DPP FORM E01.1 July, 1999 Page 1 of 4

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.	<u>Par</u>	ticipant Identification		В.	<u>Vi</u> s	sit Information	
	1.	Clinic number			1.	Date of visit	month day year
	2.	Participant Identification Number (Complete a O	R b)				
		a. If before randomization, Screening number	S		2.	Type of Visit	¹ Screening Step
		b. If after randomization, Participant number					 Standard Follow-up Major Follow-up
	3.	Participant's initials	first last				⁴ Interim Follow-up
	4.	Participant's date of birth	month day year		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.

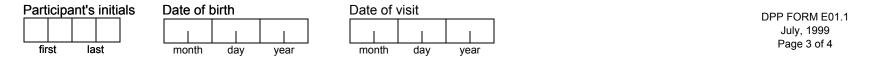
	· · · · · · · · · · · · · · · · · · ·	
Initials of person reviewing completed form		Form entered in computer?
、	first last	



D. Adverse Event(s) Summary

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

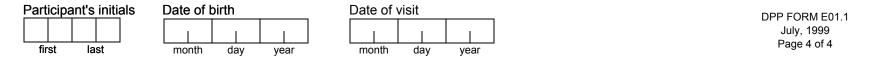
* For each serious adverse event (SAE) complete the SAE Report (Form E02).



D. Adverse Event(s) Summary

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

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



D. Adverse Event(s) Summary

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

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

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

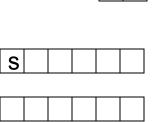
A. Participant Identification

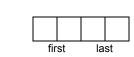
- 1. Clinic number
- 2. Participant Identification Number (Complete a OR b)
 - a. If before randomization, Screening number
 - b. If after randomization, Participant number
- 3. Participant's initials
- 4. Participant's date of birth
- B. Report Identification
 - 1. Date of report
 - 2. Date of onset of serious adverse event
 - 3. Type of report
 - 4. Type of visit

C. Instructions for Form E02 Completion

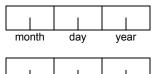
This form is to be completed if the participant has had a Serious Adverse Event (SAE) recorded on the Adverse Event Report (E01).

Initials of person reviewing completed form	first	last	Form entered in computer?] `
Signature of P.I.			Date:	,









day

year



month

In Clinic / Home Visit

Unattended

			ticip: rst	ant's initials		e of bi	rth day	year		Date of	report day	year]	DPP FORM E02.2 July, 2000 Page 2 of 4
<u>Par</u>	<u>t II /</u>	AD\	/ER	<u>SE EVENT</u>	DESCR	PTIO	<u>N</u>							
D.	<u>Gei</u>	nera	l Cla	ssification										
	1.	Eve	ent l	Number (fro	m Form	E01; o	column	1)				Γ		
		a.	Cla	assification	term fron	n Forr	n E01:							
	2.	Did	l the	adverse ex	kperience	e resu	lt in:		(che	eck all tl	nat apply)		
		a.	Re	quired or pr	rolonged	hospi	talizatio	on		[1				
		b.	Pe	rmanent or	severe d	isabili	ty			[1				
		C.	De	ath						[1				
				Death chec Death not c				stion 3.						
			i.	Date of de	eath						1	1		
			ii.	Probable of	cause of	death					month	day	year	
														_
	3.	Wa	as th	e adverse e	experienc	e:			(chec	k all tha	t apply)			
		a.	Со	ngenital and	omaly									
		b.	Са	ncer										
		C.	Life	e-threatenin	ıg					[1				

1

d.	Due to an overdose	1
e	Treatment to prevent a serious event	1

Participant's initials	Date of birth		Date of report	DPP FORM E02.2	
					July, 2000
first last	month day	year	month day	year	Page 3 of 4

E. Event Information

Complete question E1 if assigned the pharmacological treatment. Skip to question E2 for troglitazone and lifestyle participants.	
	YES NO
 Was the participant on coded metformin at the time of the adverse experience? 	1 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 NO
If YES, CONTINUE. If NO, SKIP to Question E.2.	
i. Was the adverse experience reversible when the coded metformin was withdrawn?	YES NO
ii. Was the coded metformin re-started?	1 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
) months
b) Did the symptoms recur?	NO 2
 Describe the adverse event in detail: (i.e. issues leading up to event, pro completed, date stopped intervention if applicable, etc.) 	cedures or test

3. Duration of adverse experience

<1day	1
1day - 1week	2
>1week	3

Par	ticipar	nt's initi	als	Date of	birth		-	Date of	report			DPP FORM E02.2
												July, 2000 Page 4 of 4
f	irst	last		month	day	year		month	day	year		Fage 4 01 4
1 Tr	ootmor	at admi	iniator	ed for the	advara	o vont:						
+. 110	eaunei	it aurii	IIISten		auverse	e event.		chec	k all tha	t apply		
a.	Out-j	oatient	- char	nges in me	edicatio	ns		[1				
b.	Out-	oatient	- proc	edure								
C.	Hosp	oitalizat	tion									
	i. 1	Fotal le	ngth c	of stay			days					
d.	Skille	ed nurs	sing fa	cility				1				
	i. 1	Fotal le	ngth o	of stay			days					
e.	Out-j	oatient	rehab	ilitation								
	i. 1	Fotal da	ays		[days					
f.	In-pa	itient re	ehabili	tation				1				
	i. 1	Fotal da	ays				days					
											YES	NO
5. Du	iring th	e adve	erse ev	vent was ii	nsulin th	ierapy us	ed?				1	2
lf	YES,										YES	NO
a.	ls in	sulin tł	nerapy	continuin	ıg?						1	2
6. O	utcom	e						recove	ered, no	residu	al effe	ct
0. 0	atoom	•							al effec			
								residu	al effect	, being	treate	•d 3
								p	ersisten	t, no tre	eatme	nt
								pe	ersistent	, being	treate	ed ⁵
											dea	th ⁶
onclu	sion											

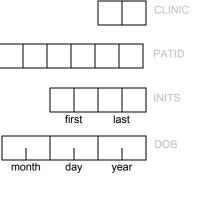
1. Additional comments: (i.e. note if former troglitazone participant, whether or not they have experienced this problem before, any follow-up plans, etc.)

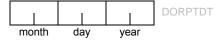
PREGNANCY CONFIRMATION REPORT

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

Part I / IDENTIFICATION

- A. Participant Identification
 - 1. Clinic number
 - 2. Participant number
 - 3. Participant's initials
 - 4. Participant's date of birth
- B. Report Identification
 - 1. Date of report

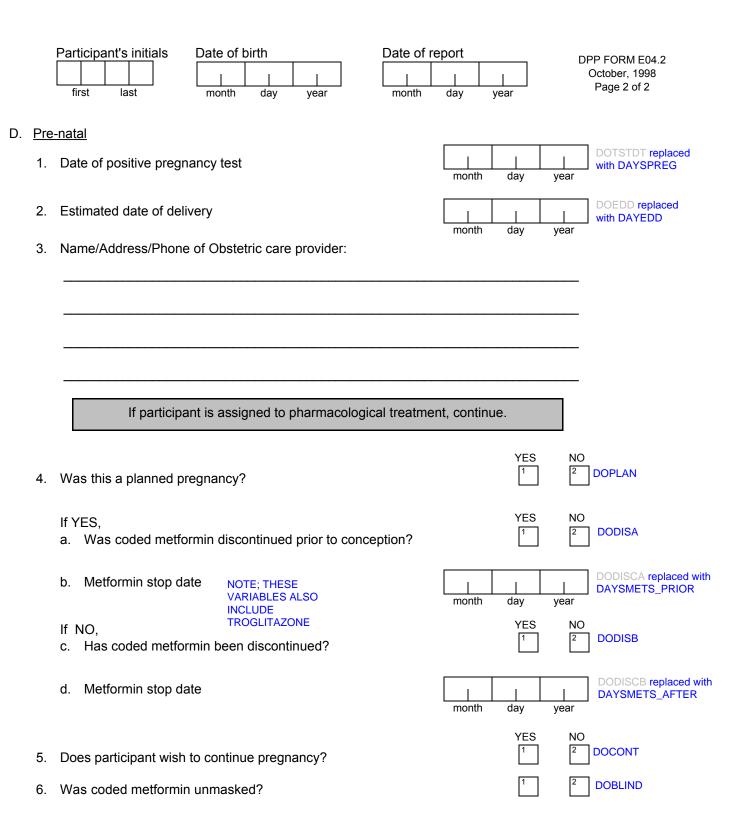




C. Instructions for Form E04 Completion

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			Form entered in computer?	
		first	last		_

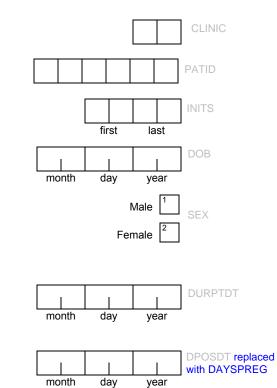


PREGNANCY OUTCOME REPORT

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

Part I / IDENTIFICATION

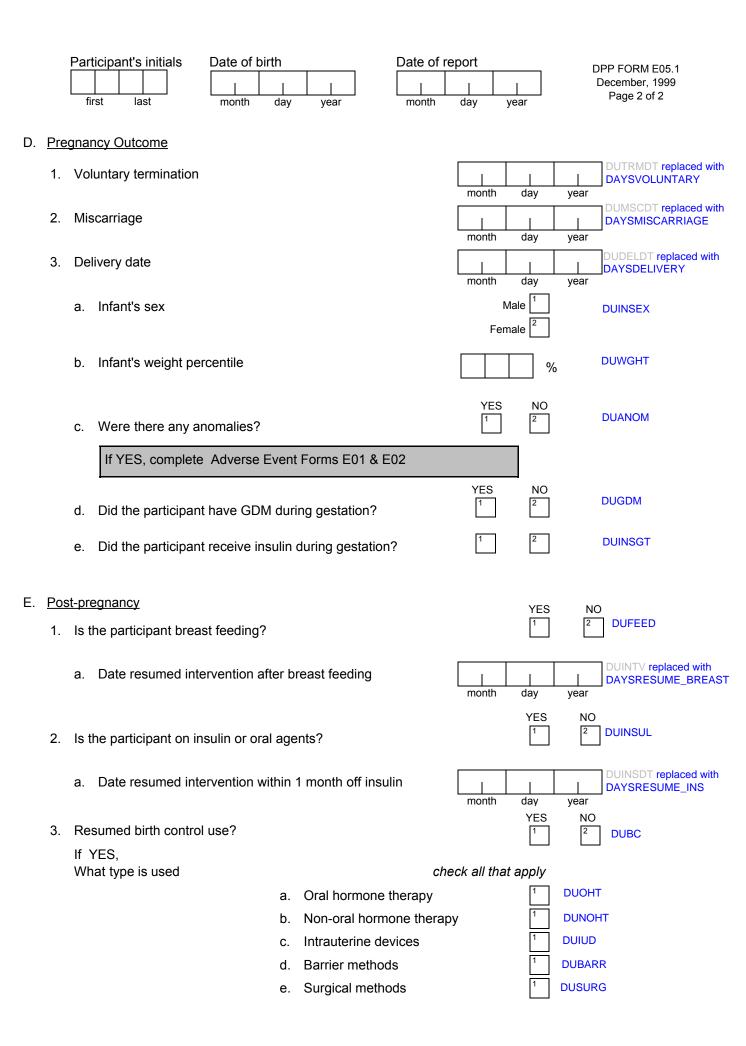
- A. Participant Identification
 - 1. Clinic number
 - 2. Participant number
 - 3. Participant's initials
 - 4. Participant's date of birth
 - 5. Participant's sex
- B. Report Identification
 - 1. Date of report
 - 2. Date of positive pregnancy test



C. Instructions for Form E05 Completion

Complete all sections of Form E05.

