DUINTV replaced with DAYSRESUME_BREAST

2. Is the participant on insulin or oral agents? — YES [1] NO [2] — DUINSUL

a. Date resumed intervention within 1 month off insulin — month day year — DUINSDT replaced with DAYSRESUME_INS

3. Resumed birth control use? — YES [1] NO [2] — DUBC

If YES,
What type is used *check all that apply*

a. Oral hormone therapy [1] — DUOHT
b. Non-oral hormone therapy [1] — DUNOHT
c. Intrauterine devices [1] — DUIUD
d. Barrier methods [1] — DUBARR
e. Surgical methods [1] — DUSURG

Diabetes Prevention Program

MORTALITY EVENT REPORT

This form is completed if a randomized participant has a mortality event. Upon notification of the death of a DPP participant, the clinical staff must complete an Adverse Event Report (Form E01), an initial Serious Adverse Event Report (Form E02) and an initial Mortality Event Report (Form E06). The E01, E02 and E06 must be FAXED to the Coordinating Center IMMEDIATELY at (301) 881-8752.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number ☐☐
2. Participant number ☐☐☐☐☐☐
3. Participant's initials ☐☐☐☐ (first last)
4. Participant's date of birth ☐☐/☐☐/☐☐ (month day year)

B. Report Identification

1. Date of report ☐☐/☐☐/☐☐ (month day year)
2. Date of death ☐☐/☐☐/☐☐ (month day year)
3. Type of Report
   - Initial [1]
   - Follow-up [2]

C. Instructions for Form E06 Completion

For the initial report, complete as many items as possible.
For the follow-up report, complete all sections of Mortality Event Report (Form E06) and attach a narrative description of the event.

Initials of person reviewing completed form ☐☐☐☐ (first last) Form entered in computer? ☐

D. General Information

1. Place of death

check only one

- Hospital [1]
- Home [2]
- Long-term care institution [3]
- Other [4]

specify: _____

- Unknown [5]

2. Was the death:

check only one

- Sudden, explained [1]
- Sudden, unexplained [2]
- Following illness [3]

3. At the time of onset of terminal event, the participant was:

check only one

- Asleep [1]
- Awake, but sedentary [2]
- Engaged in light physical [3]
- Engaged in moderate physical activity [4]
- Engaged in heavy physical activity [5]
- Unknown [6]

	YES	NO
4. Was the participant taking the coded metformin?	[1]	[2]
5. Was an autopsy performed?	[1]	[2]
If YES, a. Is the autopsy report available?	[1]	[2]
6. Is a death certificate available?	[1]	[2]

7. Specify which sources of information were used in completing this form

check all that apply

- a. Death certificate . . . . . [1]
- b. Autopsy report . . . . . [1]
- c. Hospital report on final illness . . . . . [1]
- d. Interview of attending physician at time of death . . . . . [1]
- e. Interview of family member . . . . . [1]
- f. Other . . . . . [1]

specify:_____

first	last	month	day	year	month	day	year

E. Specific Information (include narrative description)

1. Immediate cause of death:

_____

_____

_____

_____

2. Underlying cause of death: (may be the same as immediate cause of death: please specify)

_____

_____

_____

_____

3. Specify any contributory causes of death:

_____

_____

_____

_____

4. Which of the immediate, underlying and/or contributory causes were present at randomization:

_____

_____

_____

_____

Diabetes Prevention Program

STANDARD FOLLOW-UP VISIT INVENTORY

This form is completed at all quarterly follow-up visits, except for annual (i.e., Major) follow-up visits (End-month 3, 6, 9, 15. . .).
Form F01 records the following: weight, blood pressure, pregnancy information, coded and concomitant medication, and local CBC results.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number [ ][ ] CLINIC
2. Participant number [ ][ ][ ][ ][ ][ ] PATID
3. Participant's initials [ ][ ][ ][ ] INITS (first last)
4. Participant's date of birth [ ][ ] / [ ][ ] / [ ][ ] DOB (month day year)
5. Participant's sex Male [1] Female [2] SEX

B. Visit Information

1. Date of visit [ ][ ] / [ ][ ] / [ ][ ] QVSTDT (month day year)
2. Week of visit [ ][ ][ ] QVSTWK
3. Type of visit In Clinic [1] Home Visit [2] QVSTVIS
4. Outcome visit [ ][ ][ ] VISIT
5. End of Study Yes [1] No [2] QVEOS

C. Instructions for Form F01 Completion

If this is a Mid-year visit (End-month 6, 18, 30, 42, 54, 66) the data collector completes sections D - Anthropometrics and E - Blood Pressure.
If this is not a Mid-year visit, SKIP to Section F - Adverse Events and complete Part III - Medications.

If this is the End-month 6 Mid-year visit and the participant was assigned to the pharmacological treatment, complete Part IV - Local Laboratory Results.

Initials of person reviewing completed form [ ][ ][ ][ ] (first last) Form entered in computer? [ ]

If this is a Mid-year visit (End-month 6, 18, 30, 42, 54, 66), complete section D - Anthropometrics and section E - Blood Pressure.

Part II / PHYSICAL AND HISTORY

D. Anthropometrics - complete only at a Mid-year visit

1. Weight

a. First measurement ___.___ kg QPWGHT1

b. Second measurement ___.___ kg QPWGHT2

Record c. only if first 2 measurements are not within 0.2 kilogram (200 gm).

c. Third measurement ___.___ kg QPWGHT3

E. Blood Pressure - complete only at Mid-year visit

1. Seated Arm Blood Pressure

	Systolic	Diastolic	
a. Blood Pressure Reading 1 (after sitting 5 minutes)	QPSBP1	QPDBP1	mmHg
b. Blood Pressure Reading 2 (after waiting 30 seconds)	QPSBP2	QPDBP2	mmHg

Hypertension management aims at maintaining blood pressure < 140/90 mmHg.

Initials of data collector completing page 2 of this form (first, last)

F. Adverse Events

1. During the interval since the last visit, has the participant had any new symptoms, injuries, illness or side effects, or worsening of pre-existing conditions?

YES [1] NO [2] QPAEQ

If YES, an Adverse Event Report (Form EO1) MUST be completed.

G. Pregnancy Questions

1. Does the participant have reproductive potential?

YES [1] NO [2] QPPREM

If YES, Review menstrual diary and confirm use and form of contraception and CONTINUE.
If NO, SKIP to Part III - Medications.

2. Date of last menstrual period [ ][ ] [ ][ ] [ ][ ] (month day year) QPDOLM

If participant is assigned to pharmacologic treatment, answer 2.a.
If participant is assigned to intensive lifestyle treatment, answer 2.b.

a. Menstrual period more than one week late?

YES [1] NO [2] QP1WK

b. Menstrual period more than two weeks late?

[1] [2] QP2WK

If 2.a or 2.b. is YES, a pregnancy test must be performed.
If NO, skip to question G.5.

3. Date of pregnancy test [ ][ ] [ ][ ] [ ][ ] (month day year) QPDOPT

4. Result of pregnancy test

Positive [1]
Negative [2] QPREG

If POSITIVE, coded metformin must be discontinued and complete a Pregnancy Confirmation Report (Form E04). Skip to Section H.

5. Does the participant plan on becoming pregnant within the next 3 months?

YES [1] NO [2] QPLAN

If YES, coded metformin must be discontinued.

Part III / MEDICATIONS

Complete Section H if assigned the pharmacological

H. Coded Medication

	YES	NO	
1. Has the participant taken any coded METFORMIN since the last visit?	1	2	QMTAKM

If YES,

	850 mg	1700 mg	
a. Daily dose of METFORMIN per protocol	1	2	QMDOSE

b. What is your best estimate of the participant's level of exposure to metformin per protocol?

< 80%	1	QMCOMM
≥ 80%	2	
did not return pill container	3	

c. For the most recent typical week, what is the participant's estimate of the number of days when the metformin pills were taken as prescribed by DPP staff?

QMDAYSM ____ days

2. Dispensing of Medication

METFORMIN LABEL

Remove label from medication before dispensing and affix here. If not dispensed, check here 1 QMNOMET

I. Concomitant Medications

1. Is the participant currently taking any PRESCRIPTION medications other than the coded metformin?
   If YES, list below:

YES [1] NO [2] QMRXDQ

	Medicine Description	Route
a.	QMRXDA	
b.	QMRXDB	
c.	QMRXDC	
d.	QMRXDD	
e.	QMRXDE	
f.	QMRXDF	
g.	QMRXDG	
h.	QMRXDH	
i.	QMRXDI	
j.	QMRXDJ	

Diuretic agents, beta blockers, and fluoxetine > 20 mg/day (or equivalent dose of SSRI) are discouraged.

Part IV / LOCAL LABORATORY RESULTS

If this is the End-month 6 Mid-year visit and the participant was assigned to the pharmacological treatment, RECORD THE CBC RESULTS.
If not, STOP.

J. Complete Blood Count

1. Hemoglobin [ ][ ].[ ] g/dL QLHGLOB
2. Hematocrit [ ][ ].[ ] % QLHCRIT
3. Platelet Count [ ][ ][ ] x10³/ml QLPLATE

Diabetes Prevention Program

MAJOR FOLLOW-UP VISIT INVENTORY

This form is completed at Major follow-up visits: annual follow-up visits (End-months 12, 24, . . .) and the End of Study visit.
Form F02 records the following: anthropometrics, arm/ankle blood pressures, adverse events, pregnancy information, coded and concomitant medications and local CBC results.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number ☐☐ CLINIC
2. Participant number ☐☐☐☐☐☐ PATID
3. Participant's initials ☐☐☐☐ INITS (first last)
4. Participant's date of birth ☐☐ ☐☐ ☐☐ DOB (month day year)
5. Participant's sex Male [1] Female [2] SEX

B. Visit Information

1. Date of visit ☐☐ ☐☐ ☐☐ AVSTDT (month day year)
2. Week of visit ☐☐☐ AVSTWK
3. Type of visit In Clinic [1] Home Visit [2] AVSTTYP
4. Outcome visit ☐☐☐ VISIT
5. End of Study Yes [1] No [2] AVEOS

C. Instructions for Form F02 Completion

Complete all sections of Form F02 with the following exceptions:

- Sections D.4 - skin-fold thickness and D.5 - sagittal diameter are completed at End-month 12 and End of Study visits.
- Section E.2 - supine ankle-arm systolic blood pressure is completed at End-months 12 and 36, and End of Study visits.
- Part IV - Local Laboratory Results is completed for participants assigned to the pharmacological treatment.

Initials of person reviewing completed form ☐☐☐☐ (first last) Form entered in computer? ☐

Signature of P.I. _____ Date: _____

Part II / PHYSICAL AND HISTORY

D. Anthropometrics

- For D.1 - Weight, record Measure 3 only if first 2 measurements are not within 0.2 kilograms.
- For D.2 - Waist Circumference, and D.3 - Hip Girth, record measure 1 for each before completing Measure 2 and only record Measure 3 if first 2 measurements are not within 0.5 cm.

	Measure 1	Measure 2	Measure 3	
1. Weight	APWGHTI1	APWGHT2	APWGHT3	kg
2. Waist Circumference	APWSTC1	APWSTC2	APWSTC3	cm
3. Hip Girth	APHIP1	APHIP2	APHIP3	cm

If this is the End-month 12 or the End of Study visit, CONTINUE.
If not, SKIP to Section E - Blood Pressure.

