

## Diabetes Prevention Program

### SCREENING STEP 4 INVENTORY - RANDOMIZATION

This form is completed during the Randomization Visit (Screening Step 4).  
 Form S07 records the following: adverse event assessment, pregnancy test result and current prescription medications; final eligibility review, micro-computer randomization and dispensing of coded medication.

#### Part I / IDENTIFICATION

##### A. Participant Identification

1. Clinic number [ ][ ] CLINIC
2. Screening number S [ ][ ][ ][ ] SCREEN
3. Participant's initials [ ][ ] [ ][ ] INITS  
first last
4. Participant's date of birth [ ][ ][ ][ ][ ] DOB  
month day year
5. Participant's sex Male  SEX  
Female

##### B. Visit Information

1. Date of Randomization Visit [ ][ ][ ][ ][ ] SRVSTDT  
month day year
2. Date of Screening Step 2 OGTT [ ][ ][ ][ ][ ] SRST2DT  
month day year

##### C. Instructions for Form S07 Completion

Complete sections D through F of Form S07. A final eligibility review is conducted by completing section G. Signature of P.I. indicates review of participant eligibility prior to randomization. After entering sections A through G in the Remote Data Management System, the computer will prompt you to randomize the participant. The prompt will occur if all required forms have been entered and the participant is eligible.

Initials of person reviewing completed form [ ][ ] [ ][ ] Form entered in computer?   
first last

Signature of P.I. \_\_\_\_\_ Date: \_\_\_\_\_

Participant's initials

first		last	

Date of birth

month	day	year

Date of visit

month	day	year

Part II / PRE-RANDOMIZATION INFORMATION

D. Adverse Events

1. Since the last screening visit, has the participant had any new symptoms, injuries, illness or side effects, or worsening of pre-existing conditions?

YES

 1

NO

 2

SRAEQ

If YES, an Adverse Event Report (Form EO1) MUST be completed.

E. Pregnancy

1. Does the participant have reproductive potential?

YES

 1

NO

 2

SRPREM

If YES,

- a. Result of pregnancy test

Positive

 1

SRPREG

Negative

 2

If positive fill in Eligibility Checklist item E.10.a, recall after pregnancy and breast-feeding are complete

F1

F. Current Medications

1. Is the participant currently taking any PRESCRIPTION medications?

YES

 1

NO

 2

SRRXDQ

If YES, list below - confirm by inspection of bottles:

	Medicine Description	Route
a.	SRXDA1	<del> </del>
b.	B1	<del> </del>
c.	C1	<del> </del>
d.	D1	<del> </del>
e.	E1	<del> </del>
f.	F1	<del> </del>
g.	G1	<del> </del>
h.	H1	<del> </del>
i.	I1	<del> </del>
j.	J1	<del> </del>

Participant's initials

first		last	

Date of birth

month	day	year

Date of visit

month	day	year

Part III / RANDOMIZATION PROCESS

G. Final Eligibility Review

- |   | YES                                   | NO   |        |
|---|---------------------------------------|--|--------|
| 1. Has the participant signed the informed consent form(s)?   | <input type="checkbox"/> <sup>1</sup> | <input type="checkbox"/> <sup>2</sup> HOLD | SRIC   |
| 2. Has the physical examination of systems been completed?  | <input type="checkbox"/> <sup>1</sup> | <input type="checkbox"/> <sup>2</sup> HOLD | SRSYST |
| 3. Is participant eligible (see S01 - Eligibility Checklist)?   | <input type="checkbox"/> <sup>1</sup> | <input type="checkbox"/> <sup>2</sup> HOLD | SRELIG |
| 4. Have the following been completed and entered:   |                                       |  |        |
| a. Eligibility Checklist (S01)  | <input type="checkbox"/> <sup>1</sup> | <input type="checkbox"/> <sup>2</sup> HOLD | SRS01  |
| b. Screening Step 2 Inventory (S03)   | <input type="checkbox"/> <sup>1</sup> | <input type="checkbox"/> <sup>2</sup> HOLD | SRS03  |
| c. Screening Step 3 Inventory - Start (S05)   | <input type="checkbox"/> <sup>1</sup> | <input type="checkbox"/> <sup>2</sup> HOLD | SRS05  |
| d. Screening Step 3 Inventory - End (S06)   | <input type="checkbox"/> <sup>1</sup> | <input type="checkbox"/> <sup>2</sup> HOLD | SRS06  |
| 5. Is the elapsed time from the date of the Step 2 - OGTT visit to the randomization visit less than or equal to 13 weeks (91 days)? (See questions B.1 and B.2)? | <input type="checkbox"/> <sup>1</sup> | <input type="checkbox"/> <sup>2</sup> STOP | SRTIME |

H. Perform Computerized Randomization

The computer will now prompt you to randomize the participant. If all forms are entered and the participant is ready to be randomized, mark an 'X' where prompted. The computer will then give the participant's Participant Number.

1. Participant number

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PATID

2. Is participant assigned to the pharmacologic intervention?

YES	NO	
<input type="checkbox"/> <sup>1</sup>	<input type="checkbox"/> <sup>2</sup>	SRPHAR

If YES,

a. Dispense Medication:

METFORMIN LABEL

SRPATM

Remove label from medication before dispensing and affix here. If not dispensed, check here

SRNOMET