

Participant ID

--	--	--	--	--	--	--	--

Nickname

--	--	--	--	--	--	--	--

Date of visit

month	day	year			

Diabetes Prevention Program Outcomes Study

F07 Metformin Discontinuation Form

Complete this form at least once for all DPPOS MLS participants not taking study metformin. If a permanent condition is reported in section B, additional F07 forms are not required. For participants off metformin temporarily/eligible to restart, form should be completed every time study metformin is not dispensed. This form, can be completed at an annual, mid-year, interim, or PNP outcome visit. PNP (Participant Not Present) should be marked as outcome visit if this form is completed without the participant's presence. If PNP is entered as outcome visit, the visit date will be the date of form completion.

A. Participant Identification

1. Clinic number 

--	--

2. Participant number 

--	--	--	--	--	--	--	--

3. Nickname 

--	--	--	--	--	--	--	--

4. Date of randomization 

month	day	year			

5. Sex Male <sup>1</sup>

--

 Female <sup>2</sup>

--

6. Outcome visit 

--	--	--

 VISIT

7. Date of visit 

month	day	year			

 F7VSTDT replaced with DAYSRAND

8. Reason for visit completion **CHECK ONLY ONE**

Initial assessment..... 

--

<sup>1</sup> F7REA

Reassessment ..... 

--

<sup>2</sup>

FORMIN

Identification code of person reviewing completed form 

--	--	--

 Form entered in computer? 

--

Participant ID

--	--	--	--	--	--	--

Nickname

--	--	--	--	--	--	--

Date of visit

month	day	year			

**B. Metformin Dispensing Information**

1. Study metformin was **not** dispensed due to the following:

**CHECK ALL THAT APPLY**

- a. Fasting hyperglycemia during DPP, or Hba1c  $\geq$  7.0% in DPPOS.....  F7BHBA1C
- b. Elevated serum creatinine on two separate occasions.....  F7SCREAT
- c. Creatinine clearance < 75 ml/min for participants over 80 years old.....  F7CRCLR
- d. Confirmed congestive heart failure.....  F7CHF
- e. Prohibitive liver condition.....  F7LIVER
- f. Elevated LFT's during DPP, permanent removal from metformin...  F7LFT
- g. Other permanent medical condition.....  F7OPERM

If any of responses a. – g. are checked, this is a permanent condition. If any of responses h.-p. are checked, this is a temporary/behavioral condition.

- h. Directive of participant's physician.....  F7PHYDIR
- i. Pregnancy/Breastfeeding.....  F7PREG
- j. Alcohol usage in excess of protocol guidelines.....  F7ALCOHOL
- k. Evaluation of possible medical condition(s) prohibitive of taking study metformin.....  F7EVAL
- l. Participant is Inactive.....  F7INACT
- m. Other medical condition.....  F7OMED

1. If **OTHER**, specify:

--

- n. GI Symptoms/problems.....  F7GI
- o. Other (temporary conditions).....  F7OTEMP

1. If **OTHER**, specify:

--

- p. Behavioral issues (participant chooses not to take metformin).....  F7BEHAV