

-
Participant ID

Nickname

RISE **SCREEN.2**

Sept 2014

Page 1 of 6



**Restoring Insulin Secretion Study
SCREEN: Screening Form**

1. Study Visit Number VISIT	SCR <input type="text"/>
2. Visit date (mm/dd/yyyy) Replaced with DAYSRAND	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
3. Staff ID	<input type="text"/> <input type="text"/> <input type="text"/>
4. Were informed consent and assent signed and dated? → IF NO, STOP. SCCONSENT	<input type="checkbox"/> 1 Yes <input type="checkbox"/> 2 No

Instructions: This form is to be completed to assess eligibility for the run-in after the participant has signed the consent to be screened.

Complete questions 5 -13 for all participants. If the participant becomes ineligible at any point following question 13, STOP—form is complete.

5. How was the participant referred to the study? **(check the main source) SCREFER**

<input type="checkbox"/> 1 Brochure/Advertisement	<input type="checkbox"/> 4 School/school nurse
<input type="checkbox"/> 2 Health fair	<input type="checkbox"/> 5 Contacted after chart review
<input type="checkbox"/> 3 Health care provider	<input type="checkbox"/> 6 Other, Specify: <input type="text"/> SCREFOTH

Demographic Information

6. Sex SCSEX	<input type="checkbox"/> 1 Male <input type="checkbox"/> 2 Female
7. Are you Spanish/Hispanic/Latino?	<input type="checkbox"/> 1 Yes <input type="checkbox"/> 2 No
8. Race (check all that apply)	
a. White <input type="checkbox"/> 1	Replaced in BASEDATA
b. Black <input type="checkbox"/> 1	
c. Asian <input type="checkbox"/> 1	
d. American Indian <input type="checkbox"/> 1	
e. Other <input type="checkbox"/> 1	
	If Other, Specify: <input type="text"/>
9. Age eligibility	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
a. Date of birth (mm/dd/yyyy)	
Age: ____ years	Replaced in BASEDATA
b. Age 20 - 65 years if adult study or 10 -19 years if pediatric study? SCAGEELIG	<input type="checkbox"/> 1 Yes <input type="checkbox"/> 2 No

-
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Height and Weight Measurements

- For height, record Measure 3 only if first 2 measurements are not within 0.5 cm.
- For weight, record Measure 3 only if first 2 measurements are not within 0.2 kg (200 g).

	Measure 1	Measure 2	Measure 3
10. Height HEIGHT1-3	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cm	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cm	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cm
11. Weight WEIGHT1-3	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> kg	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> kg	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> kg

12. Assessment of BMI eligibility

BMI (kg/m²):

- Convert height to m (height / 100) = . m
- Average weight measurement = . kg
- Square result from step 1 (height in m × height in m) = . m²
- Divide weight (from step 2) by squared height (from step 3)
= . kg ÷ . m²

a. BMI = kg/m² **SCBMI**

Answer b. for Adult study participants only.

b. Is BMI ≥25 kg/m² and ≤50 kg/m²? **SCBMI2540**
(For Asian Americans BMI ≥23 kg/m² and ≤50 kg/m²)

☐ 1 Yes

☐ 2 No

Answer c. and d. for Pediatric study participants only.

c. 85th percentile for age and sex (from MOP v.2 Appendix 14.2)
SCBMIPERC

. kg/m²

d. Is BMI ≥85th percentile and ≤50 kg/m²? **SCBMI8540**

☐ 1 Yes

☐ 2 No

Diabetes information

13. Does this participant have diabetes? **SCDIABET**

☐ 1 Yes

☐ 2 No

IF YES,

a. Date of diabetes diagnosis (mm/yy)

Months since diagnosis: months

/

b. Duration since diabetes diagnosis <1 year for adults and <6 months for pediatric study participants? **SCT2DDU**

☐ 1 Yes

☐ 2 No

→ Duration of diabetes must be less than 12 months at time of screening for adults and less than 6 months at time of screening for pediatrics.

If participant is ineligible at this point, STOP. Form is complete. Otherwise, continue.

14. Has the participant ever used metformin? **SCMET**

☐ 1 Yes

☐ 2 No

→ If YES and in Adult study, participant is ineligible. STOP.

a. **If YES and in Pediatric study:** How months has the participant ever taken metformin? **SCMETDUR**

→ If Option 3, >6 months, participant is ineligible. STOP.

☐ 1 <3 months

☐ 2 3-6 months

☐ 3 >6 months

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Participant ID

Nickname

RISE **SCREEN.2**

Sept 2014

Page 3 of 6

15. Has the participant ever used insulin (including during pregnancy)? **SCINSUL**

1 Yes 2 No

→ If YES and in Adult study, participant is ineligible. STOP.

- a. If YES and in Pediatric study: Has the participant ever used insulin for more than 1 week (including during pregnancy)? **SCINSULDUR**

1 Yes 2 No

→ If YES, participant is ineligible. STOP.

16. Has the participant ever used any other diabetes medication (either oral or other injectable glucose lowering agents)? **SCDIAMED**

1 Yes 2 No

→ If YES, participant is ineligible. STOP.

Historical Eligibility Criteria. STOP at the point participant becomes ineligible.