(
Initials of person reviewing completed form				Form entered in computer?
	first	la	ast	

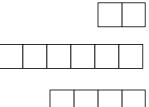


MORTALITY EVENT REPORT

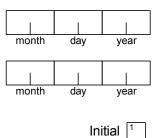
This form is completed if a randomized participant has a mortality event. Upon notification of the death of a DPP participant, the clinical staff must complete an Adverse Event Report (Form E01), an initial Serious Adverse Event Report (Form E02) and an initial Mortality Event Report (Form E06). The 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
 - 4. Participant's date of birth
- B. Report Identification
 - 1. Date of report
 - 2. Date of death
 - 3. Type of Report







Follow-up

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				Form entered in computer?	
	first	la	st	·	

	Participant's initials	Date of birth	year	Date of view of which we have a second secon	sit day	year	DPP FORM E06.2 October, 1998 Page 2 of 3
<u>Ger</u>	neral Information						
1.	Place of death					check o	nly one
						Hospital	1
						Home	2
				Long-te	erm care	e institution	3
		speci	fv:			Other	4
						Unknown	5
_							
2.	Was the death:				Suddo	check or	
				S		n, explained unexplained	2
				0		wing illness	3
3.	At the time of onset of t the participant was:	erminal event,				check d	onlv one
						Asleep	1
				Av	vake, bı	ut sedentary	2
				Enga	ged in lig	ght physical	3
			Eng	aged in modera	ate phys	sical activity	4
				Engaged in hea	vy phys	sical activity	5
						Unknown	6
						YES	NO
4.	Was the participant taki	ng the coded me	etformin?			1	2
5.	Was an autopsy perform	ned?				1	2
	If YES, a. Is the autopsy repo	rt available?				1	2
6.	Is a death certificate av	ailable?				1	2
7.	Specify which sources used in completing this		ere			check all	that apply
	a. Death certificate .						1
	b. Autopsy report						1
	c. Hospital report on	final illness					1
	d. Interview of attendi	ing physician at	time of d	eath			1
	e. Interview of family	- · ·					
	f. Other						
	specify:						

D.

Participa	nt's initials	Date of b	birth		Date o	f visit	DPP FORM E06.2	
								October, 1998 Page 3 of 3
first	last	month	day	year	month	day	year	r age 5 or 5

- E. <u>Specific Information</u> (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:

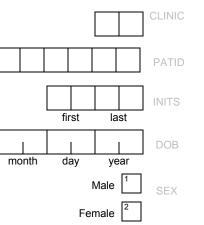
STANDARD FOLLOW-UP VISIT INVENTORY

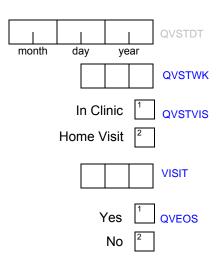
This form is completed at all quarterly follow-up visits, except for annual (i.e., Major) follow-up visits (End-month 3, 6, 9, 15. . .).

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
 - 2. Participant number
 - 3. Participant's initials
 - 4. Participant's date of birth
 - 5. Participant's sex
- B. Visit Information
 - 1. Date of visit
 - 2. Week of visit
 - 3. Type of visit
 - 4. Outcome visit
 - 5. End of Study





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

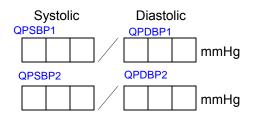
Form entered in computer?

		ticipant's initials	Date of birth	year	Date of visit	year	_	PP FORM F01.2 November, 1999 Page 2 of 5
		/lid-year visit (End- Blood Pressure.	-month 6, 18, 30, 42,	54, 66), com	plete section D	- Anthropome	etrics a	and
<u>Part II</u>	<u>/ PH</u>	YSICAL AND HIST	<u>FORY</u>					
D. <u>Ar</u>	ithrop	ometrics - comple	ete only at a Mid-yea	r visit				
1.	We	eight						
	a.	First measureme	nt				kg	QPWGHT1
	b.	Second measure	ment				kg	QPWGHT2
		Record c. only if f	first 2 measurements	are not with	in 0.2 kilogram	(200 gm).		
	C.	Third measureme	ent				kg	QPWGHT3

- E. Blood Pressure complete only at Mid-year visit
 - 1. Seated Arm Blood Pressure

D.

- a. Blood Pressure Reading 1 (after sitting 5 minutes)
- b. Blood Pressure Reading 2 (after waiting 30 seconds)



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

Initials of data	collector	completing	page 2	2 of this fo	orm
------------------	-----------	------------	--------	--------------	-----

first	last

		Participant's		Date of bin	th day year		Date of v	/isit day	year		P FORM F01.2 ovember, 1999 Page 3 of 5
F.		verse Events During the in had any nev	nterval sii v symptoi	nce the last ms, injuries,	visit, has the j illness or side		nt	uay	YES	NO 2	QPAEQ
If	VEQ	worsening c , an Adverse		-			atad				
"		, an Auverse									
G.		egnancy Ques				10			YES	NO 2	
	1.	Does the pa	articipant	have reprod	uctive potenti	al?					QPPREM
		YES, Review NO, SKIP to F			onfirm use a	nd form	of contra	ception a	IND CONT	INUE.	
	2.	Date of last	menstrua	al period				month	day	year	QPDOLM
			•	-	pharmacolog intensive life	-			b.		
		a. Menstru	ıal period	more than c	one week late	?			YES	NO 2	QP1WK
		b. Menstru	al period	more than t	wo weeks lat	e?			1	2	QP2WK
				or 2.b. is YE skip to que	S, a pregnan stion G.5.	cy test n	nust be p	erformed			
	3.	Date of prec	gnancy te	st				month	day	year	QPDOPT
	4.	Result of pro	egnancy	test					Posi Nega	0	QPREG
					must be disc . Skip to Sec		l and com	nplete a F	Pregnancy		
	5.	Does the pa	articipant	plan on beco	oming pregna	nt within	the next	3 month	YES s? 1	NO 2	QPLAN
				If YES, cod	ed metformin	must b	e discont	inued.			

Participant's initials Date of birth Date of visit	DPP FORM F01.2 November, 1999 Page 4 of 5
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 a. Daily dose of METFORMIN per protocol	1700 mg ² QMDOSE
 b. What is your best estimate of the participant's level of < 80% exposure to metformin per protocol? ≥ 80% did not return pill contained 	6 2 QMCOMM
c. For the most recent typical week, what is the participant's estimate of the <u>number of days</u> when the metformin pills were taken as prescribed by DPP staff?	QMDAYSM days
2. Dispensing of Medication	
METFORMIN LABEL	

ĩ.	······································
	Remove label from medication before dispensing and
	affix here. If not dispensed, check here
' -	

Participant's initials		Date of birth				Date of v	isit		DPP FORM F01.2	
	first	last	month	day	year		month	day	year	November, 1999 Page 5 of 5
I. <u>Con</u>	comita	nt Medications							YES	NO
 Is the participant currently taking any PRE medications other than the coded metform If YES, list below: 					ION			1	2 QMRXDQ	
			Medi	cine Des	scription				Route	
	a.	QMRXDA								
	b.	QMRXDB								

a.		
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

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 PATID 2. Participant number 3. Participant's initials INITS first last 4. Participant's date of birth month day vear Male 5. Participant's sex SEX Female B. Visit Information AVSTDT 1. Date of visit year month day 2. Week of visit AVSTWK In Clinic AVSTTYP Type of visit Home Visit VISIT Outcome visit 4. Yes AVEOS End of Study 5. No 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.

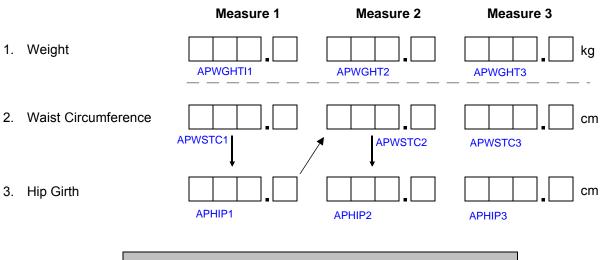
Initials of person reviewing completed form	first	last	Form entered in computer?
Signature of P.I.			Date:

Particip	ant's initials	Date of	birth		Date	of visit		DPP FORM F02.2
								November, 1999 Page 2 of 6
first	last	month	day	year	mon	h day	year	. ugo 2 01 0

Part II / PHYSICAL AND HISTORY

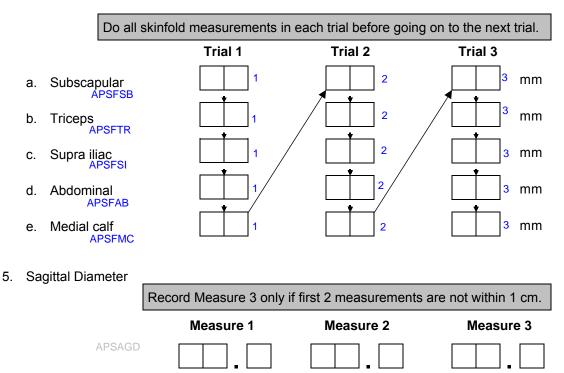
D. Anthropometrics

- 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.

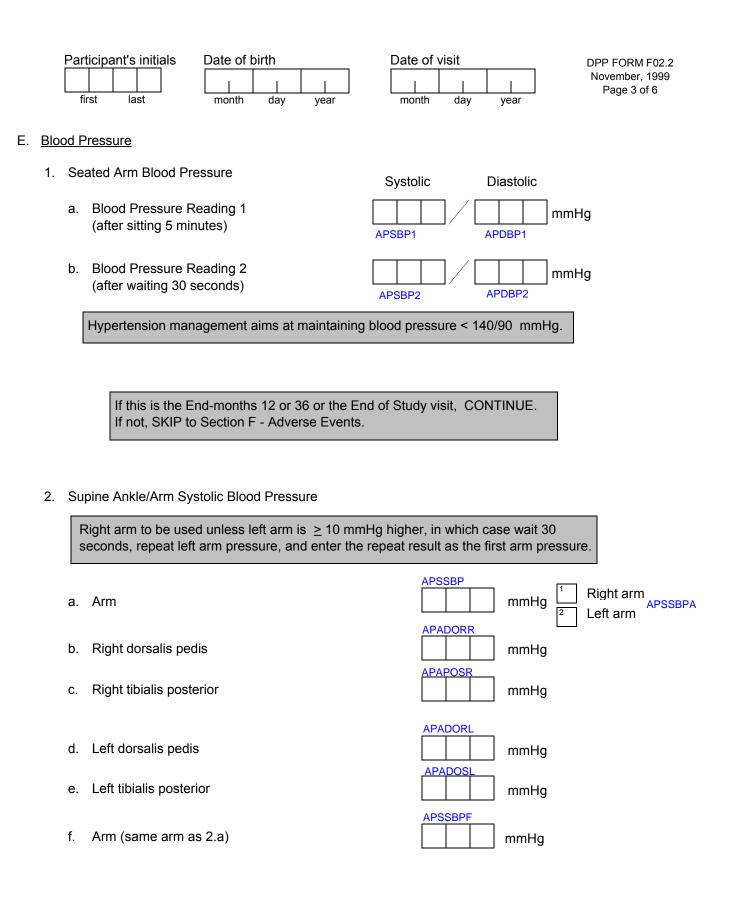


If this is the End-month 12 or the End of Study visit, CONTINUE. If not, SKIP to Section E - Blood Pressure.