4. Skin-fold Thickness

Do all skinfold measurements in each trial before going on to the next trial.

	Trial 1	Trial 2	Trial 3	
a. Subscapular APSFSB	1	2	3	mm
b. Triceps APSFTR	1	2	3	mm
c. Supra iliac APSFSI	1	2	3	mm
d. Abdominal APSFAB	1	2	3	mm
e. Medial calf APSFMC	1	2	3	mm

5. Sagittal Diameter

Record Measure 3 only if first 2 measurements are not within 1 cm.

	Measure 1	Measure 2	Measure 3	
APSAGD				cm

E. 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

Hypertension management aims at maintaining blood pressure < 140/90 mmHg.

If this is the End-months 12 or 36 or the End of Study visit, CONTINUE.
If not, SKIP to Section F - Adverse Events.

2. Supine Ankle/Arm Systolic Blood Pressure

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.

a. Arm	APSSBP	mmHg 1 Right arm 2 Left arm 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 2.a)	APSSBPF	mmHg

Initials of data collector completing pages 2 and 3 of this form (first, last)

F. Adverse Events

	YES	NO	
1. Interval History Questionnaire (Form Q08) completed?	1	2	APQ08
2. During the interval since the last visit, has the participant had any new symptoms, injuries, illness or side effects, or worsening of pre-existing conditions?	1	2	APAEQ

If YES to F.2, an Adverse Event Report (Form E01) MUST be completed.

G. Pregnancy Questions

	YES	NO	
1. Does the participant have reproductive potential?	1	2	APREM

If YES, review menstrual diary and confirm use and form of contraception and CONTINUE.
If NO, SKIP to Part III - Medications.

2. Date of last menstrual period [ ][ ] [ ][ ] [ ][ ] (month day year) APDOLM

If participant is assigned to pharmacologic treatment, answer 2.a.
If participant is assigned to intensive lifestyle treatment, answer 2.b.

	YES	NO	
a. Menstrual period more than one week late?	1	2	AP1WK
b. Menstrual period more than two weeks late?	1	2	AP2WK

If 2.a or 2.b. is YES, a pregnancy test must be performed.
If NO, skip to question G.5.

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

4. Result of pregnancy test

Positive	1	APREG
Negative	2	

If POSITIVE, coded metformin must be discontinued and complete a Pregnancy Confirmation Report (Form E04). Skip to Section H.

	YES	NO	
5. Does the participant plan on becoming pregnant within the next 3 months?	1	2	APLAN

If YES, coded metformin must be discontinued.

Participant's initials [ ][ ][ ][ ] (first last) Date of birth [ ][ ] [ ][ ] [ ][ ] (month day year) Date of visit [ ][ ] [ ][ ] [ ][ ] (month day year)

Part III / MEDICATIONS

Complete Section H if assigned the pharmacological treatment.

H. Coded Medication

1. Has the participant taken any coded METFORMIN since the last visit? YES [1] NO [2] AMTAKM

If YES,

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?
< 80% [1]
≥ 80% [2] AMCOMPM
did not return pill container [3]

c. For the most recent typical week, what is the participant's estimate of the number of days when the metformin pills were taken as prescribed by DPP staff? [ ] AMDAYSM days

2. Dispensing of Medication

METFORMIN LABEL

Remove label from medication before dispensing and affix here. If not dispensed, check here [1] AMNOMET

Participant's initials (first last) | Date of birth (month day year) | Date of visit (month day year)

I. Concomitant Medications

1. Is the participant currently taking any PRESCRIPTION medications other than the coded metformin? If YES, list below:

YES [1] NO [2] AMRXDQ

	Medicine Description	Route
a.	AMRXDA	
b.	B	
c.	C	
d.	D	
e.	E	
f.	F	
g.	G	
h.	H	
i.	I	
j.	J	

Diuretic agents, beta blockers, and fluoxetine > 20 mg/day (or equivalent dose of SSRI) are discouraged.

Part IV / LOCAL LABORATORY RESULTS

If the participant was assigned to the pharmacological treatment, RECORD THE CBC RESULTS. If not, STOP.

J. Complete Blood Count

1. Hemoglobin — ALHGLOB ___.___ g/dL
2. Hematocrit — ALHCRIT ___.___ %
3. Platelet Count — ALPLATE ___ x10³/ml

Diabetes Prevention Program

INTERIM FOLLOW-UP VISIT INVENTORY

This form is completed at titration visits for coded metformin and follow-up visits when the Standard Follow-up Visit Inventory (Form F01) and Major Follow-up Visit Inventory (Form F02) are not completed. Form F03 records the following: adverse events, pregnancy questions, coded medication and arm blood pressure for hypertension management.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number [ ][ ] CLINIC
2. Participant number [ ][ ][ ][ ][ ][ ] PATID
3. Participant's initials [ ][ ][ ][ ] (first last) INITS
4. Participant's date of birth [ ][ ] / [ ][ ] / [ ][ ] (month day year) DOB
5. Participant's sex Male [1] Female [2] SEX

B. Visit Information

1. Date of visit [ ][ ] / [ ][ ] / [ ][ ] (month day year) JIVSTDT
2. Week of visit [ ][ ][ ] JIVSTWK
3. Type of visit In Clinic [1] Unattended [2] JVSTTYPE

C. Reason for Interim Visit

Complete Part II of this form for all reasons listed below.

check all that apply

1. Coded metformin management JIMEDMG [1]
2. Hypertension management JIHYPMG [1] Complete Part II and Part III
3. Lipid management JILIPMG [1]
4. Pregnancy management JIPRGMG [1]
5. Adverse event management JIAEMG [1]
6. Collection of specimen for CBL (e.g. OGTT) JISPEC [1] Complete CBL Specimen Transmittal Form
7. Repeat collection of outcome found to be deficient JIOUT [1]
8. Other JIOTH [1]
   a. specify:_____

Initials of person reviewing completed form [ ][ ][ ][ ] (first last) Form entered in computer? [ ]

Part II / HISTORY

D. Adverse Events

1. During the interval since the last visit, has the participant had any new symptoms, injuries, illness or side effects, or worsening of pre-existing conditions? YES [1] NO [2] JIAEQ

If YES, an Adverse Event Report (Form EO1) MUST be completed.

E. Pregnancy Questions- Women Only

If the participant was randomized to troglitazone, skip section E pregnancy questions.

1. Does the participant have reproductive potential? YES [1] NO [2] JIPREM

If YES, Review menstrual diary and confirm use and form of contraception and CONTINUE.
If NO, SKIP to Section F - Coded Medication.

2. Date of last menstrual period (month, day, year) JIDOLM

If participant is assigned to pharmacologic treatment, answer 2.a.
If participant is assigned to intensive lifestyle treatment, answer 2.b.

a. Menstrual period more than one week late? YES [1] NO [2] JI1WK

b. Menstrual period more than two weeks late? [1] [2] JI2WK

If 2.a or 2.b. is YES, a pregnancy test must be performed.
If NO, skip to question E.5.

3. Date of pregnancy test (month, day, year) JIDOPT

4. Result of pregnancy test Positive [1] Negative [2] JIPREG

If POSITIVE, coded metformin must be discontinued and complete a Pregnancy Confirmation Report (Form E04). Skip to Section F - Coded Medication.

5. Does the participant plan on becoming pregnant within the next 3 months? YES [1] NO [2] JIPLAN

If YES, coded metformin must be discontinued.

F. Coded Medication

Complete Section F if the participant was assigned metformin/placebo. Do not complete for troglitazone or lifestyle participants.

1. Has the participant taken any coded METFORMIN since the last visit? YES [1] NO [2] JITAKMT

If YES,

a. Daily dose of METFORMIN per protocol 850 mg [1] 1700 mg [2] JIDOSE

b. What is your best estimate of the participant's level of exposure to metformin per protocol? < 80% [1] ≥ 80% [2] did not return pill container [3] JICOMPM

c. For the most recent typical week, what is the participant's estimate of the number of days when the metformin pills were taken as prescribed by DPP staff? [ ] days JIDAYSM

2. Dispensing of Medication

METFORMIN LABEL

Remove label from medication before dispensing and affix here. If not dispensed, check here [1] JINOMET

Part III / HYPERTENSION MANAGEMENT

G. Blood Pressure

1. Seated Arm Blood Pressure

a. Blood Pressure Reading 1 (after sitting 5 minutes) JISBP1 Systolic [ ] / JISBP1 Diastolic [ ] mmHg

b. Blood Pressure Reading 2 (after waiting 30 seconds) JISBP2 [ ] / JIDBP2 [ ] mmHg

Hypertension management aims at maintaining blood pressure < 140/90 mmHg.

Diabetes Prevention Program

MISSED FOLLOW-UP VISIT REPORT

This form is completed anytime a participant misses either a standard or major scheduled follow-up visit. Form F04 records the date and reason for the missed visit.

A. Participant Identification

1. Clinic number [ ][ ] CLINIC
2. Participant number [ ][ ][ ][ ][ ][ ] PATID
3. Participant's initials [ ][ ][ ][ ] INITS (first last)
4. Participant's date of birth [ ][ ] [ ][ ] [ ][ ] DOB (month day year)

B. Visit Information

1. Date follow-up visit was scheduled [ ][ ] [ ][ ] [ ][ ] JMVSTDT (month day year)
2. Week of visit missed [ ][ ][ ] JMVSTWK
3. Type of visit missed
   - Standard follow-up [1] JMVSTTY
   - Major follow-up [2]
4. Outcome visit [ ][ ][ ] VISIT
5. End of Study
   - Yes [1] JMEOS
   - No [2]
6. Has there been any contact with the participant concerning the missed visit? YES [1] NO [2] JMCONT

   If YES,

   a. In the coordinator's opinion, what was the primary reason for the missed visit?
      - Illness, surgery, or hospitalization [1]

      If so, an Adverse Event Report (Form E01) MUST be completed.

      - Moved to a less convenient location [2]
      - General decline in motivation [3]
      - Conflicting responsibilities (job, birthday, family) [4]
      - Other (specify below) [5]

      JMRSN

      Other Specified: _____
7. Is the participant considered on inactive follow-up status? (i.e., scheduled follow-up protocol suspended) YES [1] NO [2] JMINACT

Initials of person completing form [ ][ ][ ][ ] (first last) Form entered in computer? [ ]

Diabetes Prevention Program

MEDICATION ADHERENCE INTERVIEW

This form must be completed when medication adherence is assessed on the Standard (form F01) or Major (form F02) Follow-up Visit Inventory. This form is also completed at the Month 1 Titration Visit with the Interim (form F03) Follow-up Visit Inventory. Complete this form only if the participant has taken any coded metformin since the last visit. The Medication Adherence Interview is for all DPP participants taking coded metformin, regardless of level of adherence. Complete the interview and F05 form, and then transfer appropriate data to Section H (Coded Medication) of the corresponding Follow-up Visit Inventory.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number [ ][ ] CLINIC
2. Participant number [ ][ ][ ][ ][ ][ ] PATID
3. Participant's initials [ ][ ][ ][ ] (first, last) INITS
4. Participant's date of birth [ ][ ] / [ ][ ] / [ ][ ] (month / day / year) DOB
5. Participant's sex
   - Male [1]
   - Female [2]

   SEX

B. Visit Information

1. Date of visit [ ][ ] / [ ][ ] / [ ][ ] (month / day / year) MAVSTDT
2. Type of visit
   - Standard Follow-up [1]
   - Major Follow-up [2]
   - Interim Follow-up [3]

   MAVSTTY
3. Week of visit [ ][ ][ ] MAVSTWK
4. Outcome visit [ ][ ][ ] VISIT
5. End of Study
   - Yes [1]
   - No [2]

   MAEOS

C. Instructions for Form F05 Completion

Complete Part II of this form during the interview, keeping as close to the wording of the interview questions as possible and as appropriate for the DPP participant. For items which require the Code Sheet, choose the code which you think best describes the response most important to the participant and list on line a. If the participant offers additional responses, list as b and c. If code 99 is used, please specify response on the line under the item.

