

Diabetes Prevention Program

ELIGIBILITY CHECKLIST

This form is completed during the screening period for all participants attending a Screening Step 2 Visit. Form S01 documents the inclusion and exclusion criteria for potential participants.

Part I / IDENTIFICATION

A. Participant Identification

- | | | |
|--------------------------------|--|--------|
| 1. Clinic number | <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> | CLINIC |
| 2. Screening number | <input style="width: 20px; height: 20px;" type="text"/> S <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> | SCREEN |
| 3. Participant's initials | <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> | INITS |
| | first last | |
| 4. Participant's date of birth | <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> | DOB |
| | month day year | |
| 5. Participant's sex | Male <input style="width: 20px; height: 20px;" type="checkbox"/> | SEX |
| | Female <input style="width: 20px; height: 20px;" type="checkbox"/> | |

B. Visit Information

- | | | |
|-----------------------------|---|--------|
| 1. Date of Screening Step 2 | <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> | SCT2DT |
| | month day year | |

Part II / INCLUSION CRITERIA

C. Inclusion Criteria

- | | YES | NO | |
|--|---|---|---------|
| 1. The participant is at least 25 years of age. | <input style="width: 20px; height: 20px;" type="checkbox"/> | <input style="width: 20px; height: 20px;" type="checkbox"/> | SC25YR |
| 2. Impaired glucose tolerance with elevated fasting plasma glucose. | | | |
| a. Fasting plasma glucose 95-125 mg/dL. | <input style="width: 20px; height: 20px;" type="checkbox"/> | <input style="width: 20px; height: 20px;" type="checkbox"/> | SCFPGI |
| b. 2-hr plasma glucose 140-199 mg/dL. | <input style="width: 20px; height: 20px;" type="checkbox"/> | <input style="width: 20px; height: 20px;" type="checkbox"/> | SC2HPGI |
| 3. Body-mass index ≥ 24 kg/m ² (≥ 22 kg/m ² for Asians) | <input style="width: 20px; height: 20px;" type="checkbox"/> | <input style="width: 20px; height: 20px;" type="checkbox"/> | SCBMI |

All inclusion criteria must have been answered YES for the participant to be randomized.

Initials of person completing 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	

Part III/ EXCLUSION CRITERIA

D. Exclusion for underlying disease likely to limit life span and/or increase risk of

- | | YES | NO | |
|--|----------------------------|----------------------------|---------|
| 1. Cancer requiring treatment in the past 5 years, with the exception of cancers which have been cured or, in the opinion of the investigator, carry a good prognosis. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCCNCR |
| | | | |
| 2. Infectious diseases. | | | |
| a. Self-reported HIV positivity. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCHIV |
| b. Active tuberculosis. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCTB |
| | | | |
| 3. Cardiovascular disease. | | | |
| a. Hospitalization for treatment of heart disease in the past 6 months. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCHDHOS |
| b. New York Heart Association Functional Class >2. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCNYHAH |
| c. Left bundle branch block on ECG. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCLBBB |
| d. Third degree atrioventricular block on ECG. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SC3RDB |
| e. Uncontrolled hypertension:
SBP >180 mmHg or DBP >105 mmHg on treatment. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCHYPER |
| f. Stroke or transient ischemic attack in the past 6 months. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCSTROK |
| | | | |
| 4. Gastrointestinal disease. | | | |
| a. Self-reported chronic hepatitis or cirrhosis, or serum AST or ALT elevated by the following criteria:
serum AST ≥ 66 U/L
serum ALT ≥ 58 U/L if over 47 years
serum ALT ≥ 118 U/L if male ≤ 47 years
serum ALT ≥ 46 U/L if female ≤ 47 years | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCAST |
| b. Episode of alcoholic hepatitis or alcoholic pancreatitis ever. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCALCHL |
| c. Inflammatory bowel disease requiring treatment in the past year. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCBOWL |
| d. Recent or significant abdominal surgery (e.g. gastrectomy). | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCABSUR |

