

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

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
first		last	
4. Participant's date of birth

<input type="text"/>	<input type="text"/>	<input type="text"/>
month	day	year

B. Report Identification

1. Date of report

<input type="text"/>	<input type="text"/>	<input type="text"/>
month	day	year
2. Date of death

<input type="text"/>	<input type="text"/>	<input type="text"/>
month	day	year
3. Type of Report

Initial	<input style="width: 20px; height: 20px;" type="text"/>
Follow-up	<input style="width: 20px; height: 20px;" type="text"/>

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

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
first		last	

Form entered in computer?

Participant's initials

first		last	

Date of birth

month	day	year

Date of visit

month	day	year

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

4. Was the participant taking the coded metformin?

YES 1

NO 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: _____

Participant's initials

first		last	

Date of birth

month	day	year

Date of visit

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:
