Pa	rticipant ID Nickname	RISE SCREEN.2 Sept 2014 Page 1 of 6
	T Se Restoring Insulin SCREEN: Scree	-
1.	Study Visit Number VISIT	SCR
2.	Visit date (mm/dd/yyyy) Replaced with DAYSRAND	
3.	Staff ID	
4.	Were informed consent and assent signed ar → IF NO, STOP. ^{SCCONSENT}	nd dated? Yes 2 No
the Co i	consent to be screened.	ligibility for the run-in after the participant has signed participant becomes ineligible at any point following
<u>дие</u> 5.	How was the participant referred to the study	
	Brochure/Advertisement	/school nurse ted after chart review
Dei	mographic 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 Re	eplaced in BASEDATA
	b. Black	
	c. Asian	
	d. American Indian	
	e. Other	If Other, Specify:
9.	Age eligibility	
	a. Date of birth (mm/dd/yyyy)	
	Age: years Rep	placed in BASEDATA
	b. Age 20 - 65 years if adult study or 10 - 19 ye study? SCAGEELIG	ears if pediatric 1 Yes 2 No

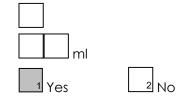
Participant ID Nickname	RISE SCREEN.2 Sept 2014 Page 2 of 6						
Height and Weight Measurements							
 For height, record Measure 3 only if first 2 measurements are not 	within 0.5 cm						
 For weight, record Measure 3 only if first 2 measurements are not 							
Measure 1 Measure 2	Measure 3						
10. Height HEIGHT1-3	cm						
11. Weight WEIGHT1-3	kg						
 12. Assessment of BMI eligibility BMI (kg/m²): (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) = (4) Divide weight (from step 2) by squared height (from step 3) = kg ÷ m² a. BMI = kg/m² SCBMI 							
a. BMI = []. []kg/m ² SCBMI Answer b. for Adult study participants only.							
b. Is BMI ≥25 kg/m² and ≤50 kg/m²? scbMl2540 (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. 85 th percentile for age and sex (from MOP v.2 Appendix 14.2) SCBMIPERC	kg/m ²						
d. Is BMI ≥85 th percentile and ≤50 kg/m²? ^{SCBMI8540}	1 Yes 2 No						
Diabetes information							
13. Does this participant have diabetes? SCDIABET							
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	e, continue.						
 Has the participant <u>ever</u> used metformin? SCMET →If YES and in Adult study, participant is ineligible. STOP. 	1 Yes 2 No						
 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. 	 3 months 3-6 months >6 months 						

	_				RISE SCRE		
Pc	irticipant ID	Nickname			Sept 2014 Page 3 of		
15	 Has the participant of pregnancy)? SCINSUL 	ever used insulin (inclu	uding during		¹ Yes	2 Nc)
		study , participant is in	neligible. STOP.				
		iatric study : Has the po nan 1 week (including			1 Yes	² Nc)
		ant is ineligible. STOP.					
16	. Has the participant of the contract of the c	ever used any other d injectable glucose lov			1 Yes	2 Nc)
	→If YES, participant						
Hi	storical Eligibility Criteri	ia. STOP at the point p	articipant beco	omes ineligible			
	•					Yes	No
17	. Has the participant within past 30 days?		er interventiond	al research stud	y	1	2
18	. Is the participant like years? SCLEAVE	ely to leave the geogr	raphic area wit	hin two calenc	lar	1	2
Μ	edical and Behavioral	Eligibility Criteria—Co	mplete physico	al exam (PE wo	orksheet)		
						Yes	No

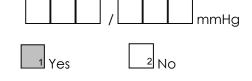
- 19. Is participant taking any exclusionary medications (MOP v.1 Appendix 14.1.1)?
- 20. Does the participant have any allergies or history of adverse drug reaction that would preclude them from participating in the study? **SCALLERGY**
- 21. Does participant have any exclusionary medical conditions as assessed by oral medical history, chart review, and physical exam (MOP v.1 Appendix 14.1.2)? SCMEDCON
- 22. Does participant meet all behavioral eligibility criteria (MOP v.1 Appendix 14.1.3)? SCBEHAV

Complete Question 23 for Pediatric study participants only

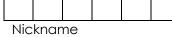
- 23. Sexual Maturity
 - a. Girls only: Breast Tanner stage SCBRST
 - b. Boys only: Testicular volume SCTESTVOL
 - c. Tanner Stage eligible (Breast Tanner Stage >1 or testicular volume >3cc)? SCTANNER
- 24. Seated arm blood pressure reading (Discard 1st reading and record 2nd BP measure, after sitting 5 minutes)^{SBP1 /} DBP1
- 25. Is participant eligible based on blood pressure? SCBPELIG
 - Adults: Exclude if SBP >160 mmHg or DBP >100 mmHg on treatment
 - Pediatrics: <u>Exclude</u> if SBP or DBP >99th percentile for age (MOP v.2 Appendix 14.1), or >135/90 mm Hg on treatment



Systolic / Diastolic







If participant meets all above requirements, proceed with eligibility laboratory screening and OGIT.								
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; i a. Value SCPOCHBAC 	f available for pediatric study)							
b. Type of measurement SCPOCTYPE	Tabletop machine	2 Loc	al lab					
	a. Value	b. Eligi	ible?					
		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		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					
 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 reprodu	uctive po	tential					
35. Participant meets all laboratory eligibility criteria al	bove SCLABELIG		² No					

		_						
Participant ID						Nic	knar	ne



____ False

False

False

_ False

²No

2 No

True

_ True

True

True

1 Yes

1 Yes

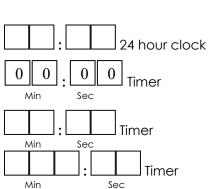
Oral Glucose Tolerance Test (OGTT)

Confirm the participant's readiness for the OGTT:

- a. Had no illness within past week
- b. Did not exercise, other than walk, within past 10 hours
- c. Has fasted at least 10 hours
- d. Had regular diet over last 3 days
- 36. Is the participant prepared for the glucose tolerance test? All above readiness questions must be true. SCPREP
- 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

 \rightarrow 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
- 39. Time glucose consumption ended SCGLUENDM / SCGLUENDS
- 40. Time of 2 hour blood sample SC2HRTIMEM / SC2HRTIMES



Participant ID Nickname								

1

2

3

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

Completed **without** problem Completed **with** a problem

Not completed

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

Vomited after glucose load		1	
Fainted or felt ill after glucose lo	ad	2	
Sample not obtained within +/- hour blood draw	5 minutes of 2	3	
Participant did not drink entire g minutes	lucose load in 5	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	1	2				
43.	Participant meets eligibility for run-in (All gray boxes must be checked) ^{SCELIG}	1	2				
44.	Will the participant proceed to run-in? SCPROCEED	1	2				