Initials of person reviewing completed form [ ][ ][ ][ ] (first, last) Form entered in computer? [ ]

Participant's initials [ ][ ][ ][ ] (first last) Date of birth [ ][ ] [ ][ ] [ ][ ] (month day year) Date of visit [ ][ ] [ ][ ] [ ][ ] (month day year)

Part II / MEDICATION ADHERENCE INTERVIEW

PROMPT: For the most recent typical week, what is your estimate of the number of days when you took your metformin pills as prescribed? ____ of 7 days

Record results on the corresponding Follow-up Visit Inventory, section H.

D. Interview Responses

1. How did you remember to take your DPP pills as prescribed since the last visit? (see Code Sheet, 700 series)

MAHOW a. 7 [ ][ ]
MAHOWB b. 7 [ ][ ]
MAHOWC c. 7 [ ][ ]

2. How helpful was the plan we decided on at the last visit to help you take your DPP medications as prescribed?

MAHELD
- [1] No plan specified/Not applicable
- [2] Very helpful
- [3] Somewhat helpful
- [4] Not at all helpful
- [5] Did not try that plan (i.e., not implemented)

3. Taking pills every day is hard for some people. What is your main problem, if any, in trying to take your DPP pills as prescribed? (see Code Sheet, 800 series)

MAPROB a. 8 [ ][ ]
MAPRJBB b. 8 [ ][ ]
MAPROBC c. 8 [ ][ ]

4. What plan or strategy do you think could be helpful to deal with this problem? (see Code Sheet, 900 series)

MAPLAN a. 9 [ ][ ]
MAPLANB b. 9 [ ][ ]
MAPLANC c. 9 [ ][ ]

5. Do you intend to follow this plan (from question # 4) until the next visit?

MAINTEN
- [1] No plan specified/Not applicable
- [2] Definitely
- [3] Probably
- [4] Probably not
- [5] Definitely not

For DPP Staff Use Only

6. Do you consider the participant's estimation of medication adherence "for the most recent week" to be reliable?

MAREL1
- [1] Not applicable
- [2] Definitely
- [3] Probably
- [4] Probably not
- [5] Definitely not

Code Sheet for the Medication Adherence Interview (F05.1)

Record the code most important to the participant (their primary response) on the "a" line. If participant offers additional response(s), record on lines "b" and "c."

1. How did you remember to take your DPP pills as described since the last visit? (700 series) (Do <u>not</u> read options)

700 *no specific strategy reported*
701 *keeping to a time "routine" (e.g., time of day; meal-time activity)*
702 *keeping to a "strategy/routine" (e.g., medication in a convenient place, within sight, or marking dates on blister packs)*
703 *used calendar or log book to document pills taken*
704 *used pill-taking reminder devices (e.g., pillbox)*
705 *family/friends reminded me*
706 *DPP staff phone contact*
707 *stopped taking study medication since last visit*
799 *other (please specify):*

3. What is your main problem, if any, in trying to take your DPP pills as prescribed? (800 series) (Do <u>not</u> read options)

800 *no barriers reported*
801 *forgets to take DPP pills*
802 *reports doesn't like to take pills*
803 *fear of taking DPP pills*
804 *adverse reaction to DPP pills (please specify)*
805 *inconvenient to take pills as prescribed (e.g., with meals)*
806 *difficult to swallow DPP pills*
807 *forgets to take evening (second dose) of metformin*
808 *specifically a GI reaction to DPP pills*
809 *sometimes takes too many DPP pills*
810 *outside influence to stop taking medication (e.g., MD, family, friends, media)*
811 *disruption of regular routine (e.g., vacation, significant life events)*
812 *hospitalization/new illness/medical reasons*
813 *study fatigue/lack of motivation*
814 *lost/misplaced pills*
815 *excessive alcohol usage*
816 *unwilling to take DPP pills as prescribed*
899 *other (please specify):*

4. What plan or strategy do you think could be helpful to deal with this problem? (900 series) (May suggest options, as needed)

900 *no barriers reported, not applicable*
901 *will continue current plan*
902 *new device (e.g., pill box)*
903 *new routine/strategy (e.g., take with other pills, mark dates on blister packs)*

904 *remedy for adverse reactions to pills*
905 *change type and/or frequency of DPP staff communication (e.g., phone calls, letters, e-mail)*
906 *interim visits for adherence counseling*
907 *given tip sheet to address specific barriers*
908 *remedy for difficulty swallowing pills (please specify)*
909 *staff-prescribed deviation of taking a half tablet of metformin daily*
910 *DPP staff- prescribed deviation from medication protocol during this quarter, <u>other than</u> a half tablet of metformin daily (please specify)*
911 *accept participant's proposed level of adherence to DPP pills to promote retention*
912 *use new tool/strategy to <u>assess barriers</u> (i.e., record when and how often adverse events occur, monitor eating patterns)*
913 *Reduce alcohol intake to acceptable levels*
914 *Staff use of percent exposure data with selected participant*
915 *Scheduled a meeting with behavior therapist on DPP staff*
999 *other (please specify):*

Diabetes Prevention Program

HOME VISIT INVENTORY

This form is only completed for inactive participants off their coded medication for any Mid-Year or Annual visit conducted outside the DPP clinic.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number [ ][ ] CLINIC
2. Participant number [ ][ ][ ][ ][ ][ ] PATID
3. Participant's initials [ ][ ][ ][ ] INITS (first last)
4. Participant's date of birth [ ][ ] / [ ][ ] / [ ][ ] DOB (month day year)
5. Participant's sex SEX
   - Male [1]
   - Female [2]

B. Visit Information

1. Date of visit [ ][ ] / [ ][ ] / [ ][ ] KGVSTDT (month day year)
2. Week of visit [ ][ ][ ] KGVSTWK
3. Outcome visit [ ][ ][ ] VISIT
4. End of Study KGEOS
   - Yes [1]
   - No [2]

C. Instructions for Form F06 Completion

Complete all sections of Form F06.

Initials of person reviewing completed form [ ][ ][ ][ ] (first last) Form entered in computer? [ ]

D. Adverse Events

	YES	NO	
1. During the interval since the last visit (clinic or home visit), has the participant had any new symptoms, injuries, illness or side effects, or worsening of pre-existing conditions?	1	2	KGAEQ

If YES, an Adverse Event Report (Form E01) MUST be completed.

E. Prescription Medications

	YES	NO	
1. Is the participant currently taking any PRESCRIPTION medications? If YES, list below:	1	2	KGRXDQ

	Medicine Description	Route
a.	KGRXDA	
b.	KGRXDB	
c.	KGRXDC	
d.	KGRXDD	
e.	KGRXDE	
f.	KGRXDF	
g.	KGRXDG	
h.	KGRXDH	
i.	KGRXDI	
j.	KGRXDJ	

Diuretic agents, beta blockers, and fluoxetine > 20 mg/day (or equivalent dose of SSRI) are discouraged.

Diabetes Prevention Program

LIFESTYLE CONTACT - IN PERSON

This form is completed for all in-person contacts with participants in the Intensive Lifestyle Intervention. Form L03 records the following: nature of session, self-monitoring information and the physical activity and weight status.

A. Participant Identification

1. Clinic number ☐☐ CLINIC

2. Participant number ☐☐☐☐☐☐ PATID

3. Participant's initials ☐☐☐☐ INITS
   first last

4. Participant's date of birth ☐☐ ☐☐ ☐☐ DOB
   month day year

B. Contact Information

1. Date of In-Person Contact ☐☐ ☐☐ ☐☐ ZVSTDT
   month day year

2. Week of In-Person Contact
   (weeks since randomization, refer to participant calendar) ☐☐☐ ZVSTWK

C. Instructions For Form Completion

Complete all sections of Form L03 - Lifestyle Contact - In Person.

Initials of person completing form ☐☐☐☐ Form entered in computer? ☐
first last

Participant's initials: first last | Date of birth: month day year | Date of visit: month day year

Part II / LIFESTYLE CONTACT - IN PERSON

D. Nature of Session

1. Attendance (check only one)

alone [1]
with significant other [2]
with other participants [3]
ZNATTEN

2. Type (check only one)

core curriculum [1] (go to 2a.)
continued contact after core [2] (go to 2c.)
ZNTYPE

If CORE CURRICULUM,

2a. Session # [ ][ ] ZNLESS

i. If session #1, which topic did the participant choose?

diet /weight loss [1]
physical activity [2]
ZNTOPIC

2b. Repeat — Yes [1] No [2]
ZNREV

Skip to question 3.

If CONTINUED CONTACT AFTER CORE,

2c. Majority of contact time devoted to:

diet [1]
physical activity [2]
participant support [3]
other [4]
ZNMAJOR

Several topics may have been addressed; indicate which topic received the greatest amount of attention.

3. Duration of contact

less than 5 minutes [1]
5 - 14 minutes [2]
15 - 30 minutes [3]
more than 30 minutes [4]
ZNDUR

Part II / LIFESTYLE CONTACT - IN PERSON (continued)

E. Self-Monitoring Information

		Yes	No
1.	Has the participant self-monitored diet since the last In-Person Contact? ZNDIET	1	2
2.	Has the participant self-monitored physical activity since the last In-Person Contact? ZNEXER	1	2

If YES to either question 1 or 2, continue.
If NO to both question 1 and 2, skip to question 5.

3. Self-monitoring data (from written record only) from the most recent week available since the last In-Person Contact:

	DAY	FAT (g)	CALORIES	MINUTES OF PHYSICAL ACTIVITY
ZSG	a. GOAL	FAT	CAL	EX
		1 NA FNA	1 NA CNA	1 NA ENA
ZSD1	b. DAY 1	FAT	CAL	EX
ZSD2	c. DAY 2	FAT	CAL	EX
ZSD3	d. DAY 3	FAT	CAL	EX
ZSD4	e. DAY 4	FAT	CAL	EX
ZSD5	f. DAY 5	FAT	CAL	EX
ZSD6	g. DAY 6	FAT	CAL	EX
ZSD7	h. DAY 7	FAT	CAL	EX
	TOTAL (sum of Day 1 through Day 7)			ZSTOTEX

Participant's initials [ ][ ][ ][ ] (first last)

Date of birth [ ][ ] / [ ][ ] / [ ][ ] (month day year)

Date of visit [ ][ ] / [ ][ ] / [ ][ ] (month day year)

Part II / LIFESTYLE CONTACT - IN PERSON (continued)

4. Is more than one week of dietary self-monitoring available since the last In-Person Contact? Yes [1] No [2] ZSDIARY

If NO, skip to Question 5.

a. If YES, did other records look similar? Yes [1] No [2] ZSSIMIL

i . If NO, how much did the other diaries differ from this one?

other diaries show less success at behavior change [1] ZSDIFER

other diaries show more success at behavior change [2]

5.

