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.

<u>Pa</u>	rt I /	<u>IDENTIFICATION</u>							
Α.	<u>Par</u>	ticipant Identification				В.	<u>Vis</u>	it Information	
	1.	Clinic number					1.	Date of visit	
	2.	Participant Identification Number (Complete a O	R b)						month day year
		a. If before randomization, Screening number	S				2.	Type of Visit	Screening Step
		b. If after randomization, Participant number							² Standard Follow-up
									Major Follow-up
	3.	Participant's initials		first	last				Interim Follow-up
	4.	Participant's date of birth	month	day	year		3.	Week of visit (If Follow-up)	
C.	Inst	ructions for Form E01 Completion							
С	omp	lete one or more Adverse Event's per visit. If an A	Adverse	Event is	serious, th	ne Ser	iou	s Adverse Event Form (E02) n	must also be completed.
		Initials of person reviewing completed form	first	last				Form entered in computer?	

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Participa	nt's initials	Date of b	Date of birth				Date of visit				
			1								
first	last	month	day	year	_	month	day	year			

D. Adverse Event(s) Summary

						Intervention	
Event Number	Adverse Event (short description)	Classification Term	Date Resolve Onset Date Continuing	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
1.			month day year month day y Continuing	ear			
2.			month day year month day y Continuing	ar			
3.			month day year month day y Continuing	ar			
4.			month day year month day y Continuing	ar			
5.			month day year month day y Continuing	ear			
6.			month day year month day y Continuing	ear			

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

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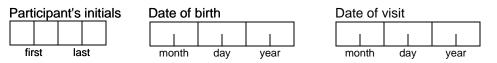
Participa	nt's initials	Date of b	Date of birth				Date of visit				
first	last	month	day	year	•	month	day	year			

D. Adverse Event(s) Summary

						Intervention	
Event Number	Adverse Event (short description)	Classification Term	()ncot l)ato	ate Resolved/ ontinuing	Serious? 1 = YES* 2 = NO	Suspended 1 = YES 2 = NO	If YES, Which Intv? 1 = Metformin 3 = Diet 4 = Exercise
7.			month day year mont	th day year			
8.			month day year mont	th day year			
9.			month day year mont	th day year			
10.			month day year mont	th day year			
11.			month day year mont	th day year			
12.			month day year mont	th day year			

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

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D. Adverse Event(s) Summary

							Intervention	
Event Number	Adverse Event (short description)	Classification Term	Onset Date	Date Resolved/ Continuing	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 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).