4. Skin-fold Thickness



cm



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

		Participant's initials	Date of birth	year	Date of vi		ar	No	P FORM F02.2 vember, 1999 Page 4 of 6
F.	<u>Ad</u> 1. 2.	worsening of pre-ex	since the last visit, h oms, injuries, illnes	as the particips or side effect	oant st, or	be complet	YES 1 1 ed.	NO 2 2	APQ08 APAEQ
G.	<u>Pre</u> 1.	egnancy Questions Does the participan	strual diary and conf	-	orm of contra	aception ar	YES 1 Ind CONTI	NO 2 NUE.	APREM
	2.		ual period ant is assigned to pl	-				ear	APDOLM
		a. Menstrual perio	ant is assigned to in od more than one we od more than two we	eek late?	ie reament,	, answer 2.	YES 1	NO 2 2	AP1WK AP2WK
	3.		a or 2.b. is YES, a p O, skip to question test		t must be pe	erformed.	l day y	 ear	APDOPT
	4.	Result of pregnanc	y test /E, coded metformir	n must be disc	continued an	nd complete	Positive Negative	<u> </u>	APREG
	5.		Confirmation Report Confirmation Report	ort (Form E04)). Skip to Se	ection H.	YES 1	NO 2	APLAN

G.

If YES, coded metformin must be discontinued.

	Part	icipant's initials	Date of birth	ı	Date of vi	sit	DPP FORM F02.2
							November, 1999
	fir	rst last	month d	lay year	month	day yea	Page 5 of 6
<u>Part III</u>	<u>/ ME</u>	DICATIONS		. ,		, ,	
		Comple	te Section H it	f assigned the	pharmacologic	al treatment	
Н. <u>Со</u>	ded	<u>Medication</u>					YES NO
1.	На	as the participant ta	aken any code	ed METFORM	IN since the las	t visit?	1 2 AMTAKM
	lf ک a.	YES, Daily dose of ME	ETFORMIN pe	er protocol		850 mg 1	700 mg ² AMDOSE
	b.	What is your bes exposure to met				< 80% ≥ 80%	2 AMCOMPM
					did not return p	oill container	3
	C.	For the most rece estimate of the <u>nu</u> were taken as pre	umber of days	when the me			AMDAYSM days

2. Dispensing of Medication

	METFORMIN LABEL	
Remo	ove label from medication before dispensing affix here. If not dispensed, check here 1	and MŇŌMĒT



YES

1

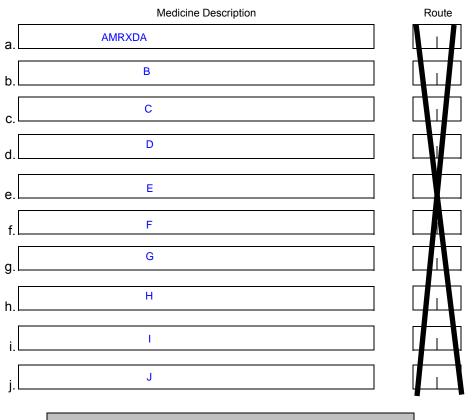
NO

2

AMRXDQ

I. Concomitant Medications

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



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

DPP FORM F03.2 November, 1999 Page 1 of 3

CLINIC

PATID

INITS

SEX

JIVSTDT

JIVSTWK

JVSTTYPE

first

day

day

last

year

year

Male

Female

In Clinic

Unattended²

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

Clinic number
Participant number
Participant's initials
Participant's date of birth
Participant's sex

B. Visit Information

Date of visit
Week of visit

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	
2.	Hypertension management . JIHYPMG	Complete Part II and Part II
3.	Lipid management .JILIPMG.	
4.	Pregnancy management	
5.	Adverse event management JIAEMG	
6.	Collection of specimen for CBL (e.g. OGTT) . JISPEC	Complete CBL Specimen
7.	Repeat collection of outcome found to be deficient	
8.	Other . JIOTH	1
	a. specify:	
Initi	als of person reviewing completed form	Form entered in computer?

Participant's initials Date of birth Date of visit	DPP FORM F03.2 November, 1999 Page 2 of 3
Part II / HISTORY	
D. <u>Adverse Events</u> YES	NO
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?	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.	
YES 1. Does the participant have reproductive potential?	NO 2 JIPREM
If YES, Review menstrual diary and confirm use and form of contraception and CONT If NO, SKIP to Section F - Coded Medication.	INUE.
2. Date of last menstrual period month day	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?	NO ² JI1WK
b. Menstrual period more than two weeks late?	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	JIDOPT
4. Result of pregnancy test Positiv Negativ	
If POSITIVE, coded metformin must be discontinued and complete a Pregnant Confirmation Report (Form E04). Skip to Section F - Coded Medication.	су
YES 5. Does the participant plan on becoming pregnant within the next 3 months?	NO 2 JIPLAN
If YES, coded metformin must be discontinued.	

Participa	nt's initials	Date of b	oirth		Date of visit		DPP FORM F03.2
			1				November, 1999
first	last	month	day	year	month day	y year	Page 3 of 3

F. Coded Medication

		ete Section F if the participant was assigned metformin/placeb zone or lifestyle participants.	o. Do not	complet	e for
1.	На	s the participant taken any coded METFORMIN since the last	visit?	YES 1	NO 2 JITAKMT
	lf Y a.	ES, Daily dose of METFORMIN per protocol	850 mg	1700 mg 2	JIDOSE
	b.	What is your best estimate of the participant's level of exposure to metformin per protocol?	< 80% ≥ 80%	2	JICOMPM
		did not return pil	I containe	r ³	
	C.	For the most recent typical week, what is the participant's estimate of the <u>number of days</u> when the metformin pills were taken as prescribed by DPP staff?			days JIDAYSM

2. Dispensing of Medication

METFORMIN LABEL

ī.	
i.	Remove label from medication before dispensing and
•	affix here. If not dispensed, check here JINOMET
-	

Part III / HYPERTENSION MANAGEMENT

G. Blood Pressure

 1. Seated Arm Blood Pressure
 JISBP1
 JISBP1

 a. Blood Pressure Reading 1 (after sitting 5 minutes)
 Diastolic

 b. Blood Pressure Reading 2 (after waiting 30 seconds)
 JISBP2

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

DPP FORM F04.1 November, 1999 Page 1 of 1

MISSED FOLLOW-UP VISIT REPORT

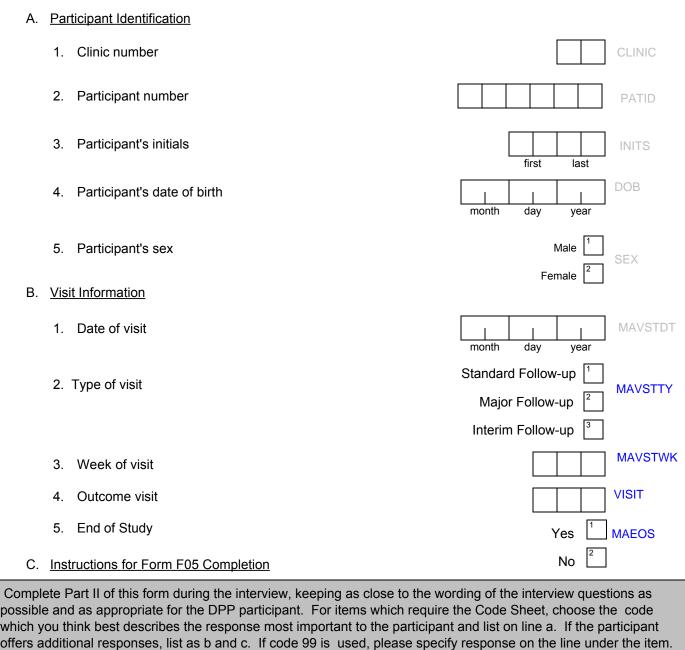
This form is completed anytime a participant misses either a standard or major scheduled follow-up visit. Form F04 records the date and reason for the missed visit.

A.	Par	icipant Identification				
	1.	Clinic number				CLINIC
	2.	Participant number				PATID
	3.	Participant's initials		first	last	INITS
	4.	Participant's date of birth	month	day		DOB
В.	<u>Visi</u>	t Information	monun	uay	year	
	1.	Date follow-up visit was scheduled	month	day	year	JMVSTDT
	2.	Week of visit missed				JMVSTWK
	3.	Type of visit missed		rd follow or follow	·	JMVSTTY
	4.	Outcome visit				VISIT
	5.	End of Study		١	Yes 1 No 2	JMEOS
	6.	Has there been any contact with the participant concerning the missed visit?		YES	NO	JMCONT
		If YES, a. In the coordinator's opinion, what was the primary reason fo	r the			
		missed visit? Illness, surgery, or ho	ospitalizati	ion 1		
		If so, an Adverse Event Report (Form E01) MUST	be comple	eted.		
		Moved to a less conven	ient locati	ion ²	-	
		General decline i	in motivati	ion 3	JMRSN	
		Conflicting responsibilities (job, birth	nday, fam	ily) ⁴		
		Other (sp	ecify belo	w) 5		
		Other Specified:				
_	7.	Is the participant considered on inactive follow-up status? (i.e., scheduled follow-up protocol suspended)		YES	NO 2	JMINACT
	Initi	als of person completing form	ed in com	puter?		

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



				<hr/>	
(
helf also of a survey and the day of a survey late of famous					
Initials of person reviewing completed form			Form entered in computer?		

last

first

Participant's initials Date of birth Date of visit	DPP FORM F05.1 November, 1999 Page 2 of 2						
]						
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							
 How did you remember to take your DPP pills as prescribed since the last visit? (see Code Sheet, 700 series) 	W a. 7						
МАНО	WB b. 7						
MAHO 2. How helpful was the plan we decided on at the last visit to help you take your DPP medications as prescribed?	WC c. 7						
1 No plan specified/Not applicable 4 Not at all helpful							

Did not try that plan (i.e., not implemented)

MAPROB

MAPRJBB

MAPLANC

MAPROBC C.

a. 8

8

8

9

9

9

b.

a.

b.

c.

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

MAHELD

Very helpful

(see Code Sheet, 800 series)

Somewhat helpful

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?

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

1No plan sp2Definitely3Probably	becified/Not applicable	 Probably not Definitely not 	MAINTEN
For DPP Staff Use Only6. Do you consider the partic to be reliable?	ipant's estimation of medic I Not applicable 2 Definitely 3 Probably	cation adherence "for the Probably not Definitely not	e most recent week" MAREL1

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):

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
 - 2. Participant number
 - 3. Participant's initials
 - 4. Participant's date of birth
 - 5. Participant's sex
- B. Visit Information
 - 1. Date of visit
 - 2. Week of visit
 - 3. Outcome visit
 - 4. End of Study

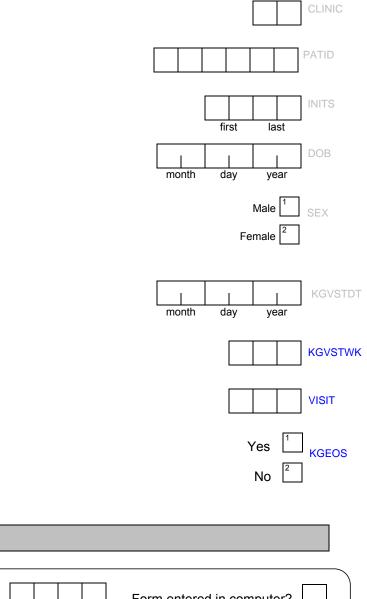
C. Instructions for Form F06 Completion

 Complete all sections of Form F06.

