

-
Participant ID

Nickname



Restoring Insulin Secretion Study
VISIT: Clinical Visit Inventory

Instructions: This form is completed at all scheduled visits following the Baseline visit (M03, M06, etc.).

1. Study Visit Number **VISITNUM** M03 M06 M09 M12 M15 M18 M21
2. Visit Start Date (MM/DD/YYYY) **Replaced with DAYSRAND** / /
3. **If Super Visit (M12, M15)**, Visit End Date (MM/DD/YYYY) **Replaced with DAYSRAND** / /
4. Staff ID **STAFFID**

PHYSICAL MEASUREMENTS

5. Seated Arm Blood Pressure Reading
VISYSBP VIDIABP

Systolic / **Diastolic** 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 HEIGHT1-3
(pediatric study only) | <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 WEIGHT1-3 | <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 |
| 8. Waist circumference
(M12, M15 and M21 only)
WAIST1-3 | <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
(M12, M15 and M21 only)
HIP1-3 | <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 |

Menstrual History and Contraception Use (Leave blank for males)

10. Do you use contraception?
VICNTRCPT

1 Yes 2 No

If YES

- a. What are you doing to avoid having a baby?
VINOBABY

- | | |
|--|---|
| <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: |

i. If other, specify:

VIBCOSPEC

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If NO, participant should discuss birth control and sexual activity with the RISE Study staff.

11. Date of last period, if applicable / /

Pregnancy Test (Leave blank for males) – required at SUPER visits (M12, M15), optional at all other visits

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

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? **OVERNIGHT** ₁

For FEMALE participants with reproductive potential only: *If participant missed a period perform a pregnancy test.*

- i. Pregnant? **PREG** ₁

→ *If any of the above is checked, complete **SAE Form**.*

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Symptom History

14. Since the last clinic visit, has the participant experienced any of the following?
- | | Yes | No |
|---|---|------------------------|
| a. Episode(s) of low blood sugar? VILOWBS | <input type="text"/> 1 | <input type="text"/> 2 |
| If YES | | |
| i. Was this repeated mild hypoglycemia? (blood glucose <70 mg/dl more than twice/week or 5 times/month) VIMILDHYP | <input type="text"/> 1 | <input type="text"/> 2 |
| ii. How many episodes of mild hypoglycemia have occurred since the last clinic visit? VIHYPONUM (1-30) | <input type="text"/> <input type="text"/> time(s) | |
| b. Skin rashes? VISKINRASH | <input type="text"/> 1 | <input type="text"/> 2 |
| c. Frequent stomach pains, bloating, nausea, vomiting, diarrhea, or loss of appetite? VISTOMACH | <input type="text"/> 1 | <input type="text"/> 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)? VISYMP | <input type="text"/> 1 | <input type="text"/> 2 |
| e. Other clinically important symptoms | <input type="text"/> 1 | <input type="text"/> 2 |

If "Other,"

i. Specify:

CONCOMITANT MEDICATIONS

15. Has the participant been taking any of the following medications since the last quarterly visit that were not provided by RISE? **VIMEDS** 1 Yes 2 No

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

- a. Antihypertensives? **VIANTHYP** 1 Yes 2 No

If YES, check all that apply:

- | | |
|--|--|
| i. <input type="text"/> 1 ACE inhibitor VIACE | iv. <input type="text"/> 1 Diuretic VIDIURET |
| ii. <input type="text"/> 1 ARB VIARB | v. <input type="text"/> 1 Other (specify: <input type="text"/>)
VIOTH1/ VIOSPECT1 |
| iii. <input type="text"/> 1 Beta blocker VIBETA | |

- b. Lipid lowering medications? **VILIPLLOW** 1 Yes 2 No

If YES, check all that apply:

- | | |
|--|---|
| i. <input type="text"/> 1 Statin VISTATIN | iv. <input type="text"/> 1 Fibrate VIFIBRATE |
|--|---|

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- ii. 1 Bile acid sequestrant **VISEQUST** v. 1 Other (**specify:**)
iii. 1 Niacin **VIINACIN** **VIOTH2/ VIOSPEC2**

c. Diabetes medication (other than assigned study medication)? **VIDIAMED** 1 Yes 2 No

If YES, check all that apply:

- i. 1 Thiazolidinedione **VITHIAZ** v. 1 Non-study Metformin **VIMET**
ii. 1 Sulfonylurea **VISULF** vi. 1 DPP-4 Inhibitor **VIDPP4**
iii. 1 Insulin **VIINSUL** vii. 1 Other (**specify:**)
iv. 1 Exenatide or liraglutide **VIEXENLIRA** **VIOTH3/VIOSPEC3**

d. Steroids? **VISTER** 1 Yes 2 No

If YES, check all that apply:

- i. 1 Oral steroids → Total days oral steroids used since last visit: **VIORALST/VIOSTDAYS (1-28)**
ii. 1 Injection steroids **VIINJECT**
iii. 1 Inhaled steroids **VIINHALE**

