Participant ID _ Nickname

Restoring Insulin Secretion Study
BASELINE: Baseline Visit Inventory

1. Study Visit Number VISITNUM	BAS
2. Visit Date #1(MM/DD/YYYY) Replaced with DAYSRAND	__ __ / __ __ / __ __ __ __
3. Visit Date #2 (MM/DD/YYYY)	__ __ / __ __ / __ __ __ __
4. Staff ID	__ __ __

Instructions: *This form is completed at the Baseline visit. All physical measurements and medication assessment must be completed on the first day of the visit prior to the OGTT or Clamp.*

PHYSICAL MEASUREMENTS

	Systolic	Diastolic
5. Seated arm blood pressure SBP / DBP (Discard 1st reading and record 2nd BP measure, after sitting 5 minutes)	___ /	___ mmHg

- 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 (200g).
- For waist & hip circumference, record Measure 3 only if first 2 measurements are not within 0.5 cm.

	Measure 1	Measure 2	Measure 3
6. Height **(pediatric study only)** HEIGHT1, HEIGHT2, HEIGHT3	___.__ cm	___.__ cm	___.__ cm
7. Weight WEIGHT1, WEIGHT2, WEIGHT3	___.__ kg	___.__ kg	___.__ kg
8. Waist circumference WAIST1, WAIST 2, WAIST 3	___.__ cm	___.__ cm	___.__ cm
9. Hip circumference HIP1, HIP2, HIP3	___.__ cm	___.__ cm	___.__ cm

Menstrual History and Contraception Use (Leave blank for males)

10. Do you use contraception (including abstinence)? BACNTRCPT
☐ 1 Yes ☐ 2 No

If YES

a. What are you doing to avoid having a baby? BANOBABY

☐ 1 Not Sexually Active
☐ 2 Post-menopausal
☐ 3 Tubal ligation/ hysterectomy
☐ 4 IUD
☐ 5 NorPlant
☐ 6 Depo-Provera
☐ 7 Birth Control Pills
☐ 8 Barrier method
☐ 9 Rhythm &/or withdrawal
☐ 10 Other

i. If other, specify: ☐

If NO, participant should discuss birth control and sexual activity with the RISE Study staff. Participant is ineligible if sexually active and unwilling to use contraception.

11. Date of last period, if applicable ☐☐ / ☐☐ / ☐☐☐☐

12. Result of pregnancy test BAPREGTEST ☐1 Positive ☐2 Negative ☐3 No reproductive potential

ADVERSE EVENTS AND INTERVAL MEDICAL HISTORY

Serious Adverse events

13. Since the last clinic visit, has the participant experienced any of the following?

Check all that apply

a. Any acute life-threatening event? THREAT ☐1

b. Required or prolonged hospitalization? HOSPITAL ☐1

c. Permanent or severe disability? DISABILITY ☐1

d. Pregnancy resulting in congenital anomaly or birth defect? BIRDEF ☐1

e. Required intervention to prevent permanent impairment or damage? PREVENT ☐1

f. Overdose of a study medication? OVERDOSE ☐1

g. An episode of hypoglycemia that required help from someone else to bring the blood sugar back to normal? (e.g. due to loss of consciousness, confusion or severe lethargy) SEVHYPO ☐1

h. Other serious medical event? OTHMED ☐1

For FEMALE participants with reproductive potential only:

i. Pregnant? PREG ☐1

➔ *If any of the above are checked, complete **SAE Form**.*

Symptom History

	Yes	No
14. Since the last clinic visit, did the participant experience any of the following?		
a. Episode(s) of low blood sugar? BALOWBS	1	2
If YES		
i. Was this repeated mild hypoglycemia? (blood glucose <70 mg/dl more than twice/week or 5 times/month) BAMILDHYP	1	2
ii. How many episodes of mild hypoglycemia have occurred since the last clinic visit? BAHYPONUM	☐☐ time(s)	
b. Skin rashes? BASKINRASH	1	2
c. Frequent stomach pains, bloating, nausea, vomiting, diarrhea, or loss of appetite? BASTOMACH	1	2
d. Symptoms of diabetes out of control (nocturia more than once a night on a regular basis, enuresis, increased thirst, urinating more often than usual)? BASYMP	1	2

CONCOMITANT MEDICATIONS

Participants taking exclusionary medications are ineligible. See MOP Volume 1 Section 5.4.2 for details.

