

-

Participant ID

Nickname



Restoring Insulin Secretion Study
BASELINE: Baseline Visit Inventory

1. Study Visit Number VISITNUM	<input type="text"/> BAS <input type="text"/>
2. Visit Date #1 (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. Visit Date #2 (MM/DD/YYYY)	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
4. Staff ID	<input type="text"/> <input type="text"/> <input type="text"/>

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

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

- 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	<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
7. Weight WEIGHT1, WEIGHT2, WEIGHT3	<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
8. Waist circumference WAIST1, WAIST 2, WAIST 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
9. Hip circumference HIP1, HIP2, HIP3	<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

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

- | | |
|--|--|
| <input type="checkbox"/> ₁ Not Sexually Active | <input type="checkbox"/> ₆ Depo-Provera |
| <input type="checkbox"/> ₂ Post-menopausal | <input type="checkbox"/> ₇ Birth Control Pills |
| <input type="checkbox"/> ₃ Tubal ligation/ hysterectomy | <input type="checkbox"/> ₈ Barrier method |
| <input type="checkbox"/> ₄ IUD | <input type="checkbox"/> ₉ Rhythm &/or withdrawal |
| <input type="checkbox"/> ₅ NorPlant | <input type="checkbox"/> ₁₀ Other |

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RISE **BASELINE.1**

Sept 2013

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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**.

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Participant ID

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Symptom History

14. Since the last clinic visit, did the participant experience any of the following?
- | | Yes | No |
|---|---|---|
| a. Episode(s) of low blood sugar? BALOWBS | <input style="width: 30px; height: 20px;" type="text"/> | <input style="width: 30px; height: 20px;" type="text"/> |
| If YES | | |
| i. Was this repeated mild hypoglycemia? (blood glucose <70 mg/dl more than twice/week or 5 times/month) BAMILDHYP | <input style="width: 30px; height: 20px;" type="text"/> | <input style="width: 30px; height: 20px;" type="text"/> |
| ii. How many episodes of mild hypoglycemia have occurred since the last clinic visit? BAHYPONUM | <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> time(s) | |
| b. Skin rashes? BASKINRASH | <input style="width: 30px; height: 20px;" type="text"/> | <input style="width: 30px; height: 20px;" type="text"/> |
| c. Frequent stomach pains, bloating, nausea, vomiting, diarrhea, or loss of appetite? BASTOMACH | <input style="width: 30px; height: 20px;" type="text"/> | <input style="width: 30px; height: 20px;" type="text"/> |
| 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 | <input style="width: 30px; height: 20px;" type="text"/> | <input style="width: 30px; height: 20px;" type="text"/> |

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**
- | | | | | |
|--|---|-----|---|----|
| | <input style="width: 30px; height: 20px;" type="text"/> | Yes | <input style="width: 30px; height: 20px;" type="text"/> | No |
|--|---|-----|---|----|

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

- a. Antihypertensives? **BAANTIHYP**
- | | | | | |
|--|---|-----|---|----|
| | <input style="width: 30px; height: 20px;" type="text"/> | Yes | <input style="width: 30px; height: 20px;" type="text"/> | No |
|--|---|-----|---|----|

If YES, check all that apply:

- | | |
|---|---|
| <p>i. <input style="width: 30px; height: 20px;" type="text"/> ACE inhibitor BAACE</p> <p>ii. <input style="width: 30px; height: 20px;" type="text"/> ARB BAARB</p> <p>iii. <input style="width: 30px; height: 20px;" type="text"/> Beta blocker BABETA</p> | <p>iv. <input style="width: 30px; height: 20px;" type="text"/> Diuretic BADIURET</p> <p>v. <input style="width: 30px; height: 20px;" type="text"/> Other (specify: <input style="width: 150px; height: 20px;" type="text"/>)
BAOOTH1</p> |
|---|---|

- b. Lipid lowering medications? **BALILOW**
- | | | | | |
|--|---|-----|---|----|
| | <input style="width: 30px; height: 20px;" type="text"/> | Yes | <input style="width: 30px; height: 20px;" type="text"/> | No |
|--|---|-----|---|----|

If YES, check all that apply:

- | | |
|---|--|
| <p>i. <input style="width: 30px; height: 20px;" type="text"/> Statin BASTATIN</p> <p>ii. <input style="width: 30px; height: 20px;" type="text"/> Bile acid sequestrant → <i>exclusionary</i>
BASEQUEST</p> <p>iii. <input style="width: 30px; height: 20px;" type="text"/> Niacin → <i>exclusionary</i> BANIACIN</p> | <p>iv. <input style="width: 30px; height: 20px;" type="text"/> Fibrate BAFIBRATE</p> <p>v. <input style="width: 30px; height: 20px;" type="text"/> Other (specify: <input style="width: 150px; height: 20px;" type="text"/>)
BAOTH2</p> |
|---|--|

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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

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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:

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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**