Diabetes Prevention Program

ADVERSE EVENT REPORT

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

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number ☐☐

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

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

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

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

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

B. Visit Information

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

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

3. Week of visit (If Follow-up) ☐☐☐

C. Instructions for Form E01 Completion

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

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

Form entered in computer? ☐

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

D. Adverse Event(s) Summary

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

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

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

D. Adverse Event(s) Summary

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

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

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

D. Adverse Event(s) Summary

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

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