Participant's initials

first		last	

Date of birth

month	day	year	

Part III / EXCLUSION CRITERIA (continued)

- | | YES | NO | |
|--|--------------------------|--------------------------|---------|
| 5. Renal disease. | | | |
| a. Serum creatinine ≥ 1.4 mg/dL (124 μ mol/L) for men; ≥ 1.3 mg/dL (115 μ mol/L) for women. | <input type="checkbox"/> | <input type="checkbox"/> | SCRENAL |
| b. Urine protein $\geq 2+$ on one occasion (dipstick), in the absence of infection or vaginal contamination. | <input type="checkbox"/> | <input type="checkbox"/> | SCOIPSK |
| 6. Lung disease. | | | |
| a. Chronic obstructive airway disease or asthma requiring daily therapy. | <input type="checkbox"/> | <input type="checkbox"/> | SCASTHM |
| b. New York Heart Association Functional Class > 2. | <input type="checkbox"/> | <input type="checkbox"/> | SCNYHAL |
| c. Use of oxygen at home. | <input type="checkbox"/> | <input type="checkbox"/> | SCOXYGN |
| 7. Electrolyte abnormality:
Serum Potassium <3.2 or >5.5 mmol/L. | <input type="checkbox"/> | <input type="checkbox"/> | SCPOTAS |
| 8. Anemia.
Hematocrit <36% in men or <33% in women. | <input type="checkbox"/> | <input type="checkbox"/> | SCHEMAT |
| 9. Other chronic disease or condition likely to limit life span to < 6 years. | <input type="checkbox"/> | <input type="checkbox"/> | SCGRAN |
| 10. Exclusions based on underlying disease not specifically mentioned above, likely to limit life span and/or increase risk of intervention. | <input type="checkbox"/> | <input type="checkbox"/> | SCCONDS |

E. Exclusion for conditions or behaviors likely to effect the conduct of the DPP.

- | | | | |
|---|--------------------------|--------------------------|---------|
| 1. Unable or unwilling to give informed consent. | <input type="checkbox"/> | <input type="checkbox"/> | SCNOCON |
| 2. Unable to communicate with the pertinent clinic staff. | <input type="checkbox"/> | <input type="checkbox"/> | SCCLANG |
| 3. Another household member is a participant or staff member of DPP. | <input type="checkbox"/> | <input type="checkbox"/> | SCHOUSE |
| 4. Unwilling to accept treatment assignment by randomization. | <input type="checkbox"/> | <input type="checkbox"/> | SCASIGN |
| 5. Current or anticipated participation in another intervention research project that would interfere with any of the interventions offered in DPP. | <input type="checkbox"/> | <input type="checkbox"/> | SCINTV |

Participant's initials

first		last	

Date of birth

month	day	year	

Part III / EXCLUSION CRITERIA (continued)

- | | YES | NO | |
|---|--------------------------|--------------------------|---------|
| 6. Weight loss of >10% in past 6 months for any reason except postpartum weight loss. | <input type="checkbox"/> | <input type="checkbox"/> | SCLLBS |
| 7. Likely to move away from participating clinics in next 5 years. | <input type="checkbox"/> | <input type="checkbox"/> | SCMOVE |
| 8. Unable to walk 0.25 mile in 10 minutes. | <input type="checkbox"/> | <input type="checkbox"/> | SCMILE |
| 9. Unable to complete DPP run-in tasks. | <input type="checkbox"/> | <input type="checkbox"/> | SCRUNIN |
| 10. Pregnancy and childbearing. | | | |
| a. Currently pregnant or less than 3 months postpartum. | <input type="checkbox"/> | <input type="checkbox"/> | SCPREG |
| b. Currently nursing or within 6 weeks of having completed nursing. | <input type="checkbox"/> | <input type="checkbox"/> | SCNURS |
| c. Pregnancy anticipated during study. | <input type="checkbox"/> | <input type="checkbox"/> | SCPLANP |
| d. Unwilling to undergo pregnancy testing or to report possible or confirmed pregnancies promptly during the course of the DPP. | <input type="checkbox"/> | <input type="checkbox"/> | SCNOTEL |
| e. Unwilling to take adequate contraceptive measures, if potentially fertile. | <input type="checkbox"/> | <input type="checkbox"/> | SCCONTR |
| 11. Major psychiatric disorder which, in opinion of clinic staff, would impede conduct of the DPP. | <input type="checkbox"/> | <input type="checkbox"/> | SCPSYC |
| 12. Excessive alcohol intake, either acute or chronic. | <input type="checkbox"/> | <input type="checkbox"/> | SCALCY |
| 13. Other condition or behavior which, in opinion of clinic staff, would affect the conduct of DPP. | <input type="checkbox"/> | <input type="checkbox"/> | SCOTH2 |

