

-      
Participant ID

Nickname



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

1. Study Visit Number **VISIT**

2. Visit date (mm/dd/yyyy) **Replaced with DAYSRAND**  /  /

3. Staff ID

4. Were informed consent and assent signed and dated?  
→ **IF NO, STOP.** **SCCONSENT**  1 Yes  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**

1 Brochure/Advertisement  4 School/school nurse

2 Health fair  5 Contacted after chart review

3 Health care provider  6 Other, Specify:

**Demographic Information**

6. Sex **SCSEX**  1 Male  2 Female

7. Are you Spanish/Hispanic/Latino?  1 Yes  2 No

8. Race **(check all that apply)**

a. White  1 **Replaced in BASEDATA**

b. Black  1

c. Asian  1

d. American Indian  1

e. Other  1 If Other, Specify:

9. Age eligibility   /   /

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**  1 Yes  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 <b>HEIGHT1-3</b>	<table border="1"><tr><td> </td><td> </td><td> </td><td> </td></tr></table> cm					<table border="1"><tr><td> </td><td> </td><td> </td><td> </td></tr></table> cm					<table border="1"><tr><td> </td><td> </td><td> </td><td> </td></tr></table> cm				
11. Weight <b>WEIGHT1-3</b>	<table border="1"><tr><td> </td><td> </td><td> </td><td> </td></tr></table> kg					<table border="1"><tr><td> </td><td> </td><td> </td><td> </td></tr></table> kg					<table border="1"><tr><td> </td><td> </td><td> </td><td> </td></tr></table> kg				

12. Assessment of BMI eligibility

BMI (kg/m<sup>2</sup>):

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

a. BMI = 

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 kg/m<sup>2</sup> **SCBMI**

**Answer b. for Adult study participants only.**

b. Is BMI ≥25 kg/m<sup>2</sup> and ≤50 kg/m<sup>2</sup>? **SCBMI2540**  
 (For Asian Americans BMI ≥23 kg/m<sup>2</sup> and ≤50 kg/m<sup>2</sup>)

1 Yes       2 No

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

c. 85<sup>th</sup> percentile for age and sex (from MOP v.2 Appendix 14.2)  
**SCBMIPERC**

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 kg/m<sup>2</sup>

d. Is BMI ≥85<sup>th</sup> percentile and ≤50 kg/m<sup>2</sup>? **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

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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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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? <b>SCOSTUDY</b> | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 18. Is the participant likely to leave the geographic area within two calendar years? <b>SCLEAVE</b>               | <input type="checkbox"/> 1 | <input type="checkbox"/> 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)? <b>SCEXCLSRX</b>  | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 20. Does the participant have any allergies or history of adverse drug reaction that would preclude them from participating in the study? <b>SCALLERGY</b>                    | <input type="checkbox"/> 1 | <input type="checkbox"/> 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)? <b>SCMEDCON</b> | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 22. Does participant meet all behavioral eligibility criteria (MOP v.1 Appendix 14.1.3)? <b>SCBEHAV</b>   | <input type="checkbox"/> 1 | <input type="checkbox"/> 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 >99<sup>th</sup> percentile for age (MOP v.2 Appendix 14.1), or >135/90 mm Hg on treatment
- 1 Yes  2 No

<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>
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**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**

<input type="text"/>	<input type="text"/>	.	<input type="text"/>	%
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b. Date of measure

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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27. Screening local HbA1c

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

a. Value **SCPOCHBAC**

<input type="text"/>	<input type="text"/>	.	<input type="text"/>	%
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b. Type of measurement **SCPOCTYPE**

<input type="checkbox"/>	1	Tabletop machine	<input type="checkbox"/>	2	Local lab
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**a. Value**

**b. Eligible?**

**Yes**

**No**

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

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mg/dl
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<input type="checkbox"/>	1	<input type="checkbox"/>	2
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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**

<input type="text"/>	.	<input type="text"/>	mg/dl
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<input type="checkbox"/>	1	<input type="checkbox"/>	2
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30. Serum potassium (3.4 - 5.5 mmol/l) **SCPOTAS / SCPOTASELIG**

<input type="text"/>	.	<input type="text"/>	mmol/l
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<input type="checkbox"/>	1	<input type="checkbox"/>	2
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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.

<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	mcu/ml
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<input type="checkbox"/>	1	<input type="checkbox"/>	2
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32. ALT (<3 times local lab ULN) **SCALT / SCALTELIG**

<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	U/L
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<input type="checkbox"/>	1	<input type="checkbox"/>	2
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33. Hemoglobin (males ≥12 g/dl; females ≥11 g/dl)

**SCHGB / SCHGBELIG**

<input type="text"/>	<input type="text"/>	.	<input type="text"/>	g/dl
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<input type="checkbox"/>	1	<input type="checkbox"/>	2
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34. Pregnancy Test (females only)

**SCUPT**

<input type="checkbox"/>	1	Positive	<input type="checkbox"/>	2	Negative	<input type="checkbox"/>	3	No reproductive potential
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35. Participant meets all laboratory eligibility criteria above **SCLABELIG**

<input type="checkbox"/>	1	Yes	<input type="checkbox"/>	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 *SCFASTIME*  
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*
40. Time of 2 hour blood sample *SC2HRTIMEM / SC2HRTIMES*

		:			Timer
Min			Sec		

  

		:			Timer
Min			Sec		

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

Completed <b>without</b> problem	<input checked="" type="checkbox"/>	1
Completed <b>with</b> a problem	<input type="checkbox"/>	2
<b>Not completed</b>	<input type="checkbox"/>	3

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

Vomited after glucose load	<input type="checkbox"/>	1
Fainted or felt ill after glucose load	<input type="checkbox"/>	2
Sample not obtained within +/- 5 minutes of 2 hour blood draw	<input type="checkbox"/>	3
Participant did not drink entire glucose load in 5 minutes	<input type="checkbox"/>	4
Difficult blood draw	<input type="checkbox"/>	5
Other	<input type="checkbox"/>	6

If "Other," Specify:

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**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. <b>SCABLE</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
43. Participant meets eligibility for run-in <b>(All gray boxes must be checked)</b> <b>SCELIG</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
44. Will the participant proceed to run-in? <b>SCPROCEED</b>	<input type="checkbox"/>	<input type="checkbox"/>