If this contact is for the CORE CURRICULUM, skip to section F.
If this contact is CONTINUED CONTACT AFTER CORE, continue.

If a written record is not available, indicate how many minutes of physical activity the participant verbally reported during the previous week (one week only).

Start date [ ][ ] / [ ][ ] / [ ][ ] (month day year) ZSEX1ST

End date [ ][ ] / [ ][ ] / [ ][ ] (month day year) ZSEX1EN

Minutes [ ][ ][ ][ ] ZSEX1MN

Participant's initials (first last) | Date of birth (month day year) | Date of visit (month day year)

F. Physical Activity Status

		Yes	No
1.	Is the participant at study goal for physical activity? ZEXGOAL	1	2

2. What are the barriers? (see code book; 100 series) ZEXBAR1 ZEXBAR2 ZEXBAR3

a. 1 ☐☐
b. 1 ☐☐
c. 1 ☐☐

3. What approaches are taken to improve or maintain? (see code book; 200 series) ZEXAPP1 ZEXAPP2 ZEXAPP3

a. 2 ☐☐
b. 2 ☐☐
c. 2 ☐☐

G. Weight Status

1. Study weight goal? ZWTGOAL
(based on the line of reduction during core or 7% loss post-core) ☐☐☐.☐ pounds

2. Current weight? ZWTCURR ☐☐☐.☐ pounds

		Yes	No
3.	Is the participant at weight goal? ZWEIGHT	1	2
4.	Is the participant self-monitoring weight? ZWTSELF	1	2

5. What are the barriers? (see code book; 300 series) ZWTBAR1 ZWTBAR2 ZWTBAR3

a. 3 ☐☐
b. 3 ☐☐
c. 3 ☐☐

6. What approaches are taken to improve or maintain? (see code book; 400 series) ZWTAPP1 ZWTAPP2 ZWTAPP3

a. 4 ☐☐
b. 4 ☐☐
c. 4 ☐☐

Diabetes Prevention Program
LIFESTYLE PHYSICAL ACTIVITY LOG

This form is completed for each supervised physical activity session. If more than 15 participants attend a session please attach an additional form.

Part I / CLASS IDENTIFICATION

A. Clinic number [ ][ ] CLINIC

B. Date of exercise class [ ][ ] [ ][ ] [ ][ ] PADATE
month day year

C. Start time of exercise class [ ][ ] : [ ][ ] PATIME
time (24 hour clock)

D. Type of exercise
(see code book; 500 series)
1. [5][ ][ ] PATYPE

E. Exercise Leader (s)
1. [ ][ ][ ][ ] PALEAD1
first last
2. [ ][ ][ ][ ] PALEAD2
first last

Part II / ATTENDEES

	Name	Participant Identification Number	Initials (first last)	
1.	_____ RELEASE_ID1	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	INITS1
2.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
3.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
4.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
5.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
6.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
7.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
8.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
9.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
10.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
11.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
12.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
13.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
14.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
15.	_____ RELEASE_ID15	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	INITS15

Note: Optional page 2 listed RELEASE_ID16 - RELEASE_ID30

Initials of person completing form [ ][ ][ ][ ] (first last)

Form entered in computer? [ ]

Diabetes Prevention Program
LIFESTYLE GROUP SESSION LOG

This form is completed for each group session. If more than 15 participants attend a session please attach an additional form.

Part I / GROUP SESSION IDENTIFICATION

A. Clinic number [ ][ ] CLINIC

B. Date of group session [ ][ ][ ] GRDATE
month day year

C. Start time of group session [ ][ ] : [ ][ ] GRTIME
time (24 hour clock)

D. Type of session (see code book; 600 series) 6[ ][ ] GRTYPE

E. Group Leader (s)

1. [ ][ ][ ][ ] GRLEAD1
first last

2. [ ][ ][ ][ ] GRLEAD2
first last

Part II / ATTENDEES

	Name	Participant Identification Number	Initials first last	
1.	RELEASE_ID1 _____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	GINIT1
2.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
3.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
4.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
5.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
6.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
7.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
8.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
9.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
10.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
11.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
12.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
13.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
14.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	
15.	RELEASE_ID15 _____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]	GINIT15

Note: Optional page 2 listed RELEASE_ID16 - RELEASE_ID30

Initials of person completing form [ ][ ][ ][ ] (first last)

Form entered in computer? [ ]

Diabetes Prevention Program

CHD RISK STATUS REPORT

This form is completed whenever samples are collected for CBL determination of lipid profile. Form R04 records the non-lipid coronary heart disease (CHD) risk factors based on 1993 NCEP guidelines in adults.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic — CLINIC
2. Participant Identification Number (Complete a **OR** b)
   a. If screening step 4, Screening number — S — SCREEN
   b. If follow-up, Participant number — PATID
3. Participant's initials — INITS (first, last)
4. Participant's date of birth — DOB (month, day, year)
5. Participant's sex — SEX
   Male 1
   Female 2

B. Visit Information

1. Date of visit — CHVSTDT (month, day, year)
2. Type of visit — CHVSTTY
   Screening Step 4 1
   Standard Follow-up 2
   Major Follow-up 3
   Interim Follow-up 4
3. Week of visit (If Follow-up) — CHVSTWK
4. Outcome visit — VISIT
5. End of Study — CHEOS
   Yes 1
   No 2

C. Instructions For Administration

Complete Section D - CHD/ Unmasking Status. If any question in Section D is answered YES then the participant's lipid profile for this visit will be reported as an unmasked result.
If all questions in Section D are answered NO then complete Section E and F. Section E will document the participant's visit-specific CHD risk status for determination of intensity of treatment according to NCEP guidelines and unmasking of lipid results. Section F will document any non-CHD reason for unmasking the lipid results. If the question in Section F is answered YES then fax form R04 to the Coordinating Center for review of the unmasking request.

Initials of person reviewing completed form (first, last) — Form entered in computer?

Participant's initials [ ][ ][ ][ ] (first last) Date of birth [ ][ ] / [ ][ ] / [ ][ ] (month / day / year) Date of visit [ ][ ] / [ ][ ] / [ ][ ] (month / day / year)

Part II / PARTICIPANT STATUS

D. CHD/ Unmasking Status

		YES	NO	
1.	Has the participant's past lipid profile been unmasked by the Coordinating Center?	1	2	CHUNMA
2.	Is the participant on lipid-lowering drug therapy?	1	2	CHDRUG
3.	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)	1	2	CHATHER

If NO to questions D1 through D3, CONTINUE.
If any question in section D is answered YES, STOP.

E. CHD Risk Factor Status

		YES	NO	
1.	Male ≥ 45 years **or** Female ≥ 55 years **or** menopause without estrogen replacement therapy.	1	2	CHSEX
2.	Family history of premature CHD (definite myocardial infarction or sudden death before age 55 in father or other male first-degree relative, or before age 65 in mother or other female first-degree relative).	1	2	CHHIST
3.	Current cigarette smoking.	1	2	CHSMOKE
4.	Confirmed hypertension.	1	2	CHHYPER
5.	Diabetes mellitus.	1	2	CHDIAB

F. Other Reasons for Unmasking

		YES	NO	
1.	Is there any other reason to unmask lipid results for this participant?	1	2	CHREAS

If YES, explain below and fax form R04 to the Coordinating Center for review of explanation.

_____

_____

_____

_____

Diabetes Prevention Program

ELIGIBILITY CHECKLIST

This form is completed during the screening period for all participants attending a Screening Step 2 Visit. Form S01 documents the inclusion and exclusion criteria for potential participants.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number [ ][ ] CLINIC
2. Screening number S[ ][ ][ ][ ][ ] SCREEN
3. Participant's initials [ ][ ][ ][ ] INITS (first last)
4. Participant's date of birth [ ][ ] / [ ][ ] / [ ][ ] DOB (month day year)
5. Participant's sex Male [1] Female [2] SEX

B. Visit Information

1. Date of Screening Step 2 [ ][ ] / [ ][ ] / [ ][ ] SCT2DT (month day year)

Part II / INCLUSION CRITERIA

C. Inclusion Criteria

	YES	NO	
1. The participant is at least 25 years of age.	[1]	[2]	SC25YR
2. Impaired glucose tolerance with elevated fasting plasma glucose.			
a. Fasting plasma glucose 95-125 mg/dL.	[1]	[2]	SCFPGI
b. 2-hr plasma glucose 140-199 mg/dL.	[1]	[2]	SC2HPGI
3. Body-mass index ≥ 24 kg/m² (≥ 22 kg/m² for Asians)	[1]	[2]	SCBMI

All inclusion criteria must have been answered YES for the participant to be randomized.

Initials of person completing form [ ][ ][ ][ ] (first last) Form entered in computer? [ ]

Part III/ EXCLUSION CRITERIA

D. Exclusion for underlying disease likely to limit life span and/or increase risk of

	YES	NO	
1. Cancer requiring treatment in the past 5 years, with the exception of cancers which have been cured or, in the opinion of the investigator, carry a good prognosis.	1	2	SCCNCR
2. Infectious diseases.			
a. Self-reported HIV positivity.	1	2	SCHIV
b. Active tuberculosis.	1	2	SCTB
3. Cardiovascular disease.			
a. Hospitalization for treatment of heart disease in the past 6 months.	1	2	SCHDHOS
b. New York Heart Association Functional Class >2.	1	2	SCNYHAH
c. Left bundle branch block on ECG.	1	2	SCLBBB
d. Third degree atrioventricular block on ECG.	1	2	SC3RDB
e. Uncontrolled hypertension: SBP >180 mmHg or DBP >105 mmHg on treatment.	1	2	SCHYPER
f. Stroke or transient ischemic attack in the past 6 months.	1	2	SCSTROK
4. Gastrointestinal disease.			
a. Self-reported chronic hepatitis or cirrhosis, or serum AST or ALT elevated by the following criteria: serum AST $\geq$ 66 U/L; serum ALT $\geq$ 58 U/L if over 47 years; serum ALT $\geq$ 118 U/L if male $\leq$ 47 years; serum ALT $\geq$ 46 U/L if female $\leq$ 47 years	1	2	SCAST
b. Episode of alcoholic hepatitis or alcoholic pancreatitis ever.	1	2	SCALCHL
c. Inflammatory bowel disease requiring treatment in the past year.	1	2	SCBOWL
d. Recent or significant abdominal surgery (e.g. gastrectomy).	1	2	SCABSUR

Participant's initials (first last) | Date of birth (month day year)

Part III / EXCLUSION CRITERIA (continued)