 Initials of person reviewing completed form

 first
 last

Form entered in computer?





YES

YES

1

NO

NO

2

2

KGAEQ

KGRXDQ

- D. Adverse Events
 - 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?

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

E. Prescription Medications

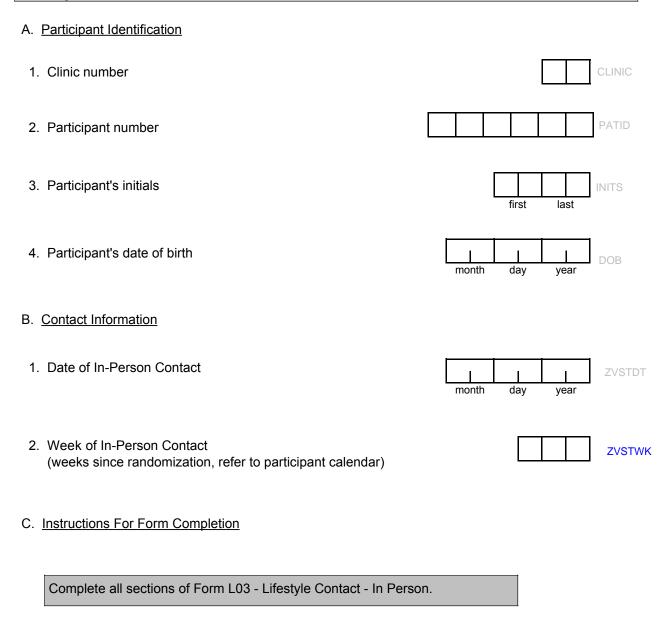
1. Is the participant currently taking any PRESCRIPTION medications? If YES, list below:

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

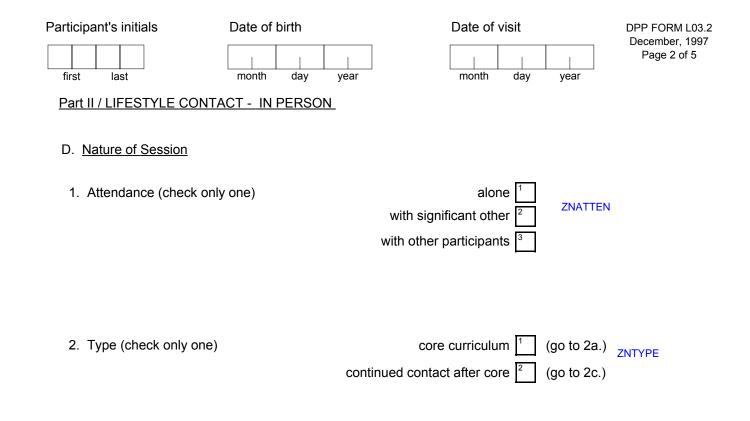
> > Diuretic agents, beta blockers, and fluoxetine > 20 mg/day (or equivalent dose of SSRI) are discouraged.

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.



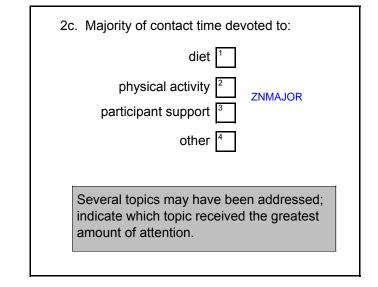
Initials of person completing form			Form entered in computer?	
	first	last		

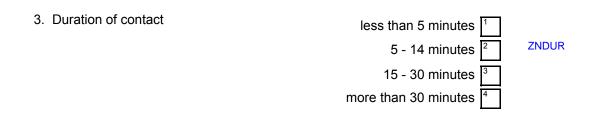


If CORE CURRICULUM,

2a. Session #	ZNLESS
i. If session #1, which participant choose?	topic did the
diet /weight loss	
physical activity	2
2b. Repeat	Yes No
Skip to question 3.	ZNREV

If CONTINUED CONTACT AFTER CORE,

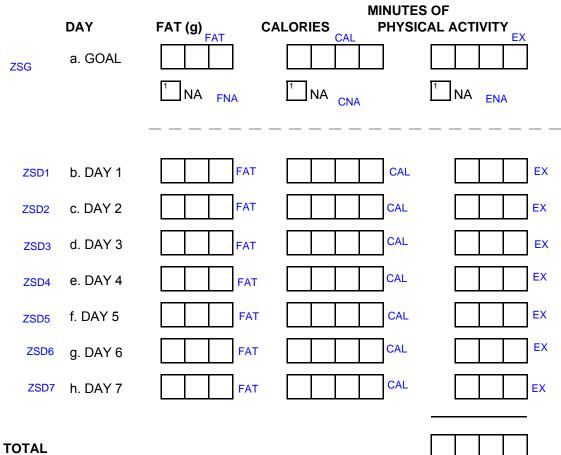




Participant's initials	Date of birth	Date of visit	DPP FORM L03.2
first last	month day year	month day year	December, 1997 Page 3 of 5
Part II / LIFESTYLE CON	ITACT - IN PERSON (contir	nued)	
E. Self-Monitoring Inform	nation		
1. Has the participant s	elf-monitored diet since the	last In-Person Contact? ZNDIET	Yes No
2. Has the participant s	elf-monitored physical activi	ty since the last In-Person Contact? _{ZNEXE}	R 1 2
lf	YES to either question	1 or 2, continue.	

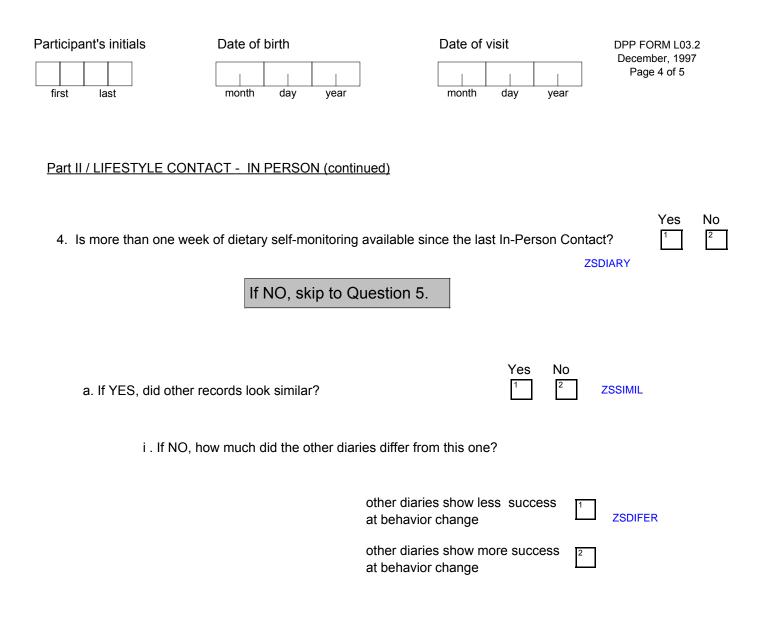
If NO to both question 1 and 2, skip to question 5.

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



(sum of Day 1 through Day 7)

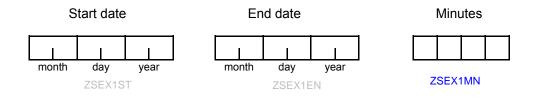
ZSTOTEX



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).



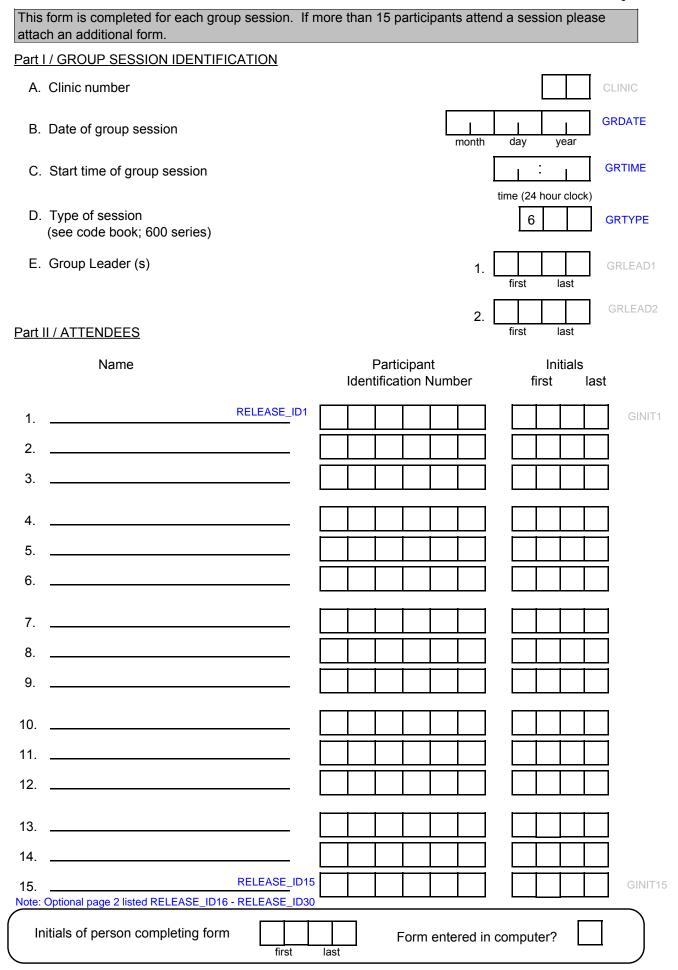
Participant's initials Date of birth Date of visit DPP FORM L03.2 December, 1997 Page 5 of 5 day first month month day last year year F. Physical Activity Status Yes No 2 1 1. Is the participant at study goal for physical activity? ZEXGOAL ZEXBAR1 2. What are the barriers? ZEXBAR2 1 (see code book; 100 series) a. **ZEXBAR3** 1 b. 1 C. 2 3. What approaches are taken to improve or maintain? **ZEXAPP1** a. (see code book; 200 series) **ZEXAPP2** 2 **ZEXAPP3** b. 2 c. G. Weight Status **ZWTGOAL** 1. Study weight goal? (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 No Yes 4. Is the participant self-monitoring weight? ZWTSELF 3 ZWTBAR1 5. What are the barriers? a. **ZWTBAR2** (see code book; 300 series) 3 **ZWTBAR3** b. 3 C. 4 6. What approaches are taken to improve or maintain? ZWTAPP1 a. ZWTAPP2 (see code book; 400 series) **ZWTAPP3** 4 b.

4

c.

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 PADATE B. Date of exercise class month day year PATIME C. Start time of exercise class : time (24 hour clock) D. Type of exercise 5 PATYPE 1. (see code book; 500 series) PALEAD1 E. Exercise Leader (s) 1. first last PALEAD2 2 first last Part II / ATTENDEES Name Participant Initials **Identification Number** first last 1. _____ RELEASE_ID1 INITS1 2. _____ 3. _ 4. 5. ____ 6. _____ 7. ____ 8. 9. 10. _____ 11. _____ 12. _____ 13. _____ 14. _____ RELEASE_ID15 15. INITS15 Note: Optional page 2 listed RELEASE_ID16 - RELEASE_ID30 Initials of person completing form Form entered in computer? first last



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
- 2. Participant Identification Number (Complete a OR b)
 - a. If screening step 4, Screening number
 - b. If follow-up, Participant number
- 3. Participant's initials
- 4. Participant's date of birth
- 5. Participant's sex
- B. Visit Information
- 1. Date of visit
- 2. Type of visit

4. Outcome visit

5. End of Study

S PATID INITS first last day month vear Male SEX Female CHVSTDT day month vear Screening Step 4 Standard Follow-up CHVSTTY Major Follow-up Interim Follow-up 3. Week of visit (If Follow-up) СНУЗТЖК VISIT Yes CHEOS No

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.