15. Has the participant taken any of the following medications since the last clinic visit? BAMEDS — 1 Yes 2 No

If YES, continue. If NO, skip to question 16.

a. Antihypertensives? BAANTIHYP — 1 Yes 2 No

***If YES, check all that apply*:**

i. 1 ACE inhibitor BAACE
ii. 1 ARB BAARB
iii. 1 Beta blocker BABETA
iv. 1 Diuretic BADIURET
v. 1 Other (**specify:** BAOSPEC1) BAOTH1

b. Lipid lowering medications? BALIPLOW — 1 Yes 2 No

***If YES, check all that apply*:**

i. 1 Statin BASTATIN
ii. 1 Bile acid sequestrant → ***exclusionary*** BASEQUEST
iii. 1 Niacin → ***exclusionary*** BANIACIN
iv. 1 Fibrate BAFIBRATE
v. 1 Other (**specify:** BAOSPEC2) BAOTH2

c. Diabetes medication? BADIAMED ☐1 Yes ☐2 No

***If YES, check all that apply*:**

i. ☐1 Thiazolidinedione BATHIAZ

ii. ☐1 Sulfonylurea BASULF

iii. ☐1 Insulin BAINSUL

iv. ☐1 Exenatide or liraglutide BAEXENLIRA

v. ☐1 Study-provided metformin BASTDYMET **(Pediatric Study Only)**

vi. ☐1 Non-study metformin BANONMET

vii. ☐1 DPP-4 Inhibitor BADPP4

viii. ☐1 Other (**specify**: _____) BAOTH3

➔ ***All diabetes medications except study metformin in pediatric participants are exclusionary***

d. Steroids? → ***Possibly exclusionary*** BASTER ☐1 Yes ☐2 No

***If YES, check all that apply*:**

i. ☐1 Oral steroid → Total days oral steroids used since last visit: ☐☐ BAORALST/BAOSTDAYS

ii. ☐1 Injection steroids BAINJECT

iii. ☐1 Inhaled steroids BAINHALE

iv. Last date participant used any steroids (oral, injection, inhaled): ☐☐ / ☐☐ / ☐☐☐☐

e. Weight loss treatments? **(Check only one)**

BAWGHTLOSS

☐1 No, nothing

☐2 Yes, medications or supplements → ***Possibly exclusionary***

☐3 Yes, banding (laparoscopic or open)

☐4 Yes, sleeve gastrectomy

☐5 Yes, bypass (including gastric Roux en Y and ileal)

☐6 Yes, other (**specify:** _____)

f. Atypical psychotropics? → ***Possibly exclusionary*** BAPSYCHO ☐1 Yes ☐2 No

g. Stimulants? → ***Possibly exclusionary*** BASTIM ☐1 Yes ☐2 No

h. Hormonal contraception (women only)? BAHORMCON ☐1 Yes ☐2 No

RANDOMIZATION

16. Was participant randomized? ☐ 1 Yes ☐ 2 No

If YES,

a. Randomization Date ☐☐ / ☐☐ / ☐☐☐☐

b. Treatment assignment

☐ 1 Metformin/Placebo **(Adult Study ONLY)**
☐ 2 Glargine + Metformin **Included in BASEDATA**
☐ 3 Liraglutide + Metformin
☐ 4 Metformin alone **(Pediatric Study ONLY)**

c. Drug ID ☐☐☐☐☐

If NO,

d. What was the primary reason participant chose not to enroll in RISE? **(check only one)**

☐ 1 Concern about side effects of treatment(s)
☐ 2 Participant discomfort with study or conflict with study staff
☐ 3 Study burden (including testing procedures)
☐ 4 Personal issues (e.g. transportation, family, work, school)
☐ 5 Study staff decision (e.g., inappropriate behavior, alcohol or drug abuse, etc.
☐ 6 Other

i. If "Study staff decision" or "Other," specify:

MEDICATION DISPENSING

17. Was metformin/placebo dispensed? BAMETDISP ☐1 Yes ☐2 No

If YES,

a. Date dispensed ☐☐ / ☐☐ / ☐☐☐☐

b. Number of bottles: BAMETNUM ☐

18. Was liraglutide dispensed **(Adult Study Only)**? BALIRADISP ☐1 Yes ☐2 No

If YES,

a. Date dispensed ☐☐ / ☐☐ / ☐☐☐☐

b. Number of pens: BALIRANUM ☐

19. Was insulin glargine dispensed? BAGLRGDISP ☐1 Yes ☐2 No

If YES,

a. Date dispensed ☐☐ / ☐☐ / ☐☐☐☐

b. Number of pens: BAGLRGDISNUM ☐