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

di. Weight loss treatments? **VIWGTLOSS**

- 1 No, nothing 4 Yes, sleeve gastrectomy
 2 Yes, medications or supplements 5 Yes, bypass (including gastric Roux en Y and ileal)
 3 Yes, banding (laparoscopic or open) 6 Yes, other (**specify:** **VIWGTOSPEC**)

f. Atypical psychotropics **VIPSYCHO** 1 Yes 2 No

g. Stimulants **VISTIM** 1 Yes 2 No

h. Hormonal contraception (women only) **VIHORMCON** 1 Yes 2 No

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MEDICATION ADHERENCE

16. Was the participant supposed to have taken study metformin/placebo since the last visit? **VIMETADHER** 1 Yes 2 No

IF YES,

a. Current dose of metformin/placebo **VIMETDOSE**

1 500 mg/day 2 1000 mg/day
 3 1500 mg/day 4 2000 mg/day

b. **Ask participant:** People sometimes forget to take their study medicine or take less study medicine than was ordered. In the past three months, what percent of time were you able to take your metformin/placebo exactly as the RISE study staff prescribed? **VIMETSELF**

1 0% 2 10% 3 20% 4 30% 5 40% 6 50%
 7 60% 8 70% 9 80% 10 90% 11 100%

c. Did the participant return their pill bottles? **VIMETRET** 1 Yes 2 No

IF YES,

i. Percent of expected pills taken (per staff pill count) **VIMETPERC**

%

17. Was the participant supposed to have taken study liraglutide since the last visit? **VILIRADHER** 1 Yes 2 No

IF YES,

a. Current dose of liraglutide **VILIRDOSE**

1 0.6 mg/day 2 1.2 mg/day 3 1.8 mg/day

b. **Ask participant:** People sometimes forget to take their study medicine or take less study medicine than was ordered. In the past three months, what percent of time were you able to take your liraglutide exactly as the RISE study staff prescribed? **VILIRASELF**

1 0% 2 10% 3 20% 4 30% 5 40% 6 50%
 7 60% 8 70% 9 80% 10 90% 11 100%

c. Did the participant return their liraglutide pens? **VILIRARET** 1 Yes 2 No

IF YES,

i. Percent of expected liraglutide taken (per staff measurement) **VIMETPERC**

1 0% 2 1 - 49% 3 50 - 79%
 4 80 - 100% 5 >100%

18. Was the participant supposed to have taken study insulin glargine since the last visit? **VIGLRADHER** 1 Yes 2 No

IF YES,

a. Current dose of glargine **VIGLRDOSE**

units/day

<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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b. **Ask participant:** People sometimes forget to take their study medicine or take less study medicine than was ordered. In the past three months, what percent of time were you able to take your glargine exactly as the RISE study staff prescribed? **VIGLRSELF**

<input type="text"/> 1 0%	<input type="text"/> 2 10%	<input type="text"/> 3 20%	<input type="text"/> 4 30%	<input type="text"/> 5 40%	<input type="text"/> 6 50%
<input type="text"/> 7 60%	<input type="text"/> 8 70%	<input type="text"/> 9 80%	<input type="text"/> 10 90%	<input type="text"/> 11 100%	

c. Did the participant return their glargine pens? **VIGLRRET** 1 Yes 2 No

IF YES,

<input type="text"/> 1 0%	<input type="text"/> 2 1 - 49%	<input type="text"/> 3 50 - 79%
<input type="text"/> 4 80 - 100%	<input type="text"/> 5 >100%	

19. What has gotten in the way of taking each study medication as prescribed? (**Note: A response is required for any treatment with compliance <80% or >100%**)

(Check all that apply)

	<u>Metformin/ Placebo</u>	<u>Glargine</u>	<u>Liraglutide</u>
a. Permanently discontinued study medication	<input type="text"/> METFORM1	<input type="text"/> GLARG1	<input type="text"/> LIRA 1
b. Temporarily stopped study medication due to intercurrent illness	<input type="text"/> METFORM2	<input type="text"/> GLARG2	<input type="text"/> LIRA 2
c. Forgets to take study medication in general	<input type="text"/> METFORM3	<input type="text"/> GLARG3	<input type="text"/> LIRA 3
d. GI reaction to medication	<input type="text"/> METFORM4	<input type="text"/> GLARG4	<input type="text"/> LIRA 4
e. Believes medication causes weight gain or other side effect	<input type="text"/> METFORM5	<input type="text"/> GLARG 5	<input type="text"/> LIRA 5
f. Disruption of regular routine or travel	<input type="text"/> METFORM6	<input type="text"/> GLARG 6	<input type="text"/> LIRA 6
g. Depressed mood or other psychiatric issue	<input type="text"/> METFORM7	<input type="text"/> GLARG 7	<input type="text"/> LIRA 7
h. Lost/misplaced study medication	<input type="text"/> METFORM8	<input type="text"/> GLARG 8	<input type="text"/> LIRA 8
i. Dislikes using needles or size of pills is a problem	<input type="text"/> METFORM9	<input type="text"/> GLARG 9	<input type="text"/> LIRA 9
j. Other (specify: <input type="text"/>)	<input type="text"/> METFORM10	<input type="text"/> GLARG 10	<input type="text"/> LIRA 10

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k. No specific reason given

1 METFORM11 1 GLARG 11 1 LIRA11

MEDICATION DISPENSING

20. Was metformin/placebo dispensed at this visit? **VIMETDISP**

1 Yes

2 No

If YES,

a. Date dispensed?

/ /

b. Number of bottles:

VIMETNUM (3)

21. **Adult Study ONLY:** Was liraglutide dispensed at this visit? **VILIRADISP**

1 Yes

2 No

If YES,

a. Date dispensed?

/ /

b. Number of pens:

VILIRANUM (9)