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 — **Systolic** / **Diastolic**
VISYSBP VIDIABP
(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 HEIGHT1-3 **(pediatric study only)**	__ __ __ . __ cm	__ __ __ . __ cm	__ __ __ . __ cm
7. Weight WEIGHT1-3	__ __ __ . __ kg	__ __ __ . __ kg	__ __ __ . __ kg
8. Waist circumference **(M12, M15 and M21 only)** WAIST1-3	__ __ __ . __ cm	__ __ __ . __ cm	__ __ __ . __ cm
9. Hip circumference **(M12, M15 and M21 only)** HIP1-3	__ __ __ . __ cm	__ __ __ . __ cm	__ __ __ . __ 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

- [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: VIBCOSPEC _____

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 VIPREGTEST ☐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? 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***.

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	1	2
If YES		
i. Was this repeated mild hypoglycemia? (blood glucose <70 mg/dl more than twice/week or 5 times/month) VIMILDHYP	1	2
ii. How many episodes of mild hypoglycemia have occurred since the last clinic visit? VIHYPONUM (1-30)	___ time(s)	
b. Skin rashes? VISKINRASH	1	2
c. Frequent stomach pains, bloating, nausea, vomiting, diarrhea, or loss of appetite? VISTOMACH	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)? VISYMP	1	2
e. Other clinically important symptoms	1	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? VIANTIHYP 1 Yes 2 No

If YES, check all that apply:

i. 1 ACE inhibitor VIACE
ii. 1 ARB VIARB
iii. 1 Beta blocker VIBETA
iv. 1 Diuretic VIDIURET
v. 1 Other (**specify:** _____) VIOTH1/ VIOSPEC1

b. Lipid lowering medications? VILIPLOW 1 Yes 2 No

If YES, check all that apply:

i. 1 Statin VISTATIN
iv. 1 Fibrate VIFIBRATE

ii. ☐ 1 Bile acid sequestrant VISEQUEST

iii. ☐ 1 Niacin VINIACIN

v. ☐ 1 Other (**specify**: _____) 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

ii. ☐ 1 Sulfonylurea VISULF

iii. ☐ 1 Insulin VIINSUL

iv. ☐ 1 Exenatide or liraglutide VIEXENLIRA

v. ☐ 1 Non-study Metformin VIMET

vi. ☐ 1 DPP-4 Inhibitor VIDPP4

vii. ☐ 1 Other (**specify**: _____) 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? VIWGHTLOSS

☐ 1 No, nothing

☐ 2 Yes, medications or supplements

☐ 3 Yes, banding (laparoscopic or open)

☐ 4 Yes, sleeve gastrectomy

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

☐ 6 Yes, other (**specify:** _____) VIWGHTOSPEC

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

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

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

☐ 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 glargine pens? VIGLRRET ☐ 1 Yes ☐ 2 No

IF YES,

i. Percent of expected insulin glargine taken (per staff measurement) VIMETPERC ☐ 1 0% ☐ 2 1 - 49% ☐ 3 50 - 79% ☐ 4 80 - 100% ☐ 5 >100%

19. What has gotten in the way of taking each study medication as prescribed? **(Note: A response is <u>required</u> 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	☐ 1 METFORM1	☐ 1 GLARG1	☐ 1 LIRA 1
b. Temporarily stopped study medication due to intercurrent illness	☐ 1 METFORM2	☐ 1 GLARG2	☐ 1 LIRA 2
c. Forgets to take study medication in general	☐ 1 METFORM3	☐ 1 GLARG3	☐ 1 LIRA 3
d. GI reaction to medication	☐ 1 METFORM4	☐ 1 GLARG4	☐ 1 LIRA 4
e. Believes medication causes weight gain or other side effect	☐ 1 METFORM5	☐ 1 GLARG 5	☐ 1 LIRA 5
f. Disruption of regular routine or travel	☐ 1 METFORM6	☐ 1 GLARG 6	☐ 1 LIRA 6
g. Depressed mood or other psychiatric issue	☐ 1 METFORM7	☐ 1 GLARG 7	☐ 1 LIRA 7
h. Lost/misplaced study medication	☐ 1 METFORM8	☐ 1 GLARG 8	☐ 1 LIRA 8
i. Dislikes using needles or size of pills is a problem	☐ 1 METFORM9	☐ 1 GLARG 9	☐ 1 LIRA 9
j. Other (specify: _____)	☐ 1 METFORM10	☐ 1 GLARG 10	☐ 1 LIRA 10

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)