1	(1
	Initials of person reviewing completed form			Form entered in computer?	
		first	last)

	articipant's initials	Date of birth	Date of visit	year	DPP FORM R04.1 November, 1999 Page 2 of 2						
D. <u>CHD/</u>	Unmasking Status			YE	ES NO						
1.	Has the participan Coordinating Cent	nt's past lipid profile been ter?	unmasked by the	1	2 CHUNMA						
2.	Is the participant on lipid-lowering drug therapy?										
3.	Does the participa coronary disease, disease? (NOTE: signs or symptoms	2 CHATHER									
		01 through D3, CONTINU ction D is answered YES									
E. <u>CHD F</u>	Risk Factor Status										
1.	Male ≥ 45 years o Female ≥ 55 years	o r s or menopause without	estrogen replacement tl	YE herapy.							
2.	death before age	premature CHD (definite 55 in father or other male or other female first-degr	e first-degree relative, or	11	2 CHHIST						
3.	Current cigarette	smoking.		1	² CHSMOKE						
4.	Confirmed hyperte	ension.		1	² CHHYPER						
5.	Diabetes mellitus.			1	² CHDIAB						
F. <u>Other</u>	Reasons for Unmasl	king		YE	ES NO						
1.	Is there any other	reason to unmask lipid n	esults for this participan		² CHREAS						

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

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 S 2. Screening number 3. Participant's initials first last 4. Participant's date of birth month day year 5. Participant's sex Male Female B. Visit Information Date of Screening Step 2 SCT2DT month day year Part II / INCLUSION CRITERIA C. Inclusion Criteria NO YES SC25YR 1. The participant is at least 25 years of age. 2. Impaired glucose tolerance with elevated fasting plasma glucose. a. Fasting plasma glucose 95-125 mg/dL. **SCFPGI** SC2HPGI b. 2-hr plasma glucose 140-199 mg/dL. 3. Body-mass index \geq 24 kg/m² (\geq 22 kg/m² for Asians) **SCBMI** All inclusion criteria must have been answered YES for the participant to be randomized. Initials of person completing form Form entered in computer?

first

last

Participant's initials

Date of birth

month

first last

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

day

year

- 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.
- 2. Infectious diseases.
 - a. Self-reported HIV positivity.
 - b. Active tuberculosis.
- 3. Cardiovascular disease.
 - a. Hospitalization for treatment of heart disease in the past 6 months.
 - b. New York Heart Association Functional Class >2.
 - c. Left bundle branch block on ECG.
 - d. Third degree atrioventricular block on ECG.
 - e. Uncontrolled hypertension: SBP >180 mmHg or DBP >105 mmHg on treatment.
 - f. Stroke or transient ischemic attack in the past 6 months.
- 4. Gastrointestinal disease.
 - a. Self-reported chronic hepatitis or cirrhosis, or serum AST or ALT elevated by the following criteria: serum AST $\geq 66 \text{ U/L}$ serum ALT $\geq 58 \text{ U/L}$ if over 47 years serum ALT $\geq 118 \text{ U/L}$ if male ≤ 47 years serum ALT $\geq 46 \text{ U/L}$ if female ≤ 47 years
 - b. Episode of alcoholic hepatitis or alcoholic pancreatitis ever.
 - c. Inflammatory bowel disease requiring treatment in the past year.
 - d. Recent or significant abdominal surgery (e.g. gastrectomy).

NO

SCCNCR

SCHIV

SCTB

SCHDHOS

SCNYHAH

SCLBBB

SC3RDB

SCHYPER

SCSTROK

SCAST

SCALCHL

SCBOWL

SCABSUR

YES

Particip		ant's initials Date	of birth		DPP FORM S01.3		
				October, 1998 Page 3 of 6			
	rst						
<u>Pa</u>	<u>π III</u>	/ EXCLUSION CRITERIA (c	<u>continuea)</u>				
	5.	Renal disease.		YES	NO		
		 a. Serum creatinine ≥1.4 (115 µmol/L) for womer 	mg/dL (124 μmol/L) for men; ≥1.3 mg/dL n.	1	² SCRENAL		
		 b. Urine protein ≥ 2+ on o or vaginal contaminatio 	one occasion (dipstick), in the absence of infection on.	1	² SCOIPSK		
	6.	Lung disease.					
		a. Chronic obstructive air	way disease or asthma requiring daily therapy.	1	² SCASTHM		
		b. New York Heart Associ	siation Functional Class > 2.	1	² SCNYHAL		
		c. Use of oxygen at home	2 .	1	² SCOXYGN		
	7.	Electrolyte abnormality: Serum Potassium <3.2 or	r >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 co	condition likely to limit life span to < 6 years.	1	² SCGRAN		
	10.		rlying disease not specifically mentioned above, /or increase risk of intervention.	1	² SCCONDS		
E.	<u>Exc</u>	clusion for conditions or beha	aviors likely to effect the conduct of the DPP.				
	1.	Unable or unwilling to give	informed consent.	1	² SCNOCON		
	2.	Unable to communicate wit	th the pertinent clinic staff.	1	² SCCLANG		
	3.	Another household member	r is a participant or staff member of DPP.	1	² SCHOUSE		
	4.	Unwilling to accept treatme	ent assignment by randomization.	1	² SCASIGN		
	5.		icipation in another intervention research with any of the interventions offered in DPP.	1	² SCINTV		

Participa	nt's initials Date of birth	DPP FORM S01.3 October, 1998 Page 4 of 6			
<u>Part III</u>	/ 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		

fir <u>Pa</u>	rst rt III	Int's initials Date of birth	0	P FORM S01.3 ctober, 1998 Page 5 of 6
	1.	Diabetes at baseline evaluation evidenced by any of the following:	YES	NO
		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.	<u>Exc</u>	clusions 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

	ant's initials Date of birth	C	DPP FORM S01.3 October, 1998 Page 6 of 6							
first last month day year <u>Part III / EXCLUSION CRITERIA</u> (continued)										
5.	Antineoplastic agents.	YES	NO 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 ran	ndomized.								
Н. <u>Сс</u>	nclusion									
		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 ra	ndomized.								
3.	Will the participant be randomized?	YES	NO 2 SCRNDM							
	a. If NO, and the reason is not documented in part II or III, specify below.									
-										

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				
2.	Screening number	S			
3.	Participant's initials		first	last	
4.	Participant's date of birth	month	day	year	
	If age is \geq 25 years continue, if age < 25 years, STOP. Fill in Elig	jibility Ch	ecklist i	tem C.1.	
5.	Participant's sex		F	Male 1	SEX
Visi	t Information				
1.	Date of visit	month	day	year	SOVSTDT

C. Instructions for Form S03 Completion

Β.

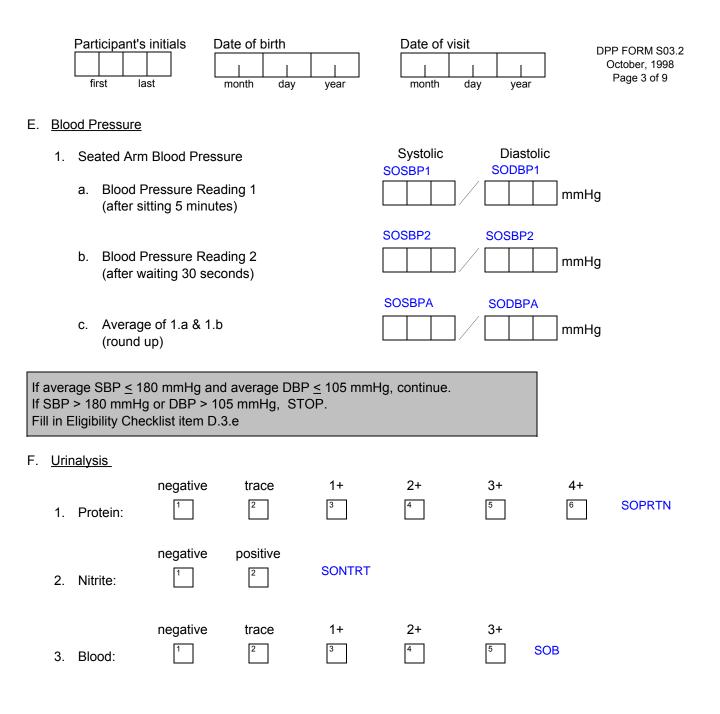
Prior to the OGTT procedure, complete all of sections D through J of Form S03 unless a STOP is encountered. Sections K and L should be completed during the OGTT procedure. The remaining sections, M through O, should be completed during or after the OGTT procedure.

first last

			ticipant's initials	Date of birth	year	Date of visit	year		DPP FORM S03.2 October, 1998 Page 2 of 9
			FORE OGTT						
D.	<u>BM</u>								
	1.	He	ight						
		a.	First measureme	nt			_	cm	SOHGHT1
		b.	Second measure	ment				cm	SOHGHT2
			Record c. o	nly if first 2 measu	urements are no	ot within 0.5 cm .			
		C.	Third measureme	ent				cm	SOHGHT3
	2.	We	eight						
		a.	First measureme	nt				kg	SOWGHT1
		b.	Second measure	ment				kg	SOWGHT2
			Record c. only if f	irst 2 measureme	nts are not with	in 0.2 kilogram (2	:00 gm).		
		C.	Third measureme	ent				kg	SOWGHT3
	3.	ls I	BMI ≥ 24 kg/m² (≥ 2	22 kg/m² for Asiar	ns)?			NO 2	SOBMI

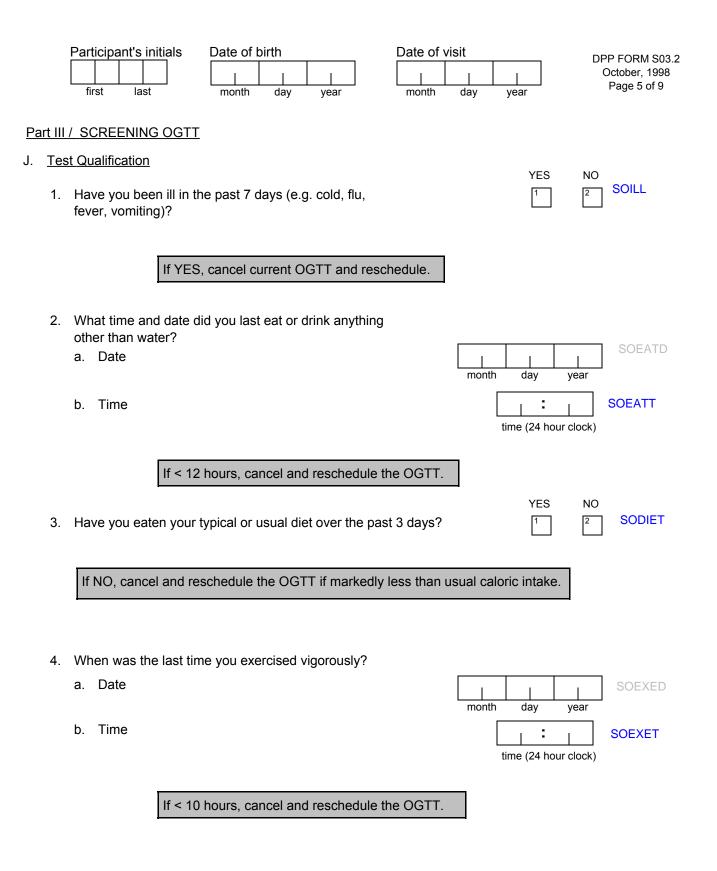
Use largest height and smallest weight for eligibility. See chart.