Participant's initials

first		last	

Date of birth

month	day	year	

Part III / EXCLUSION CRITERIA (continued)

F. Exclusion related to metabolism .

- | | YES | NO | |
|--|----------------------------|----------------------------|---------|
| 1. Diabetes at baseline evaluation evidenced by any of the following: | | | |
| a. Diabetes diagnosed by a physician and confirmed by other clinical data. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCDIAB |
| b. Ever used hypoglycemic medication, except during GDM. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCHYMED |
| 2. Disease associated with disordered glucose metabolism. | | | |
| a. Cushing's Syndrome. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCUSHNG |
| b. Acromegaly. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCACROM |
| c. Pheochromocytoma currently under treatment. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCPHEO |
| d. Chronic pancreatitis. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SPANCR |
| 3. Thyroid disease, suboptimally treated. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCTYRD |
| 4. Fasting plasma triglyceride level >600 mg/dL (6.77 mmol/L) on one occasion despite treatment. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCFPT |
| 5. Exclusions related to metabolism, not specifically mentioned above. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCOTH3 |

G. Exclusions related to medications.

- | | | | |
|--|----------------------------|----------------------------|---------|
| 1. Antihypertensives. | | | |
| a. Thiazide diuretics. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCTHZD |
| b. Beta-blockers. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCBLCK |
| 2. Lipid-lowering agents - Niacin only. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCNIAC |
| 3. Glucocorticoids other than topical, ophthalmic, and inhaled preparations. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCRDIDS |
| 4. Antibiotics. | | | |
| a. HIV-related agents. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCHIVMD |
| b. Antituberculous agents. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCTBMED |

Participant's initials

first		last	

Date of birth

month	day	year	

Part III / EXCLUSION CRITERIA (continued)

- | | YES | NO | |
|--|----------------------------|----------------------------|---------|
| 5. Antineoplastic agents. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCNPLST |
| 6. Psychoactive agents. | | | |
| a. Antipsychotic agents. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCPSYMD |
| b. Fluoxetine (Prozac) >20 mg daily, or other equivalent dose of SSRI. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCSSRI |
| 7. Bronchodialators. | | | |
| a. Aminophylline, if used daily. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCAMINO |
| b. Inhaled beta-agonists, if used daily. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCBETAA |
| 8. Other medications. | | | |
| a. Phenytoin. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCPHEN |
| b. Amphetamines. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCAMPH |
| c. Prescription weight-loss drugs. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCRXWL |
| 9. Exclusions based on medications not specifically mentioned above. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCOTHMD |

All exclusion criteria must have been answered NO for participant to be randomized.

H. Conclusion

- | | YES | NO | |
|---|----------------------------|----------------------------|--------|
| 1. Are all inclusion criteria answered YES? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCINCL |
| 2. Are all exclusion criteria answered NO? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCEXCL |

If question 1 or 2 in section H is answered NO, the participant cannot be randomized.

- | | YES | NO | |
|--|----------------------------|----------------------------|--------|
| 3. Will the participant be randomized? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | SCRNDM |
| a. If NO, and the reason is not documented in part II or III, specify below. | | | |