	YES	NO	
5. Renal disease.			
a. Serum creatinine ≥1.4 mg/dL (124 μmol/L) for men; ≥1.3 mg/dL (115 μmol/L) for women.	1	2	SCRENAL
b. Urine protein ≥ 2+ on one occasion (dipstick), in the absence of infection or vaginal contamination.	1	2	SCOIPSK
6. Lung disease.			
a. Chronic obstructive airway disease or asthma requiring daily therapy.	1	2	SCASTHM
b. New York Heart Association Functional Class > 2.	1	2	SCNYHAL
c. Use of oxygen at home.	1	2	SCOXYGN
7. Electrolyte abnormality: Serum Potassium <3.2 or >5.5 mmol/L.	1	2	SCPOTAS
8. Anemia. Hematocrit <36% in men or <33% in women.	1	2	SCHEMAT
9. Other chronic disease or condition likely to limit life span to < 6 years.	1	2	SCGRAN
10. Exclusions based on underlying disease not specifically mentioned above, likely to limit life span and/or increase risk of intervention.	1	2	SCCONDS

E. Exclusion for conditions or behaviors likely to effect the conduct of the DPP.

1. Unable or unwilling to give informed consent.	1	2	SCNOCON
2. Unable to communicate with the pertinent clinic staff.	1	2	SCCLANG
3. Another household member is a participant or staff member of DPP.	1	2	SCHOUSE
4. Unwilling to accept treatment assignment by randomization.	1	2	SCASIGN
5. Current or anticipated participation in another intervention research project that would interfere with any of the interventions offered in DPP.	1	2	SCINTV

Participant's initials (first last) Date of birth (month day year)

Part III / EXCLUSION CRITERIA (continued)

	YES	NO	
6. Weight loss of >10% in past 6 months for any reason except postpartum weight loss.	1	2	SCLLBS
7. Likely to move away from participating clinics in next 5 years.	1	2	SCMOVE
8. Unable to walk 0.25 mile in 10 minutes.	1	2	SCMILE
9. Unable to complete DPP run-in tasks.	1	2	SCRUNIN
10. Pregnancy and childbearing.			
a. Currently pregnant or less than 3 months postpartum.	1	2	SCPREG
b. Currently nursing or within 6 weeks of having completed nursing.	1	2	SCNURS
c. Pregnancy anticipated during study.	1	2	SCPLANP
d. Unwilling to undergo pregnancy testing or to report possible or confirmed pregnancies promptly during the course of the DPP.	1	2	SCNOTEL
e. Unwilling to take adequate contraceptive measures, if potentially fertile.	1	2	SCCONTR
11. Major psychiatric disorder which, in opinion of clinic staff, would impede conduct of the DPP.	1	2	SCPSYC
12. Excessive alcohol intake, either acute or chronic.	1	2	SCALCY
13. Other condition or behavior which, in opinion of clinic staff, would affect the conduct of DPP.	1	2	SCOTH2

Part III / EXCLUSION CRITERIA (continued)

F. Exclusion related to metabolism.

	YES	NO	
1. Diabetes at baseline evaluation evidenced by any of the following:			
a. Diabetes diagnosed by a physician and confirmed by other clinical data.	1	2	SCDIAB
b. Ever used hypoglycemic medication, except during GDM.	1	2	SCHYMED
2. Disease associated with disordered glucose metabolism.			
a. Cushing's Syndrome.	1	2	SCUSHNG
b. Acromegaly.	1	2	SCACROM
c. Pheochromocytoma currently under treatment.	1	2	SCPHEO
d. Chronic pancreatitis.	1	2	SCPANCR
3. Thyroid disease, suboptimally treated.	1	2	SCTYRD
4. Fasting plasma triglyceride level >600 mg/dL (6.77 mmol/L) on one occasion despite treatment.	1	2	SCFPT
5. Exclusions related to metabolism, not specifically mentioned above.	1	2	SCOTH3

G. Exclusions related to medications.

1. Antihypertensives.			
a. Thiazide diuretics.	1	2	SCTHZD
b. Beta-blockers.	1	2	SCBBLCK
2. Lipid-lowering agents - Niacin only.	1	2	SCNIAC
3. Glucocorticoids other than topical, ophthalmic, and inhaled preparations.	1	2	SCRDIDS
4. Antibiotics.			
a. HIV-related agents.	1	2	SCHIVMD
b. Antituberculous agents.	1	2	SCTBMED

Part III / EXCLUSION CRITERIA (continued)

	YES	NO	
5. Antineoplastic agents.	1	2	SCNPLST
6. Psychoactive agents.			
a. Antipsychotic agents.	1	2	SCPSYMD
b. Fluoxetine (Prozac) >20 mg daily, or other equivalent dose of SSRI.	1	2	SCSSRI
7. Bronchodialators.			
a. Aminophylline, if used daily.	1	2	SCAMINO
b. Inhaled beta-agonists, if used daily.	1	2	SCBETAA
8. Other medications.			
a. Phenytoin.	1	2	SCPHEN
b. Amphetamines.	1	2	SCAMPH
c. Prescription weight-loss drugs.	1	2	SCRXWL
9. Exclusions based on medications not specifically mentioned above.	1	2	SCOTHMD

All exclusion criteria must have been answered NO for participant to be randomized.

H. Conclusion

	YES	NO	
1. Are all inclusion criteria answered YES?	1	2	SCINCL
2. Are all exclusion criteria answered NO?	1	2	SCEXCL

If question 1 or 2 in section H is answered NO, the participant cannot be randomized.

	YES	NO	
3. Will the participant be randomized?	1	2	SCRNDM

a. If NO, and the reason is not documented in part II or III, specify below.

_____

_____

Diabetes Prevention Program

SCREENING STEP 2 INVENTORY

This form is completed during Screening Step 2.
Form S03 records the following: BMI, arm blood pressures, urinalysis, current medications, and pregnancy/diabetes information; OGTT qualification, progression and local results; demographics and complete blood count (CBC) results.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number ☐☐ CLINIC
2. Screening number S☐☐☐☐☐ SCREEN
3. Participant's initials ☐☐☐☐ INITS (first last)
4. Participant's date of birth ☐☐/☐☐/☐☐ DOB (month day year)

If age is ≥ 25 years continue, if age < 25 years, STOP. Fill in Eligibility Checklist item C.1.

5. Participant's sex SEX
   - Male [1]
   - Female [2]

B. Visit Information

1. Date of visit ☐☐/☐☐/☐☐ SOVSTDT (month day year)

C. Instructions for Form S03 Completion

Prior to the OGTT procedure, complete all of sections D through J of Form S03 unless a STOP is encountered. Sections K and L should be completed during the OGTT procedure. The remaining sections, M through O, should be completed during or after the OGTT procedure.

Initials of person reviewing completed form ☐☐☐☐ (first last) Form entered in computer? ☐

Part II / BEFORE OGTT

D. BMI

1. Height

a. First measurement ___ . ___ cm SOHGHT1

b. Second measurement ___ . ___ cm SOHGHT2

Record c. only if first 2 measurements are not within 0.5 cm .

c. Third measurement ___ . ___ cm SOHGHT3

2. Weight

a. First measurement ___ . ___ kg SOWGHT1

b. Second measurement ___ . ___ kg SOWGHT2

Record c. only if first 2 measurements are not within 0.2 kilogram (200 gm).

c. Third measurement ___ . ___ kg SOWGHT3

3. Is BMI ≥ 24 kg/m² (≥ 22 kg/m² for Asians)? YES [1] NO [2] SOBMI

Use largest height and smallest weight for eligibility. See chart.

If BMI is ≥ 24 kg/m² (≥ 22 kg/m² for Asians) continue, if BMI < 24 kg/m² (< 22 kg/m² for Asians) STOP. Fill in Eligibility Checklist item C.3

E. Blood Pressure

1. Seated Arm Blood Pressure

	Systolic	Diastolic
a. Blood Pressure Reading 1 (after sitting 5 minutes)	SOSBP1	SODBP1
b. Blood Pressure Reading 2 (after waiting 30 seconds)	SOSBP2	SOSBP2
c. Average of 1.a & 1.b (round up)	SOSBPA	SODBPA

mmHg

If average SBP ≤ 180 mmHg and average DBP ≤ 105 mmHg, continue.
If SBP > 180 mmHg or DBP > 105 mmHg, STOP.
Fill in Eligibility Checklist item D.3.e

F. Urinalysis

1. Protein: negative [1] trace [2] 1+ [3] 2+ [4] 3+ [5] 4+ [6] SOPRTN

2. Nitrite: negative [1] positive [2] SONTRT

3. Blood: negative [1] trace [2] 1+ [3] 2+ [4] 3+ [5] SOB

If urine protein < 2+, continue. Repeat urine dipstick later if protein is 2+ or greater AND nitrite is positive or blood is 1+ or greater, continue with form. If urine protein is 2+ or greater and nitrite is negative and blood is <1+ , STOP.
Fill in Eligibility Checklist item D.5.b.

G. Current Medications

1. Has the participant taken any PRESCRIPTION medications within the past 2 weeks?
   If YES, list below - confirm by inspection of bottles:

YES [1] NO [2] SORXDQ

	Medicine Description	Route
a.	SORXDA1	
b.	B1	
c.	C1	
d.	D1	
e.	E1	
f.	F1	
g.	G1	
h.	H1	
i.	I1	
j.	J1	

check dose if SSRI (Prozac, Paxil, Zoloft, Luvox)

2. Are any of these medications exclusionary? YES [1] NO [2] SORXEX

Fill in Eligibility Checklist items G.1 - 9. Participant may be eligible if medication can be discontinued.

H. Pregnancy (Women < 50 years only)

1. Are you currently pregnant or nursing a baby? YES [1] NO [2] MAYBE [3] SOPREG

If YES, STOP. If MAYBE, probe further and do pregnancy test. If not pregnant, continue.
Fill in Eligibility Checklist items E.10.a & b.

I. Diabetes

1. Have you ever been told that you had a high sugar level or that you have diabetes?
   (women: including during pregnancy)

check only one

No [1]
Only during pregnancy [2]
Yes, borderline [3]
Yes [4]

SODIAB

If YES, and can confirm with physician, or medication, STOP. If otherwise, continue.
Fill in Eligibility Checklist item F.1.a.

Part III / SCREENING OGTT

J. Test Qualification

1. Have you been ill in the past 7 days (e.g. cold, flu, fever, vomiting)? — YES [1] NO [2] SOILL

If YES, cancel current OGTT and reschedule.

2. What time and date did you last eat or drink anything other than water?
   a. Date (month, day, year) SOEATD
   b. Time (time (24 hour clock)) SOEATT

If < 12 hours, cancel and reschedule the OGTT.

3. Have you eaten your typical or usual diet over the past 3 days? — YES [1] NO [2] SODIET

If NO, cancel and reschedule the OGTT if markedly less than usual caloric intake.

4. When was the last time you exercised vigorously?
   a. Date (month, day, year) SOEXED
   b. Time (time (24 hour clock)) SOEXET

If < 10 hours, cancel and reschedule the OGTT.

Perform local fasting capillary or venous glucose. Record results in Section L of Form S03 - Local OGTT Results.

K. Test Progression

	YES	NO	
1. Were the fasting blood samples drawn? (i.e., local CBC and CBL specimens)	1	2	SOFAST

2. Time glucose consumption started ____:____ time (24 hour clock) — SODRKT

If drink not entirely consumed within 5 minutes, cancel and reschedule the OGTT.