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



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.

	Participant's initials	Date of b	irth		Da	te of vis	sit		DPP	FORM	S03 2
			I						Oc	tober, 1	998
	first last	month	day	year	m	onth	day	year	P	age 4 of	f 9
G. <u>C</u> 1.	Current Medications Has the participant take	n any PRE	ESCRIP	TION me	dications	i		YES	NO 2	SORX	(DQ
	within the past 2 weeks	?									
	If YES, list below - conf	irm by insp	ection o	of bottles:							
	N	ledicine Desc	cription			1	Route				
а.	SORXDA1										
u	D4										
b.	B1										
[C1					ſ					
с.	01					L	₩₽				
d.	D1						\mathbf{M}				
u											
e.	E1										
ſ	E 4					I Г					
f.	F1								lose if S		Luvox)
_ [G1					Γ		(FIUZAC	<i>,</i> r axii,	201011,	LUVOX)
g.I											
h.	H1										
· · · ·							П				
i.	l1										
Г											
j.	J1										
2.	. Are any of these medi	cations ex	clusiona	ary?		YES	NO 2	SORXEX			
Fill in	Eligibility Checklist item	s G.1 - 9.	Partici	ipant may	/ be eligib	le if me	dicatior	can be disc	continue	ed.	
	regnancy (Women < 50				-						
11. <u>1 1</u>	egnancy (women < 50	years only)					YES	NO	MAYB	E
1.	. Are you currently preg	nant or nu	rsing a	baby?				1	2	3	SOPREG
	S, STOP. If MAYBE, pro Eligibility Checklist items			pregnanc	cy test. If	not pre	egnant, o	continue.			
	abetes_										
1.	,	-		nign suga	ar level of	r that yo	ou nave				
	(women: including dui	ing pregna	ancy)					cl	heck on	ly one	
								No	1		
						On	ly during	g pregnancy	2	SO	DIAB
							Yes	s, borderline	3		
								Yes	4		
If YF	S, and can confirm with	ohysician	or medi	cation S	TOP If o	otherwis	e, conti	nue.	_		
	Eligibility Checklist item						, co nd				



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

		Participant's initials Date of birth	Date of visit		P FORM S03.2 Dctober, 1998 Page 6 of 9									
K.		<u>at Progression</u> Were the fasting blood samples drawn? (i.e	local CBC and	YES NO	SOFAST									
	1.	CBL specimens)												
	2.	Time glucose consumption started time (24 hour clock)												
	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 minute is drawn outside that window record the time		•										
	4.	Time 2-hour sample drawn		time (24 hour clock)	SO2HRT									
		The sample must be drawn within 10 minute minutes. If the blood sample can not be obt test must be rescheduled.		_										
		rm local 2-hour capillary or venous glucos Results.	e. Record results in Sect	ion L of Form S03	- Local									
	5.	The OGTT was (choose only one):	completed	thout problem 1 with problem 2 ot completed 3	SORESL									
		a. Why was OGTT "completed with problem" or "not completed"?	Vomited afte Fainted or felt ill afte	r glucose load $\begin{bmatrix} 1 \\ 2 \end{bmatrix}$										
			Blood sample not obtai 10 minute window of 2-ho		SOFAIL									

Participant did not drink entire glucose load in 5 minutes

Other Specified:

Participant not eligible based on local fasting glucose

4

5

6

Other (specify below)

		ticipant's initials Date of birth	Date of visit	DPP FORM S03.2 October, 1998 Page 7 of 9
Loc	al C	OGTT Results		
1.	Fa	sting glucose		
	a.	What method was used to draw the blood?	Capillary Venous	1 SOLMETH
	b.	What machine was used to analyze the blood?	Lifescan Glucose analyzer	SOLMACH
		i. If Glucose analyzer was selected specify:	Beckman YSI Other	1 SOLSPEC
	C.	Fasting glucose level		mg/dL SOLFAST
2.	2-ł	nour glucose		
	a.	What method was used to draw the blood?	Capillary Venous	1 SOLMTH2
	b.	What machine was used to analyze the blood?	Lifescan Glucose analyzer	¹ SOLMCH2
		i. If Glucose analyzer was selected specify:	Beckman YSI Other	1 SOLSPC2 2 3
	C.	2 - hour glucose level		mg/dL _{SOL2HR}

L.

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.

		YES	NO
3.	Is participant eligible based on local glucose?	1	² SOL2HR

Participant's initials	Date of birth	Date of month	visit day year	DPP FORM S03.2 October, 1998 Page 8 of 9
Part IV / DURING OR AFTER	ROGIT			
M. <u>Demographics</u>1. What ethnic or racial	aroup do vou consider v	ourself a member	· (check only on	م
		1		
		2	S	OETHN
		3 ,	rincipal tribe:)
	n or Native American	4		/
		5		
	Islander	6		
)
If ASIAN OR PACIFIC a. Specify: (check of	CISLANDER (response = nly one)	= 6 above)		
Chinese				
Filipino		2	201	CNI
Hawaiian		3	SOA	21/
Korean		4		
Vietnamese.		5		
Japanese.		6		
Asian Indian		7		
Samoan		8		
Guamanian.		9		
Other A/PI		¹⁰ (specify: _)
 Are you of Spanish or If YES, a. Do you consider y 			YI 1	ES NO 2 SOHSP
	Mexicar	n, Mexican-Americ	can, Chicano 👖	
		I	Puerto Rican	SOHSPS
			Cuban ³	
		Other Spanisl	h or Hispanic	
	sp	ecify:		

Participant's initials	Date of birth	Date of visit	DPP FORM S03.2
			October, 1998
first last	month day year	month day year	Page 9 of 9
Part V / LOCAL LABORATC	DRY RESULTS		
N. Complete Blood Count			
1. Hemoglobin			SOHGLOB g/dL
2. Hematocrit			% SOHCRIT
Participant is ineligible if <3	36.0% for men. <33.0% for wo	men. Fill out Eligibility Checklist ite	em D.8.
		¥	
3. Platelet Count			x10³/ml SOAGRAN
Part VI / CONTINUING SCF	REENING		
O. Eligibility/Interest			
		YES	NO
1. Is participant willing	to continue with screening pro	ocess	2 3000122
-	participant for Screening Step 3		
IT NO, STOP. Fill	in Eligibility Checklist item E.1	•	

SCREENING STEP 3 INVENTORY - START

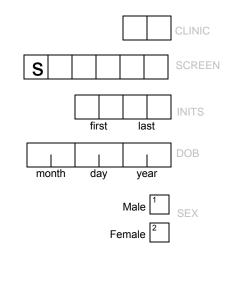
This form is completed during the Start-visit of Screening Step 3. Form S05 records the following: history on family, weight, smoking, aspirin use, cardiovascular and stroke/TIA, other diseases/symptoms, diet, and medical history for women; anthropometric and ankle/arm systolic blood pressure; dispensing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

Part I / IDENTIFICATION

- A. Participant Identification
 - 1. Clinic number
 - 2. Screening number
 - 3. Participant's initials
 - 4. Participant's date of birth
 - 5. Participant's sex

B. Visit Information

1. Date of visit





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			Form entered in computer?]
	first	last		

	Participant's initials	Date of birth	D	ate of visit		DPP FORM S05.1			
						October, 1998			
	first last	month day yea	r	month day	year	Page 2 of 16			
Part I	/ PARTICIPANT HISTO	<u>RY</u>							
D. <u>Fa</u>	mily Information			Mother	Don't	Father Don't			
				YES NO	Know	YES NO Know			
1.	Did your mother or fath	er have diabetes?	SIMDIAB	1 2	3	1 2 3 SIFDIA			
						r			
	a. If YES, age at diag	nosis	SIMDAGE		years	years SIFDAGE			
					Don't	Don't			
				YES NO	Know	YES NO Know			
2	5	er ever have a	SIMMI	1 2	3	¹ ² ³ SIFMI			
	heart attack?								
	a. If YES, age at first	heart attack	SIMMIAG		years	yearsorrange			
		6 1 · 0				1 SIFYOB			
3.	What are your parents'	years of birth	SIMYOB	1					
				Year		Year			
				Alive Dead		Alive Dead			
4	Are your parents still al	ive?		1 2 5	SIMALV	¹ ² SIFALV			
	a. If dead, year of dea	ath		1 9		1 9			
				Year	SIMYOD	Year SIFYOD			
5	5		u			SISIBS			
	have (include all living a	and deceased).				0000			
6.	How many of your brot	here and sisters have	or had diab	otos?					
0.	How many of your brou	11613 and 3131613 11dVE		5153 !		SISIBDI			
-	11	have and state as here the	h = d = 1	- #!·O	–	1-1			
1.	How many of your broth	ners and sisters have	nad a heart	attack?		SISIBMI			

Participa	nt's initials	Date of b	irth		Date of v	visit	DPP FORM S05.1	
								October, 1998
first	last	month	day	year	month	day	year	Page 3 of 16

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.

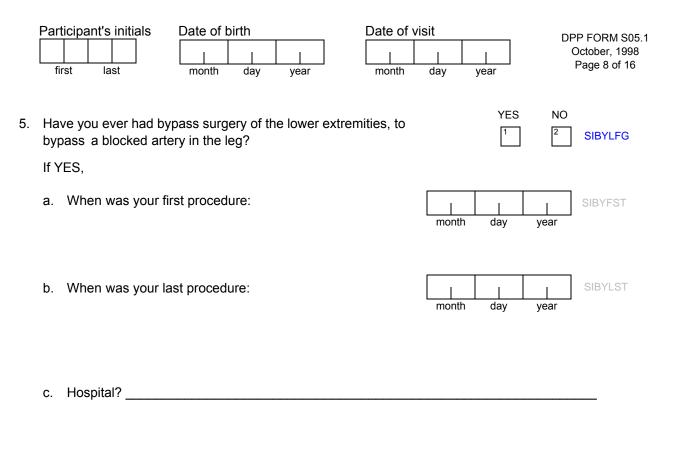
		ch <u>eck</u> only one	
		² Yes, gained	SIWGTGN
		a. How many pounds have you gained?	pounds
		b. Did you try to gain this weight?	YES NO 1 2 SITRYGN
SIWGTDF		³ Yes, lost	
		c. How many pounds have you lost?	pounds
		d. Did you try to lose this weight?	YES NO 1 2 SITRYLS
		⁴ Don't know	
2.		at did you weigh when you were 20 years old (Probe: w gnancy, what is your best estimate):	pounds SIWGT20
3.		at is the most you have weighed as an adult (age 20 or obe: do not include the times you were pregnant):	after) pounds SIMAXWT
4.	Wha	at is the least you have weighed as an adult (age 20 or	after) : pounds _{SILSTWT}
5.		w many times in your life have you lost at least 10 pound ned it back (don't count the weight lost after pregnancy).	
6.	lf YI	ve ever tried to lose weight? ES, ve you tried this by: (<i>check all that apply</i>)	YES NO 1 2 SILSWGT
		1	cation
SIWDIE ⁻ SIWEXE		2	ery
SIWEXE			al weight loss program.
SIWFEEX		1	

