Participant ID: [ ][ ] – [ ][ ][ ]   Nickname: [ ][ ][ ][ ][ ][ ]

Restoring Insulin Secretion Study
RUNEND: End of Run-in Visit Inventory

1. Study Visit Number VISIT	REN
2. Visit date (mm/dd/yyyy) Replaced with DAYSRAND	__ __ / __ __ / __ __ __ __
3. Run-in start date (mm/dd/yyyy) Available on RUNSTART form	__ __ / __ __ / __ __ __ __
4. Total weeks of run-in REWEEKS ➔ ***Must be ≥3 weeks and ≤4 weeks for randomization***	__
5. Staff ID	__ __ __

***Instructions**: This form is completed at the end of the run-in period.*

Diabetes Management

6. Has the participant used any diabetes medication (other than metformin for pediatric participants) since the last visit? REDIAMED ***→If YES, participant is ineligible.***	1 Yes	2 No
7. **If PEDIATRIC**, is the participant on metformin? REMET	1 Yes	2 No
a. **If YES**, what is the current dose? REMETDOSE	__ __ __ __ mg/day	
8. Is the participant taking any other new medications since start of run-in? RENEWMED	1 Yes	2 No
a. **If YES**, are any of the new medications exclusionary (MOP v.1 Appendix 14.1.1)? REMEDEXCL	1 Yes	2 No
9. Was the participant diagnosed with any new illness since start of run-in? RENEWILL	1 Yes	2 No
a. **If YES**, are any of the new illnesses exclusionary (MOP v.1 Appendix 14.1.2)? REILLEXCL	1 Yes	2 No

Serious Adverse Events

10. Since the last 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: *If participant missed a period perform a pregnancy test.*

i. Pregnant? PREG	1

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

Symptom History

11. Since the last visit, did the participant experience any of the following?	**Yes**	**No**
a. Episode(s) of low blood sugar? RELOWBS	1	2
If YES		
i. Was this repeated mild hypoglycemia? (blood glucose <70 mg/dl more than twice/week or 5 times/month) REMILDHYP	1	2
ii. How many episodes of mild hypoglycemia have occurred since the last clinic visit? REHYPONUM (1-14)	_ _ time(s)	
b. Skin rashes? RESKINRASH	1	2
c. Frequent stomach pains, bloating, nausea, vomiting, diarrhea, or loss of appetite? RESTOMACH	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)? RESYMP	1	2

e. Other clinically important symptoms? ☐1 ☐2

If "Other,"

i. Specify:

Run-in Medication Adherence

12. Has the participant taken run-in metformin/placebo during the run-in? RERUNMET ☐1 Yes ☐2 No

IF YES,

a. Percent of expected pills taken REMETADHERE ☐☐☐ %

13. **Adult Study**: Has the participant taken run-in injection placebo during the run-in? RERUNINJCT ☐1 Yes ☐2 No

IF YES,

a. Number of returned pens RESYRINGE ☐

b. Calculated medication adherence REINJCTADHR ☐1 0% ☐2 1 - 49% ☐3 50 - 79% ☐4 80 - 100% ☐5 >100%

14. **Pediatric Study**: Did the participant successfully demonstrate the ability to give him/herself an injection? REDEMONST ☐1 Yes ☐2 No

15. Did the participant meet adherence criteria for taking medication as prescribed (**at least 80% adherence to both**)? READHERE ☐1 Yes ☐2 No