3. Time 30 minute sample drawn ____:____ time (24 hour clock) — SO30MT

The sample should be drawn within 2 minutes of the 30 minute interval. If the sample is drawn outside that window record the time and continue with the OGTT.

4. Time 2-hour sample drawn ____:____ time (24 hour clock) — SO2HRT

The sample must be drawn within 10 minutes of the 2 hour interval with a goal of ± 5 minutes. If the blood sample can not be obtained within the 10 minute window, the test must be rescheduled.

Perform local 2-hour capillary or venous glucose. Record results in Section L of Form S03 - Local OGTT Results.

5. The OGTT was (choose only one): — SORESL

- completed **without** problem [1]
- completed **with** problem [2]
- **not completed** [3]

a. Why was OGTT "completed with problem" or "not completed"? — SOFAIL

- Vomited after glucose load [1]
- Fainted or felt ill after glucose load [2]
- Blood sample not obtained within the 10 minute window of 2-hour blood draw [3]
- Participant did not drink entire glucose load in 5 minutes [4]
- Participant not eligible based on local fasting glucose [5]
- Other (specify below) [6]

Other Specified: _____

L. Local OGTT Results

1. Fasting glucose

a. What method was used to draw the blood?

Capillary [1]
Venous [2]
SOLMETH

b. What machine was used to analyze the blood?

Lifescan [1]
Glucose analyzer [2]
SOLMACH

i. If Glucose analyzer was selected specify:

Beckman [1]
YSI [2]
Other [3]
SOLSPEC

c. Fasting glucose level [ ][ ][ ] mg/dL SOLFAST

2. 2-hour glucose

a. What method was used to draw the blood?

Capillary [1]
Venous [2]
SOLMTH2

b. What machine was used to analyze the blood?

Lifescan [1]
Glucose analyzer [2]
SOLMCH2

i. If Glucose analyzer was selected specify:

Beckman [1]
YSI [2]
Other [3]
SOLSPC2

c. 2 - hour glucose level [ ][ ][ ] mg/dL SOL2HR

If eligible based on local glucose, send all samples to Central Biochemistry Lab. If not eligible based on local glucose, STOP; participant may be rescreened in 6 months.
Complete Eligibility Checklist items C.2.a & b.

3. Is participant eligible based on local glucose?

YES [1] NO [2]
SOL2HR

Part IV / DURING OR AFTER OGTT

M. Demographics

1. What ethnic or racial group do you consider yourself a member: (*check only one*)

SOETHN

- White. . . . . [1]
- Black. . . . . [2]
- American Indian or Native American. . . . . [3] (specify principal tribe:_____)
- Eskimo. . . . . [4]
- Aleut. . . . . [5]
- Asian or Pacific Islander. . . . . [6]
- Other. . . . . [7] (specify: _____)

If ASIAN OR PACIFIC ISLANDER (response = 6 above)

a. Specify: (*check only one*)

SOASN

- Chinese. . . . . [1]
- Filipino. . . . . [2]
- Hawaiian. . . . . [3]
- Korean. . . . . [4]
- Vietnamese. . . . . [5]
- Japanese. . . . . [6]
- Asian Indian. . . . . [7]
- Samoan. . . . . [8]
- Guamanian. . . . . [9]
- Other A/PI. . . . . [10] (specify: _____)

2. Are you of Spanish or Hispanic origin? YES [1] NO [2] SOHSP

If YES,

a. Do you consider yourself:

SOHSPS

- Mexican, Mexican-American, Chicano [1]
- Puerto Rican [2]
- Cuban [3]
- Other Spanish or Hispanic [4]

specify:_____

Part V / LOCAL LABORATORY RESULTS

N. Complete Blood Count

1. Hemoglobin ___.___ g/dL SOHGLOB

2. Hematocrit ___.___ % SOHCRIT

Participant is ineligible if <36.0% for men, <33.0% for women. Fill out Eligibility Checklist item D.8.

3. Platelet Count ___ x10³/ml SOAGRAN

Part VI / CONTINUING SCREENING

O. Eligibility/Interest

1. Is participant willing to continue with screening process YES [1] NO [2] SOWILL

If YES, schedule participant for Screening Step 3 visit.
If NO, STOP. Fill in Eligibility Checklist item E.1.

Diabetes Prevention Program

SCREENING STEP 3 INVENTORY - START

This form is completed during the Start-visit of Screening Step 3.
Form S05 records the following: history on family, weight, smoking, aspirin use, cardiovascular and stroke/TIA, other diseases/symptoms, diet, and medical history for women; anthropometric and ankle/arm systolic blood pressure; dispensing of medication for run-in.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number [ ][ ] CLINIC
2. Screening number [S][ ][ ][ ][ ][ ] SCREEN
3. Participant's initials [ ][ ][ ][ ] INITS (first last)
4. Participant's date of birth [ ][ ] / [ ][ ] / [ ][ ] DOB (month day year)
5. Participant's sex Male [1] Female [2] SEX

B. Visit Information

1. Date of visit [ ][ ] / [ ][ ] / [ ][ ] SIVSTDT (month day year)

C. Instructions for Form S05 Completion

Complete all sections of Form S05, unless an EXCLUSION is encountered in section I, J or Q.

Initials of person reviewing completed form [ ][ ][ ][ ] (first last) Form entered in computer? [ ]

Part II / PARTICIPANT HISTORY

D. Family Information

		Mother	Father
1. Did your mother or father have diabetes?	SIMDIAB / SIFDIA	YES 1 / NO 2 / Don't Know 3	YES 1 / NO 2 / Don't Know 3
a. If YES, age at diagnosis	SIMDAGE / SIFDAGE	____ years	____ years
2. Did your mother or father ever have a heart attack?	SIMMI / SIFMI	YES 1 / NO 2 / Don't Know 3	YES 1 / NO 2 / Don't Know 3
a. If YES, age at first heart attack	SIMMIAG / SIFMIAG	____ years	____ years
3. What are your parents' **years** of birth	SIMYOB / SIFYOB	1___ Year	1___ Year
4. Are your parents still alive?	SIMALV / SIFALV	Alive 1 / Dead 2	Alive 1 / Dead 2
a. If dead, **year** of death	SIMYOD / SIFYOD	19__ Year	19__ Year

5. How many natural brothers and sisters do you have (include all living and deceased). SISIBS

6. How many of your brothers and sisters have or had diabetes? SISIBDI

7. How many of your brothers and sisters have had a heart attack? SISIBMI

E. Personal Weight History

1. Is your current weight different than it was one year ago? By different, I mean gaining or losing more than 5 pounds.

check only one

[1] No

[2] Yes, gained

a. How many pounds have you gained? ___ pounds SIWGTGN

b. Did you try to gain this weight? YES [1] NO [2] SITRYGN

SIWGTDF

[3] Yes, lost

c. How many pounds have you lost? ___ pounds SIWGTLS

d. Did you try to lose this weight? YES [1] NO [2] SITRYLS

[4] Don't know

2. What did you weigh when you were 20 years old *(Probe: weight before pregnancy, what is your best estimate*): ___ pounds SIWGT20

3. What is the most you have weighed as an adult (age 20 or after) *(Probe: do not include the times you were pregnant):* ___ pounds SIMAXWT

4. What is the least you have weighed as an adult (age 20 or after) : ___ pounds SILSTWT

5. How many times in your life have you lost at least 10 pounds and then gained it back (don't count the weight lost after pregnancy). ___ times SI10LBS

6. Have ever tried to lose weight? YES [1] NO [2] SILSWGT

If YES,
Have you tried this by: (*check all that apply*)

SIWDIET a. Dieting alone. . . . . [1]

SIWEXE b. Self-directed exercise. . . . . [1]

SIWCOMB c. Dieting and exercise combined. . [1]

SIWFEEXE d. Formal exercise program. . . . . [1]

e. Medication. . . . . [1] SIWMED

f. Surgery. . . . . [1] SIWSYRG

g. Formal weight loss program. [1] SIWFWL

F. Smoking History

	YES	NO	
1. Have you smoked more than 100 cigarettes in your lifetime?	1	2	SI100CG

If YES,

a. What is your current smoking status:

Current smoker 1
Former smoker 2 SISMOK

If Former Smoker,

i. How old were you when you most recently stopped smoking? ___ age quit SIQOM

b. How old were you when you started smoking cigarettes? ___ years SISTRT

c. On average, how many cigarettes per day do you smoke or did you smoke? ___ SICIGDY cigarettes/day

	YES	NO	
2. Do you currently smoke cigars?	1	2	SISGR

If YES,

a. How old were you when you started smoking cigars? ___ age started SISGRST

b. On average, how many cigars per week do you smoke? ___ cigars/week SISGRWK

	YES	NO	
3. Do you currently smoke a pipe?	1	2	SIPIPE

If YES,

a. How old were you when you started smoking a pipe? ___ age started SIPIPST

b. On average, how many pipefuls do you smoke per week? ___ pipes/week SIPIPWK

G. Aspirin History

1. During an average week, how often do you take one or more aspirin tablets?

Never 1
Less than 1 day per week 2
1 or 2 days per week 3 SIASPIR
3 to 4 days per week (includes every other day) 4
5 or 6 days per week 5
Every day 6

H. Thinking about the past 12 months please answer the following questions:

	YES	NO	
1. Have you had any pain or discomfort in your chest?	1	2	SIPAIN
2. Have you had any pressure or heaviness in your chest?	1	2	SIPRES

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

	YES	NO	
a. Do you get it when you walk uphill or hurry?	1	2	SIHURRY
b. Do you get it when you walk at an ordinary pace on the level?	1	2	SILEVEL

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

Stop 1
Slow down 2 SIDO
Continue at same pace 3

	YES	NO	
d. Does it go away when you stand still?	1	2	SISTILL

If YES,
i. How Soon?

10 min. or less 1
more than 10 min. 2 SISOON

	YES	NO	
e. Where do you get this pain or discomfort:			
i. Sternum (central chest)?	1	2	SISTER
ii. Left anterior chest?	1	2	SILCHST
iii. Left arm?	1	2	SILARM

	YES	NO	
f. Have you ever had a severe pain across the front of your chest lasting for half an hour or more?	1	2	SI30MIN

I. Cardiovascular History

1. Has a doctor ever told you that you had a myocardial infarction or heart attack? YES [1] NO [2] SIMI

   If YES,

   a. When was your first heart attack: [ ][ ][ ] (month day year) SIMIFST

   Exclude if within the past 6 months. Fill out Eligibility Checklist item D.3.a

   b. When was your last heart attack: [ ][ ][ ] (month day year) SIMILST

   Exclude if within the past 6 months. Fill out Eligibility Checklist item D.3.a

   c. Hospital? _____

   d. Doctor? _____

2. Have you ever had coronary artery bypass surgery (graft, CABG)? YES [1] NO [2] SIBABG

   If YES,

   a. When was your first surgery: [ ][ ][ ] (month day year) SICBFST

   Exclude if within the past 6 months. Fill out Eligibility Checklist item D.3.a

   b. When was your last surgery: [ ][ ][ ] (month day year) SICBLST

   Exclude if within the past 6 months. Fill out Eligibility Checklist item D.3.a

   c. Hospital? _____

   d. Doctor? _____

3. Have you ever had an angioplasty of the coronary arteries, which is an opening of a blocked artery with a plastic tube in the blood vessel? YES [1] NO [2] SIBLLN

If YES,

a. When was your first angioplasty: month day year SIBLFST

Exclude if within the past 6 months. Fill out Eligibility Checklist item D.3.a

b. When was your last angioplasty: month day year SIBLLST

Exclude if within the past 6 months. Fill out Eligibility Checklist item D.3.a

c. Hospital? _____

d. Doctor? _____

4. Have you ever had a carotid endarterectomy or any other procedure to open up the blood vessels in your neck? YES [1] NO [2] SINECK

If YES,

a. When was your first surgery: month day year SINKFST

Exclude if within the past 6 months. Fill out Eligibility Checklist item D.3.a

b. When was your last surgery: month day year SINKLST

Exclude if within the past 6 months. Fill out Eligibility Checklist item D.3.a

c. Hospital? _____

d. Doctor? _____

5. Have you ever had bypass surgery of the lower extremities, to bypass a blocked artery in the leg?

YES	NO	
1	2	SIBYLFG

If YES,

a. When was your first procedure: month day year SIBYFST

b. When was your last procedure: month day year SIBYLST

c. Hospital? _____

d. Doctor? _____

J. Stroke / TIA History

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] SINUMB

If YES,

a. How long did the symptoms last?