		Participant's initials Date of birth Date of visit DPP FORM \$05.1												
F.	<u>Sm</u>	oking History YES NO												
	1.	Have you smoked more than 100 cigarettes in your lifetime?												
	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?													
		c. On average, how many cigarettes per day do you smoke or did you smoke?												
	2.	Do you currently smoke cigars? Tes NO 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												
	3.	YES NO 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.	<u>Asp</u>	irin History												
	1. asp	During an average week, how often do you take one or more irin tablets?												
		Less than 1 day per week												
		1 or 2 days per week SIASPIR												
		3 to 4 days per week (includes every other day)												
		5 or 6 days per week 5												
		Every day ⁶												

		Par	ticipa	ant's initi	ials Date of birth D								visit			DPP FORM S05.1	
								1		1						C	October, 1998
		fi	rst	last	1	mo	onth	day	ye	ear	l	month	day	ye	ar	I	Page 5 of 16
H.	Thir		-	out the p								ving que	stions:		YES	NO 2	
	1.	Ha	ve y	ou had a	iny paii	n or d	isco	mfort in	your	r che	st?				1	2	SIPAIN
	2.	Ha	ve y	ou had a	ny pre	ssure	or h	eavine	ss in	your	chest?)			1	2	SIPRES
				stions 1 er are YE				skip to S	Section	on I							
		a.	Do	you get	it wher	ו you	walk	uphill (or hu	rry?					YES 1	NO 2	SIHURRY
		b.	Do	you get	it wher	ר you	walk	at an o	ordina	ary p	ace on	the leve	el?		1	2	SILEVEL
		c.	Wh	ien you (get it in) your	che	st, wha	it do g	you d	do?	С	continue		Stop Iow down me pace	1 2 3	SIDO
		d.		es it go a ΈS, How So	-	/hen y	/ou s	tand st	ill?				mc		YES 1 n. or less n 10 min.	NO 2 1 2	SISTILL SISOON
		e.	i. ii.	ere do y Sternur Left ant Left arr	n (cent	tral ch	nest)		omfor	rt:					YES 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	2	SISTER SILCHST SILARM
		f.		ve you e ting for h					cross	s the	front o	f your c	hest		YES	NO 2	SI30MIN

			ticipa rst	nt's initi	als]		e of b	irth day	year		Date of month	visit day	year	-	(PP FORM S05.1 October, 1998 Page 6 of 16
I.		На			-	l you	that y	vou had	d a myoo	cardial i	nfarction	or		YES	NO 2	SIMI
	If YES, a. When was your first heart attack:												lay	year	SIMIFST	
	Exclude if within the past 6 months. Fill out Eligibility Checklist item D.3.a															
	b. When was your last heart attack:												lay	year	SIMILST	
			Е	xclude	if with	in the	e past	6 mor	ths. Fil	out Eli	gibility Cł	necklist it	em D	.3.a		
		C.	Hos	pital? _												
		d.	Doct	tor? _												
	2.		ve yo .BG)?		nad co	oronai	ry arte	ery byp	ass sur	gery (gr	aft,			YES	NO 2	SIBABG
			′ES, Whe	en was '	your fi	rst su	ırgery	:				montl	h d	lay	year	SICBFST
			Е	xclude	if with	in the	e past	6 mor	nths. Fill	out Eli	gibility Cl	necklist it	em D	.3.a		
		b.	Whe	en was	your la	ast su	Irgery	:				montl	h d	lay	year	SICBLST
			E	xclude	if with	in the	e past	6 mor	nths. Fil	out Eli	gibility Ch	necklist it	em D	.3.a		
		C.	Hos	pital? _												
		d.	Doct	tor? _			1 . 1 .									

		ticipa rst	nt's init	ials		e of b	oirth day	year		Date of	visit dav	yea	ır		PP FORM S05 October, 1998 Page 7 of 16
3.	an	open			-	•	•	ne corona lastic tube	•			ŗ	YES	NO 2	SIBLLN
		ΈS, Whe	en was	your	first ar	ngiopl	asty:				mon	th o	day	year	SIBLFST
		E	Exclude	e if wit	hin the	e past	t 6 mor	nths. Fill c	out Eli	gibility Ch	necklist i	item D).3.a		
	b.	Whe	en was	your	last ar	ngiopl	asty:				mon	th o	day	year	SIBLLST
		E	Exclude	e if wit	hin the	e past	t 6 mor	nths. Fill o	out Eli	gibility Ch	necklist	item D).3.a		
	C.	Hos	pital? _												
	d.	Doc	tor? _												
4.		-						ctomy or a s in your r	-	her			YES	NO 2	SINECK
		ΈS, Whe	en was	your	first su	ırgery	<u>/:</u>				mon	th o	day	year	SINKFST
		E	Exclude	e if wit	hin the	e past	t 6 mor	nths. Fill c	out Eli	gibility Ch	necklist i	item D).3.a		
	b.	Whe	en was	your	last su	irgery	:				mon	th o	day	year	SINKLST
		E	Exclude	e if wit	hin the	e past	t 6 mor	nths. Fill c	out Eli	gibility Ch	necklist i	item D).3.a		
	c.	Hos	pital? _												



d. Doctor? _____

	Participant's initials	Date of birth	year	Date of month	visit day yea	ar	DPP FORM S05.1 October, 1998 Page 9 of 16
<u>Stro</u>	oke / TIA History						
1. ting	During the past 12 mor gling, or loss of feeling ir	•	•	-	of numbness,	YES 1	NO 2 SINUMB
	If YES, a. How long did the s	ymptoms last?			< 1 hour 1 - 24 hour(s) > 24 hours	1 2 3	SINUMBT
2.	During the past 12 mor paralysis, or loss of us		-		of	YES	NO ² SIPARL
	If YES, a. How long did the s	ymptoms last?			< 1 hour 1 - 24 hour(s) > 24 hours	2	SIPARLT
3.	During the past 12 mor or blurring of vision for		-	lden loss of e	eyesight	YES 1	NO 2 SIBLUR
	If YES, a. How long did the s	ymptoms last?			< 1 hour1 - 24 hour(s)> 24 hours	2	SIBLURT
4.	During the past 12 mor changes in speech, los than two minutes?					YES 1	NO 2 SISLUR
	If YES, a. How long did the s	ymptoms last?			< 1 hour 1 - 24 hour(s) > 24 hours	2	SISLURT
5.	During the past 12 mor difficulty in walking, ligh				SS,	YES	NO 2 SIDIZY

J.

	Particip	oant's initials	Date of birth	Date of visit	ay year	(PP FORM S October, 199 Page 10 of 1	98
6.			d you that you had a stroke, ansient ischemic attack)?		Yes, s , ministroke o es, uncertain v	r TIA 3	SISTRK	
	lf YES a. Wi	, hen was your f	irst stroke:		month day	year	SISKFS	Т
		Exclude if wit	thin the past 6 months. Fill c	out Eligibility Chec	klist item D.3.	f		
	b. Wi	hen was your l	ast stroke:	[month day	year	SISKLST	
		Exclude if wit	thin the past 6 months. Fill c	out Eligibility Chec	klist item D.3.	f		
Has	s a docto	or told you that	you had any of the following	l?			Past 12	2
					Ever		month	
1. 2. 3.	Angina High cl	a?	(hypertension)?	SIANGI1 SILIPI1	YES N(1 2 1 2 1 2 1 2		1 1 1	NO 2 SIHYPE1 2 SIANGI2 2 SILIPI2 2 SIULCR2
4. 5	Ulcer ((stomach or du	odenal), or intestinal bleedin	SIHEP1	1 2	_ T		² SIHEP2
5. 6.				01011001	··· 2		1	² SICNCR2
7.			er disease, or gallbladder su	SIGALL1	1		1	² SIGALL2
8.		-	·····	SIGOUT				² SIGOUT2
9.					2			² SITHYR2
10.	Other	major diseases	\$?	SIUTH1			Ĺ	² SIOTH2
		ES, specify						

K.

	Participant's initials	Date of birth	year	Date of visit	year	DPP FORM S05.1 October, 1998 Page 11 of 16
Dur	ing the past 12 months	have you experier	nced any of th	e following?	YES	NO
1.	Skin rashes?				1	² SIRASH
2.	Frequent stomach pai	ns, bloating, nause	a, diarrhea, c	or loss of appetite	e? 1	² SISTOM
3.	Unexplained weight lo	ss?			1	² SILOSEW
4.	Increased thirst (drink	ing more liquids the	an usual)?		1	² SITHRST
5.	Urinating more often t	han usual?			1	² SIURINT

L.

М.	<u>Diet</u>		YES	NO	
	1. Are	you now on a special diet for any reason?	1	2	SISPECD
		ΈS, ecify (check all that apply)			
	a.	Low cholesterol or low fat (for high cholesterol) 1 SILOWFT			
	b.	Low salt (for high blood pressure)			
	C.	Low calorie (for weight loss)			
	d.	Vegetarian			
	e.	Other diet (specify:) 1 SIOTHD			

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

		Participant's initials	Date of birth		month	isit day	year		PP FORM S05.1 October, 1998 Page 12 of 16
N.	Me	dical History Questionna	aire for Women						
	1.	Are you still having per	iods (menstrual bleeding	g)?					
							No		SIMENS
							Yes Uncertair		
						Never	had a period	4	
		If NO or UNCERTAIN							
		a. How long ago was	your last period?						
							< 6 month	S 1	
							6 - 12 month		SIMENST
							s (1 - 2 years	4	
			2	25 OF MORE	emonin	s (more	than 2 years	5)	
		If 13 or more mont i. At what age wa	hs as your last period?						ears _{SIMENSA}
							YES	NO	
	2.	Are you currently havir	ng hot flashes or night sv	veats?			1	2	SIHOTFL
		If YES, a. What was your age	e when you first had syn	nptoms?					vears _{SIHOTAG}
	3.		e, were your periods reg le any time when you we			•			
							N	o 1	
							Ye	s ²	SIMREG
			S	ometimes	regular	, someti	mes irregula	r ³	
	4.	-	had your first and last pe t one year? (Do not cour	•		-		NO 2	SI1YR
		If YES, a. What is the longes	t interval? (Not counting	nregnang	w and h	reast fo	edina)		
		a. what is the longes		pregnanc	y anu D		2 - 23 month	1	
							2 - 23 months 1 - 48 months		SI1YRT

more than 48 months (4 years) 3

	Participant's initials Date of birth Date of visit	DPP FORM S05.1 October, 1998 Page 13 of 16
5.	Have you ever been pregnant?	YES NO 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
6.	Have you ever tried to become pregnant for more than 1 year without becoming pregnant?	YES NO 1 2 SITRYPR
	If YES, a. Did you visit a doctor or clinic because you did not become pregnant?	YES NO 1 2 SIMDPRG
	If YES, i. Was a reason found for why you did not become pregnant?	YES NO 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	s ²
	Endometriosis	4
	Other problem with you	-
	Partner's problem Don't know	
7.	Did you ever have an operation to have one or both of your ovaries taken ou	t?
		No ¹
	Yes, one ta	
	Yes, both ta	
	Yes, part of an ovary ta	5
	Dor	י't know 🎽
	If YES, a. How old were you at your last operation?	years _{SIOVARA}