- | | Yes | No |
|--|------------------------|------------------------|
| 17. Has the participant participated in another interventional research study within past 30 days? SCOSTUDY | <input type="text"/> 1 | <input type="text"/> 2 |
| 18. Is the participant likely to leave the geographic area within two calendar years? SCLEAVE | <input type="text"/> 1 | <input type="text"/> 2 |

Medical and Behavioral Eligibility Criteria—Complete physical exam (PE worksheet)

- | | Yes | No |
|---|------------------------|------------------------|
| 19. Is participant taking any exclusionary medications (MOP v.1 Appendix 14.1.1)? SCEXCLSRX | <input type="text"/> 1 | <input type="text"/> 2 |
| 20. Does the participant have any allergies or history of adverse drug reaction that would preclude them from participating in the study? SCALLERGY | <input type="text"/> 1 | <input type="text"/> 2 |
| 21. Does participant have any exclusionary medical conditions as assessed by oral medical history, chart review, and physical exam (MOP v.1 Appendix 14.1.2)? SCMEDCON | <input type="text"/> 1 | <input type="text"/> 2 |
| 22. Does participant meet all behavioral eligibility criteria (MOP v.1 Appendix 14.1.3)? SCBEHAV | <input type="text"/> 1 | <input type="text"/> 2 |

Complete Question 23 for Pediatric study participants only

23. Sexual Maturity

- a. **Girls only:** Breast Tanner stage **SCBRST**

- b. **Boys only:** Testicular volume **SCTESTVOL**

ml

- c. Tanner Stage eligible (Breast Tanner Stage >1 or testicular volume >3cc)? **SCTANNER**

1 Yes 2 No

Systolic / Diastolic

24. Seated arm blood pressure reading (Discard 1st reading and record 2nd BP measure, after sitting 5 minutes) **SBP1 / DBP1**

/ mmHg

25. Is participant eligible based on blood pressure? **SCBPelig**

- **Adults:** Exclude if SBP >160 mmHg or DBP >100 mmHg on treatment
- **Pediatrics:** Exclude if SBP or DBP >99th percentile for age (MOP v.2 Appendix 14.1), or >135/90 mm Hg on treatment

1 Yes 2 No

-
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RISE **SCREEN.2**

Sept 2014

Page 4 of 6

If participant meets all above requirements, proceed with eligibility laboratory screening and OGTT.

Local Laboratory Screening Results (Eligible ranges in parenthesis)

26. Pre-Screening local HbA1c (if available)

a. Value **SCPREPOC**

. %

b. Date of measure

/ /

27. Screening local HbA1c

(required for adult study if prescreen HbA1c is >3 months ago; if available for pediatric study)

a. Value **SCPOCHBAC**

. %

b. Type of measurement **SCPOCTYPE**

₁ Tabletop machine ₂ Local lab

a. Value

b. Eligible?

Yes No

28. Triglycerides (<400 mg/dl) **SCTRIG / SCTRIGELIG**

mg/dl

₁ ₂

29. Serum creatinine (adults: ≤1.4 mg/dl for men; ≤1.3 mg/dl for women; pediatrics: ≤1.2 mg/dl for all)

SCCREAT / SCCREATELIG

. mg/dl

₁ ₂

30. Serum potassium (3.4 - 5.5 mmol/l) **SCPOTAS / SCPOTASELIG**

. mmol/l

₁ ₂

31. TSH (within normal range)

NOTE: TSH is only assessed in these settings: 1) reported use of anti-thyroid medication, 2) reported use of thyroid hormone, 3) reported history of thyroid disease or 4) clinical suspicion of thyroid disease on history and physical.

. mcu/ml

₁ ₂

32. ALT (<3 times local lab ULN) **SCALT / SCALTELIG**

. U/L

₁ ₂

33. Hemoglobin (males ≥12 g/dl; females ≥11 g/dl)

SCHGB / SCHGBELIG

. g/dl

₁ ₂

34. Pregnancy Test (females only)

SCUPT

₁ Positive

₂ Negative

₃ No reproductive potential

35. Participant meets all laboratory eligibility criteria above **SCLABELIG**

₁ Yes

₂ No

-
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Oral Glucose Tolerance Test (OGTT)

Confirm the participant's readiness for the OGTT:

- a. Had no illness within past week ___ True ___ False
- b. Did not exercise, other than walk, within past 10 hours ___ True ___ False
- c. Has fasted at least 10 hours ___ True ___ False
- d. Had regular diet over last 3 days ___ True ___ False
36. Is the participant prepared for the glucose tolerance test? **All above readiness questions must be true.** SCPREP ☐ 1 Yes ☐ 2 No
37. Fasting finger-stick blood sugar >150 mg/dl for adults and >200 for pediatric study (See MOP V1, section 5.7.9.4)? SCFAST150 ☐ 1 Yes ☐ 2 No

→ If YES, participant is ineligible. STOP.

38. Time of fasting blood sample SCFASTTIME
Time glucose consumption started (must be consumed within 5 minutes)

→ Start timer now

: 24 hour clock
 0 0 : 0 0 Timer
Min Sec

39. Time glucose consumption ended SCGLUENDM / SCGLUENDS

: Timer
Min Sec

40. Time of 2 hour blood sample SC2HRTIME / SC2HRTIMES

: Timer
Min Sec

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Nickname

41. The OGTT was **(Check only one):** **SCOGTTCOMPL**

Completed **without** problem

☐ 1

Completed **with** a problem

☐ 2

Not completed

☐ 3

a. Why was the OGTT "completed with a problem" or not completed" **SCOGTTWHY**

Vomited after glucose load

☐ 1

Fainted or felt ill after glucose load

☐ 2

Sample not obtained within +/- 5 minutes of 2 hour blood draw

☐ 3

Participant did not drink entire glucose load in 5 minutes

☐ 4

Difficult blood draw

☐ 5

Other

☐ 6

If "Other," Specify:

Eligibility for Run-in

	Yes	No
42. Participant willing and able to participate in the run-in period and the full-scale study in opinion of the investigator. SCABLE	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2
43. Participant meets eligibility for run-in (All gray boxes must be checked) SCELIG	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2
44. Will the participant proceed to run-in? SCPROCEED	<input type="checkbox"/> 1	<input type="checkbox"/> 2