< 1 hour [1]
1 - 24 hour(s) [2] SINUMBT
> 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] SIPARL

If YES,

a. How long did the symptoms last?

< 1 hour [1]
1 - 24 hour(s) [2] SIPARLT
> 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] SIBLUR

If YES,

a. How long did the symptoms last?

< 1 hour [1]
1 - 24 hour(s) [2] SIBLURT
> 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] SISLUR

If YES,

a. How long did the symptoms last?

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

5. During the past 12 months, have you had any spells or dizziness, difficulty in walking, lightheadedness or loss of balance? YES [1] NO [2] SIDIZY

6. Has a doctor ever told you that you had a stroke, mini-stroke or TIA (transient ischemic attack)?

SISTRK
- No [1]
- Yes, stroke [2]
- Yes, ministroke or TIA [3]
- Yes, uncertain which [4]

If YES,

a. When was your first stroke: [ ][ ] [ ][ ] [ ][ ] (month day year) SISKFST

Exclude if within the past 6 months. Fill out Eligibility Checklist item D.3.f

b. When was your last stroke: [ ][ ] [ ][ ] [ ][ ] (month day year) SISKLST

Exclude if within the past 6 months. Fill out Eligibility Checklist item D.3.f

c. Hospital? _____

d. Doctor? _____

K. Has a doctor told you that you had any of the following?

		Ever		Past 12 months		
		YES	NO	YES	NO	
1.	High blood pressure (hypertension)? SIHYPE1	1	2	1	2	SIHYPE1
2.	Angina? SIANGI1	1	2	1	2	SIANGI2
3.	High cholesterol (high blood fats)? SILIPI1	1	2	1	2	SILIPI2
4.	Ulcer (stomach or duodenal), or intestinal bleeding? SIULCR1	1	2	1	2	SIULCR2
5.	Hepatitis? SIHEP1	1	2	1	2	SIHEP2
6.	Cancer? SICNCR1	1	2	1	2	SICNCR2
7.	Gallstones, gallbladder disease, or gallbladder surgery? SIGALL1	1	2	1	2	SIGALL2
8.	Gout? SIGOUT	1	2	1	2	SIGOUT2
9.	Thyroid disease? SITHYR1	1	2	1	2	SITHYR2
10.	Other major diseases? SIOTH1	1	2	1	2	SIOTH2

a. If YES, specify _____

L. During the past 12 months have you experienced any of the following?

		YES	NO	
1.	Skin rashes?	1	2	SIRASH
2.	Frequent stomach pains, bloating, nausea, diarrhea, or loss of appetite?	1	2	SISTOM
3.	Unexplained weight loss?	1	2	SILOSEW
4.	Increased thirst (drinking more liquids than usual)?	1	2	SITHRST
5.	Urinating more often than usual?	1	2	SIURINT

M. Diet

		YES	NO	
1.	Are you now on a special diet for any reason?	1	2	SISPECD

If YES,
Specify (check all that apply)

a. Low cholesterol or low fat (for high cholesterol) 1 SILOWFT

b. Low salt (for high blood pressure) 1 SILOWNA

c. Low calorie (for weight loss) 1 SILOWCA

d. Vegetarian 1 SIVEGE

e. Other diet (specify: _____) 1 SIOTHD

If FEMALE, continue
If MALE, skip to Section O - Anthropometrics

N. Medical History Questionnaire for Women

1. Are you still having periods (menstrual bleeding)?

No [1] SIMENS
Yes [2]
Uncertain [3]
Never had a period [4]

If NO or UNCERTAIN

a. How long ago was your last period?

< 6 months [1]
6 - 12 months [2] SIMENST
13 - 24 months (1 - 2 years) [3]
25 or more months (more than 2 years) [4]

If 13 or more months

i. At what age was your last period? [ ][ ] years SIMENSA

2. Are you currently having hot flashes or night sweats? YES [1] NO [2] SIHOTFL

If YES,

a. What was your age when you first had symptoms? [ ][ ] years SIHOTAG

3. During most of your life, were your periods regular? That is, did they occur about once a month? (Do not include any time when you were pregnant or taking birth control pills).

No [1]
Yes [2] SIMREG
Sometimes regular, sometimes irregular [3]

4. Between the time you had your first and last period, did you ever go without any periods for at least one year? (Do not count times you were pregnant or breast-feeding). YES [1] NO [2] SI1YR

If YES,

a. What is the longest interval? (Not counting pregnancy and breast-feeding).

12 - 23 months [1]
24 - 48 months [2] SI1YRT
more than 48 months (4 years) [3]

	YES	NO	
5. Have you ever been pregnant?	[1]	[2]	SIPRGEV

If YES,

a. How many times have you been pregnant? [ ][ ] times SIXPEG

b. How many live births have you had? [ ][ ] live births SIBIRTH

c. How many stillbirths, miscarriages, and abortions have you had? [ ][ ] total number SIABORT

	YES	NO	
6. Have you ever tried to become pregnant for more than 1 year without becoming pregnant?	[1]	[2]	SITRYPR

If YES,

	YES	NO	
a. Did you visit a doctor or clinic because you did not become pregnant?	[1]	[2]	SIMDPRG

If YES,

	YES	NO	
i. Was a reason found for why you did not become pregnant?	[1]	[2]	SIWHYPR

If YES,

a) Major reason (check only one):

Problem with your hormones or ovulation (producing eggs)	[1]	
Problem with your tubes or uterus	[2]	
Endometriosis	[3]	SIWHYSP
Other problem with you	[4]	
Partner's problem	[5]	
Don't know	[6]	

7. Did you ever have an operation to have one or both of your ovaries taken out?

No	[1]	
Yes, one taken out	[2]	
Yes, both taken out	[3]	SIOVAR
Yes, part of an ovary taken out	[4]	
Don't know	[5]	

If YES,

a. How old were you at your last operation? [ ][ ] years SIOVARA

8. Did you ever have an operation to remove your uterus (womb) (hysterectomy)?

YES [1] NO [2] SIHYST

If YES,
a. How old were you? [ ][ ] years SIHYSTA

9. Did you ever have an operation to have your tubes tied to prevent pregnancy?

YES [1] NO [2] SITUBAL

10. Has a heath care provider ever told you that you had polycystic ovary syndrome or Stein-Leventhal syndrome?

YES [1] NO [2] SIPCOS

If YES,
a. How old were you when you were told? [ ][ ] years SIPCOSA

11. Did you ever take any type of estrogen, such as Premarin for 1) relief of menopausal symptoms such as hot flashes or night sweats, or 2) after a hysterectomy with removal of ovaries, or 3) for prevention of disease such as bone loss? (This could include pills, vaginal creams or suppositories, injections, or skin patches.)

YES [1] NO [2] SIESTR

If YES,
a. About how many years did you take this? [ ][ ] years SIESTRT

b. Are you still taking estrogen replacement therapy?

YES [1] NO [2] SIESTRN

12. Did you ever take oral contraceptives (birth control pills)?

YES [1] NO [2] SIBCP

If YES,
a. Altogether, about how long did you take oral contaceptives? [ ][ ] years SIBCPT

b. Are you still taking oral contraceptives?

YES [1] NO [2] SIBCPN

Part III / PHYSICAL

O. Anthropometrics

- For O.1 - Weight, record Measure 3 only if first 2 measurements are not within 0.2 kilograms.
- For O.2 - Waist Circumference, and O.3 - Hip Girth, record measure 1 for each before completing Measure 2 and only record Measure 3 if first 2 measurements are not within 0.5 cm.

	Measure 1	Measure 2	Measure 3	
1. Weight	SIWGHT1	SIWGHT2	SIWGHT3	kg
2. Waist Circumference	SIWSTC1	SIWSTC2	SIWSTC3	cm
3. Hip Girth	SIHIP1	SIHIP2	SIHIP3	cm

4. Skin-fold Thickness

Do all skinfold measurements in each trial before going on to the next trial.

		Trial 1	Trial 2	Trial 3	
a. Subscapular	SISFSB	1	2	3	mm
b. Triceps	SISFTR	1	2	3	mm
c. Supra iliac	SISFSI	1	2	3	mm
d. Abdominal	SISFAB	1	2	3	mm
e. Medial calf	SISFMC	1	2	3	mm

5. Sagittal Diameter

Record Measure 3 only if first 2 measurements are not within 1 cm.

	Measure 1	Measure 2	Measure 3	
SISAGD	1	2	3	cm

P. Blood Pressure

1. Supine Ankle/Arm Systolic Blood Pressure

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

a. Arm	SISSBP		mmHg	1 Right arm 2 Left arm	SISSBPA
b. Right dorsalis pedis	SIADORR		mmHg		
c. Right tibialis posterior	SIAPOSR		mmHg		
d. Left dorsalis pedis	SIADORL		mmHg		
e. Left tibialis posterior	SIADOSL		mmHg		
f. Arm (same arm as 1.a)	SISSBPF		mmHg		

Part IV / COMPLETION

Q. Eligibility/Interest

	YES	NO	
1. Is participant willing to continue with the screening process?	1	2	SIWILL

If YES, continue.
If NO, STOP. Fill in Eligibility Checklist item E.1.

R. Placebo Medication Dispensed

1. Dispensing of Medication

Run-in 1

METFORMIN LABEL

Remove label from medication before dispensing and affix here. If not dispensed, check here 1

SINOMT1

Run-in 2

METFORMIN LABEL

Remove label from medication before dispensing and affix here. If not dispensed, check here 1

SINOMT2

Diabetes Prevention Program

SCREENING STEP 3 INVENTORY - END

This form is completed during the End-visit of Screening Step 3.
Form S06 records the following: Run-in compliance and adverse event assessment; personal and socioeconomic information.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number [ ][ ] CLINIC
2. Screening number S[ ][ ][ ][ ][ ] SCREEN
3. Participant's initials [ ][ ][ ][ ] INITS (first last)
4. Participant's date of birth [ ][ ] / [ ][ ] / [ ][ ] DOB (month day year)
5. Participant's Sex Male [1] Female [2] SEX

B. Visit Information

1. Date of visit [ ][ ] / [ ][ ] / [ ][ ] SEVSTDT (month day year)

C. Instructions for Form S06 Completion

Complete all sections of Form S06 unless an EXCLUSION is encountered in section D or G.

