Diabetes Prevention Program

MORTALITY EVENT REPORT

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

Part I / IDENTIFICATION

A. Participant Identification

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

B. Report Identification

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

C. Instructions for Form E06 Completion

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

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

D. General Information

1. Place of death

check only one

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

specify: _____

- Unknown [5]

2. Was the death:

check only one

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

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

check only one

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

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

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

check all that apply

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

specify:_____

first	last	month	day	year	month	day	year

E. Specific Information (include narrative description)

1. Immediate cause of death:

_____

_____

_____

_____

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

_____

_____

_____

_____

3. Specify any contributory causes of death:

_____

_____

_____

_____

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

_____

_____

_____

_____