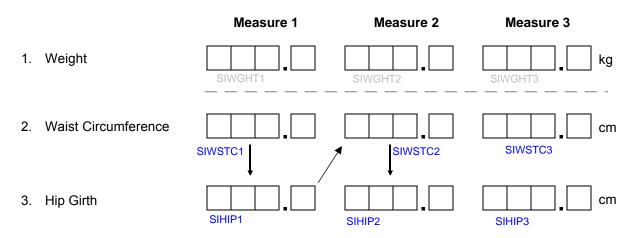
[Participant's initials Date of birth Date of visit	ay year	DPP FORM S05.1 October, 1998 Page 14 of 16
	Did you ever have an operation to remove your uterus (womb) (hysterectomy)?	YES	NO 2 SIHYST
	If YES, a. How old were you?		years _{SIHYSTA}
	Did you ever have an operation to have your tubes tied to prevent gnancy?	YES	NO 2 SITUBAL
	Has a heath care provider ever told you that you had polycystic ovary syndrome or Stein-Leventhal syndrome? If YES,	YES	NO 2 SIPCOS
	a. How old were you when you were told?		years _{SIPCOSA}
	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	NO 2 SIBCPN

Participant's initials		Date of b	Date of birth		_	Date of visit			DPP FORM S05.1
			1						October, 1998
first	last	month	day	year		month	day	year	Page 15 of 16

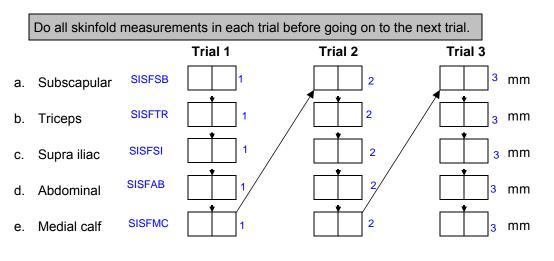
Part III / PHYSICAL

O. Anthropometrics

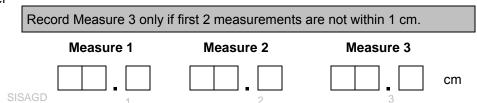
For O.1 - Weight, record Measure 3 only if first 2 measurements are not within 0.2 kilograms.
For O.2 - Waist Circumference, and O.3 - Hip Girth, record measure 1 for each before completing Measure 2 and only record Measure 3 if first 2 measurements are not within 0.5 cm.



4. Skin-fold Thickness



5. Sagittal Diameter



Participant's initials		Date of birth		Date of	visit	DPP FORM S05.1	
							October, 1998
first	last	month	day year	month	day	year	Page 16 of 16

P. Blood Pressure

1. Supine Ankle/Arm Systolic Blood Pressure

Right arm to be used unless left arm is \geq 10 mmHg higher, in which case wait 30 seconds, repeat left arm pressure, and enter the repeat result as the first arm pressure

Right arm SISSBPA SISSBP a. Arm mmHg Left arm Right dorsalis pedis b. mmHg SIADORR SIAPOSR Right tibialis posterior C. 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 YES NO Q. Eligibility/Interest SIWILL 2 1. Is participant willing to continue with the screening process?

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

- R. Placebo Medication Dispensed
 - 1. Dispensing of Medication

Run-in 1

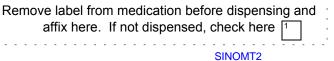
METFORMIN LABEL

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

SINOMT1

Run-in 2

METFORMIN LABEL



Diabetes Prevention Program

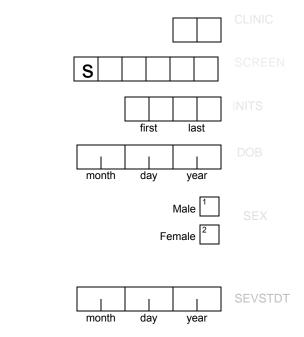
SCREENING STEP 3 INVENTORY - END

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
- 2. Screening number
- 3. Participant's initials
- 4. Participant's date of birth
- 5. Participant's Sex
- B. Visit Information
 - 1. Date of visit



C. Instructions for Form S06 Completion

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

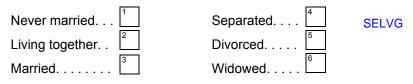
Initials of person reviewing completed form			Form entered in computer?
	first	last	

		Participant's initials Date of birth	Date of visi	t day year	DPP FORM S April, 199 Page 2 of	6	
Pa	art II /	RUN-IN COMPLETION INFORMATION	Dun in	#1	Run-in #2	,	
D.	<u>Rur</u>	n-in Compliance	Run-in SEDATE1	#1	(if repeated		
	1.	Date run-in initiated	month day	year	month day	year	
	2.	Was participant compliant with placebo pill taking?	YES	NO ² SEPILL1	YES N	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	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.	<u>Adve</u>	erse Events					
	1. Since the physical exam, has the participant had any new symptoms, injuries, illness or side effects, or worsening of pre-existing conditions? YES NO 1 2 SEAEQ						
lf `	YES,	an Adverse Event Report (Form EO1) MUST be con	npleted.				

Participant's initials		Date of b	Date of birth		Date of visit			DPP FORM S06.1	
			1						April, 1996
first	last	month	day	year	-	month	day	year	Page 3 of 3

F. Personal data & Socioeconomic Status

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



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

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

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

Currently employed full or part-time 1	Seasonally employed
Currently retired $\frac{2}{2}$	Student
Currently full-time homemaker. \dots $\frac{3}{}$	Other
Currently not employed 4	Never worked

	people	SEHOUSE

SEEMPL

4. How many individuals live in your household?

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

4

less than \$10,000	'
\$10,000 to less than \$15,000	2
\$15,000 to less than \$20,000	3
\$20,000 to less than \$35,000	4

\$35,000 to less than \$50,000	5	
\$50,000 to less than \$75,000	6	SEINC
\$75,000 to more		
Refused	8	

G.	<u>Eliç</u>	<u>jibility/Interest</u>	YES	NO	
	1.	Is participant willing to continue with the screening process?	1	2	SEWILI
		If YES, continue screening process. If NO, fill out eligibility checklist ite	em E.1		

Diabetes Prevention Program

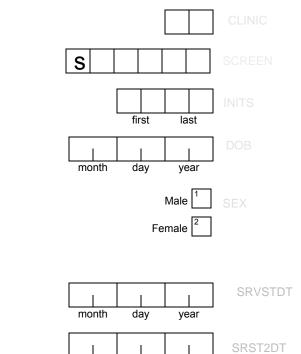
SCREENING STEP 4 INVENTORY - RANDOMIZATION

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
- 2. Screening number
- 3. Participant's initials
- 4. Participant's date of birth
- 5. Participant's sex
- B. Visit Information
 - 1. Date of Randomization Visit
 - 2. Date of Screening Step 2 OGTT



day

year

month

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	nfirst	last	Form entered in computer?	
Signature of P.I.			Date:	,

fi	first last month day year mon	of visit	DPP FORM S07.2 October, 1998 Page 2 of 3
Part II / PF D. <u>Adverse</u>	RE-RANDOMIZATION INFORMATION		
1. Sir nev	nce the last screening visit, has the participant had any w symptoms, injuries, illness or side effects, or prsening of pre-existing conditions?	YES 1	NO 2 SRAEQ
If YES, an	Adverse Event Report (Form EO1) MUST be completed.		
E. <u>Pregna</u>	ancy		
1. Do	pes the participant have reproductive potential?	YES	NO 2 SRPREM
lf Y a.	YES, Result of pregnancy test	Positive 1 Negative 2	SRPREG
	If positive fill in Eligibility Checklist item E.10.a, reafter pregnancy and breast-feeding are complete F1		
F. <u>Currer</u>	nt Medications	YES	NO
	the participant currently taking any PRESCRIPTION edications?	1	² SRRXDQ
lf Y	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	H1 I1		

Participan	<u>it's initi</u> als	Date of b	irth		Date of	visit		DPP FORM S07.2
			1					October, 1998
first	last	month	day	year	month	day	year	Page 3 of 3

Part III / RANDOMIZATION PROCESS

- G. Final Eligibility Review
 - 1. Has the participant signed the informed consent form(s)?
 - 2. Has the physical examination of systems been completed?
 - 3. Is participant eligible (see S01 Eligibility Checklist)?
 - 4. Have the following been completed and entered:
 - a. Eligibility Checklist (S01)
 - b. Screening Step 2 Inventory (S03)
 - c. Screening Step 3 Inventory Start (S05)
 - d. Screening Step 3 Inventory End (S06)
 - 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)?

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.

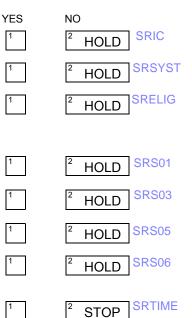
 1. Participant number
 PAILD

 YES
 NO

 YES, a. Dispense Medication:
 1

 METFORMIN LABEL
 SRPATM

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

first

last

Part I / IDENTIFICATION

A. Participant Identification

- 1. Clinic number
- 2. Participant number
- 3. Participant's initials
- 4. Participant's date of birth
- 5. Participant's sex

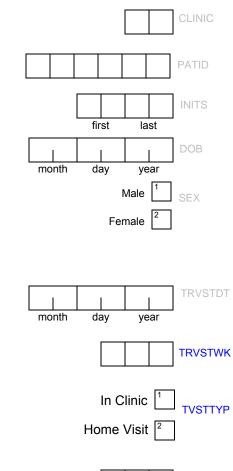
B. Visit Information

- 1. Date of visit
- 2. Week of visit
- 3. Type of visit
- 4. Outcome visit
- 5. End of Study

C. Instructions for Form TR1 Completion

Complete all sections of Form TR1.

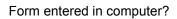
Initials of person reviewing completed form





Υ

es	1	
No	2	TREOS



		ticipant's initials	Date of birth	l	Date of vi		ear	DPP FORM TR1.1 November, 1999 Page 2 of 3
<u>Part I</u>	<u>I / PH</u>	YSICAL AND HIST	ORY					
D. <u>A</u>	nthrop	oometrics						
1	. We	eight						
	a.	First measuremer	nt				• 🗌 H	g TRWGHT1
	b.	Second measure	ment				• P	g TRWGHT2
		Record c. only if f	irst 2 measur	ements are n	ot within 0.2 kilo	gram (200	gm).	
	C.	Third measureme	ent					(g TRWGHT3
E. <u>B</u>	lood F	Pressure						
1	. Se	ated Arm Blood Pre	essure		Systolic		stolic	
	a. b.	Blood Pressure R (after sitting 5 mir Blood Pressure R	eading 2		TRSBP1 TRSBP2		mm	
		(after waiting 30 s	econds)				1	

D.

Ε.

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

Initials of data collector completing page 2 of this form			
	first	last	-

Participant's initials		Date of birth			Date of visit				DPP FORM TR1.1
									November, 1999
first last	_	month	day	year	-	month	day	year	Page 3 of 3

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?

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

G. Prescription Medications

1. Is the participant currently taking any PRESCRIPTION medications?

NO

 Provide the second secon

YES

1

YES

NO

2

TRAEQ

	Medicine Description	Route
а.	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 DPP FORM TR2.1 June, 1998 Page 1 of 1

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 CLINIC A. Clinic number TDATE B. Date of group session month day year TTIME : C. Start time of group session time (24 hour clock) D. Type of session TTYPE 2 0 (see code book; 2000 series) E. Group Leader (s) TLEAD1 1 first last TLEAD2 2 Part II / ATTENDEES last first Participant Name Initials Identification Number first last RELEASE_ID1 INITS1 1. _____ 2. 3. _____ 4. _____ 5. _____ 6. _____ 7. _____ 8. _ 9. _____ 10. _____ 11. _____ 12. _____ 13. _____ 14. _____ RELEASE_ID15 INITS15 15. Note: Optional page 2 listed RELEASE_ID16 - RELEASE_ID30 Initials of person completing form Form entered in computer? first last