Initials of person reviewing completed form [ ][ ][ ][ ] (first last) Form entered in computer? [ ]

Part II / RUN-IN COMPLETION INFORMATION

D. Run-in Compliance

	Run-in #1 (SEDATE1)		Run-in #2 (if repeated) (SEDATE2)	
1. Date run-in initiated	month day year		month day year	
	YES	NO	YES	NO
2. Was participant compliant with placebo pill taking?	1	2 SEPILL1	1	2 SEPILL2
3. Was participant compliant with keeping diet diary?	1	2 SEDEIT1	1	2 SEDIET2
4. Was participant compliant with physical activity logs?	1	2 SELOG1	1	2 SELOG2
5. Was participant compliant with keeping appointments?	1	2 SEAPPT1	1	2 SEAPPT2
6. Did participant complete interim run-in visit?	1	2 SEINT1	1	2 SEINT2
7. Was run-in completed satisfactorily?	1	2 SESAT1	1	2 SESAT2
If NO, a. Was run-in #2 started?	1	2 SERI2		

If Run-in #1 or Run-in #2 was completed satisfactorily, continue.
If neither Run-in was completed satisfactorily, STOP.
Fill out eligibility checklist item E.9.

E. Adverse Events

	YES	NO	
1. Since the physical exam, has the participant had any new symptoms, injuries, illness or side effects, or worsening of pre-existing conditions?	1	2	SEAEQ

If YES, an Adverse Event Report (Form EO1) MUST be completed.

F. Personal data & Socioeconomic Status

1. What is your current marital status or living arrangement?

Never married. . .	1	Separated. . . .	4	SELVG
Living together. .	2	Divorced.	5	
Married.	3	Widowed.	6	

2. What is the highest grade or year of school you have completed? (Code GED as 12)

Elementary/ Junior High		High School		College		Graduate School		
No schooling	1	9	5	13	9	17	13	SEEDUC
≤ 6	2	10	6	14	10	18	14	
7	3	11	7	15	11	19	15	
8	4	12	8	16	12	20+	16	

3. Which of the following best describes your current employment status? (read responses)

Currently employed full or part-time. . . .	1	Seasonally employed.	5	SEEMPL
Currently retired.	2	Student.	6	
Currently full-time homemaker.	3	Other.	7	
Currently not employed.	4	Never worked.	8	

4. How many individuals live in your household? ☐☐ people SEHOUSE

5. What is your annual household income from all sources? *(show card)*

less than $10,000.	1	$35,000 to less than $50,000. . . .	5	SEINC
$10,000 to less than $15,000. . . .	2	$50,000 to less than $75,000. . . .	6	
$15,000 to less than $20,000. . . .	3	$75,000 to more.	7	
$20,000 to less than $35,000. . . .	4	Refused.	8	

G. Eligibility/Interest

	YES	NO	
1. Is participant willing to continue with the screening process?	1	2	SEWILL

If YES, continue screening process. If NO, fill out eligibility checklist item E.1

Diabetes Prevention Program

SCREENING STEP 4 INVENTORY - RANDOMIZATION

This form is completed during the Randomization Visit (Screening Step 4).
Form S07 records the following: adverse event assessment, pregnancy test result and current prescription medications; final eligibility review, micro-computer randomization and dispensing of coded medication.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number [ ][ ] CLINIC
2. Screening number [S][ ][ ][ ][ ][ ] SCREEN
3. Participant's initials [ ][ ][ ][ ] INITS (first last)
4. Participant's date of birth [ ][ ] / [ ][ ] / [ ][ ] DOB (month day year)
5. Participant's sex Male [1] Female [2] SEX

B. Visit Information

1. Date of Randomization Visit [ ][ ] / [ ][ ] / [ ][ ] SRVSTDT (month day year)
2. Date of Screening Step 2 OGTT [ ][ ] / [ ][ ] / [ ][ ] SRST2DT (month day year)

C. Instructions for Form S07 Completion

Complete sections D through F of Form S07. A final eligibility review is conducted by completing section G. Signature of P.I. indicates review of participant eligibility prior to randomization. After entering sections A through G in the Remote Data Management System, the computer will prompt you to randomize the participant. The prompt will occur if all required forms have been entered and the participant is eligible.

Initials of person reviewing completed form [ ][ ][ ][ ] (first last) Form entered in computer? [ ]

Signature of P.I. _____ Date: _____

Part II / PRE-RANDOMIZATION INFORMATION

D. Adverse Events

1. Since the last screening visit, has the participant had any new symptoms, injuries, illness or side effects, or worsening of pre-existing conditions?

YES [1] NO [2] SRAEQ

If YES, an Adverse Event Report (Form EO1) MUST be completed.

E. Pregnancy

1. Does the participant have reproductive potential?

YES [1] NO [2] SRPREM

If YES,

a. Result of pregnancy test

Positive [1]
Negative [2]
SRPREG

If positive fill in Eligibility Checklist item E.10.a, recall after pregnancy and breast-feeding are complete

F1

F. Current Medications

1. Is the participant currently taking any PRESCRIPTION medications?

YES [1] NO [2] SRRXDQ

If YES, list below - confirm by inspection of bottles:

	Medicine Description	Route
a.	SRXDA1	
b.	B1	
c.	C1	
d.	D1	
e.	E1	
f.	F1	
g.	G1	
h.	H1	
i.	I1	
j.	J1	

Part III / RANDOMIZATION PROCESS

G. Final Eligibility Review

	YES	NO	
1. Has the participant signed the informed consent form(s)?	1	2 HOLD	SRIC
2. Has the physical examination of systems been completed?	1	2 HOLD	SRSYST
3. Is participant eligible (see S01 - Eligibility Checklist)?	1	2 HOLD	SRELIG
4. Have the following been completed and entered:			
a. Eligibility Checklist (S01)	1	2 HOLD	SRS01
b. Screening Step 2 Inventory (S03)	1	2 HOLD	SRS03
c. Screening Step 3 Inventory - Start (S05)	1	2 HOLD	SRS05
d. Screening Step 3 Inventory - End (S06)	1	2 HOLD	SRS06
5. Is the elapsed time from the date of the Step 2 - OGTT visit to the randomization visit less than or equal to 13 weeks (91 days)? (See questions B.1 and B.2)?	1	2 STOP	SRTIME

H. Perform Computerized Randomization

The computer will now prompt you to randomize the participant. If all forms are entered and the participant is ready to be randomized, mark an 'X' where prompted. The computer will then give the participant's Participant Number.

1. Participant number [ ][ ][ ][ ][ ][ ] PATID

	YES	NO	
2. Is participant assigned to the pharmacologic intervention?	1	2	SRPHAR

If YES,
a. Dispense Medication:

METFORMIN LABEL SRPATM

Remove label from medication before dispensing and affix here. If not dispensed, check here 1 [ ] SRNOMET

Diabetes Prevention Program

PARTICIPANTS RANDOMIZED TO TROGLITAZONE
FOLLOW-UP VISIT INVENTORY

This form is completed at all mid-year and annual follow-up visits for participants randomized to troglitazone. (End-month 6, 12, 18, ...)
Form TR1 records the following: weight, blood pressure, adverse events and concomitant medications.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number ☐☐ CLINIC
2. Participant number ☐☐☐☐☐☐ PATID
3. Participant's initials ☐☐☐☐ INITS (first last)
4. Participant's date of birth ☐☐ ☐☐ ☐☐☐☐ DOB (month day year)
5. Participant's sex Male [1] Female [2] SEX

B. Visit Information

1. Date of visit ☐☐ ☐☐ ☐☐☐☐ TRVSTDT (month day year)
2. Week of visit ☐☐☐ TRVSTWK
3. Type of visit In Clinic [1] Home Visit [2] TVSTTYP
4. Outcome visit ☐☐☐ VISIT
5. End of Study Yes [1] No [2] TREOS

C. Instructions for Form TR1 Completion

Complete all sections of Form TR1.

Initials of person reviewing completed form ☐☐☐☐ (first last) Form entered in computer? ☐

Part II / PHYSICAL AND HISTORY

D. Anthropometrics

1. Weight

a. First measurement ___.___ kg TRWGHT1

b. Second measurement ___.___ kg TRWGHT2

Record c. only if first 2 measurements are not within 0.2 kilogram (200 gm).

c. Third measurement ___.___ kg TRWGHT3

E. Blood Pressure

1. Seated Arm Blood Pressure

	Systolic	Diastolic	
a. Blood Pressure Reading 1 (after sitting 5 minutes)	TRSBP1 ___	TRDBP1 ___	mmHg
b. Blood Pressure Reading 2 (after waiting 30 seconds)	TRSBP2 ___	TRDBP2 ___	mmHg

Hypertension management aims at maintaining blood pressure < 140/90 mmHg.

Initials of data collector completing page 2 of this form (first, last)

F. Adverse Events

1. During the interval since the last visit, has the participant had any new symptoms, injuries, illness or side effects, or worsening of pre-existing conditions?

YES [1] NO [2] TRAEQ

If YES, an Adverse Event Report (Form EO1) MUST be completed.

G. Prescription Medications

1. Is the participant currently taking any PRESCRIPTION medications? If YES, list below:

YES [1] NO [2] TRRXDQ

	Medicine Description	Route
a.	TRRXDA	
b.	TRRXDB	
c.	TRRXDC	
d.	TRRXDD	
e.	TRRXDE	
f.	TRRXDF	
g.	TRRXDG	
h.	TRRXDH	
i.	TRRXDI	
j.	TRRXDJ	

Diuretic agents, beta blockers, and fluoxetine > 20 mg/day (or equivalent dose of SSRI) are discouraged.

Diabetes Prevention Program

PARTICIPANTS RANDOMIZED TO TROGLITAZONE GROUP SESSION LOG

This form is completed for each troglitazone group session. If more than 15 participants attend a session please attach an additional form.

Part I / GROUP SESSION IDENTIFICATION

A. Clinic number [ ][ ] CLINIC

B. Date of group session [ ][ ][ ] TDATE (month day year)

C. Start time of group session [ ][ ] : [ ][ ] TTIME (time (24 hour clock))

D. Type of session (see code book; 2000 series) [2][0][ ][ ] TTYPE

E. Group Leader (s)

1. [ ][ ][ ][ ] TLEAD1 (first last)

2. [ ][ ][ ][ ] TLEAD2 (first last)

Part II / ATTENDEES

	Name	Participant Identification Number	Initials (first last)
1.	_____ RELEASE_ID1	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ] INITS1
2.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]
3.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]
4.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]
5.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]
6.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]
7.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]
8.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]
9.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]
10.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]
11.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]
12.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]
13.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]
14.	_____	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ]
15.	_____ RELEASE_ID15	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ] INITS15

Note: Optional page 2 listed RELEASE_ID16 - RELEASE_ID30

Initials of person completing form [ ][ ][ ][ ] (first last) Form entered in computer? [ ]