Participant ID: __ __ – __ __ __   Nickname: __ __ __ __ __ __

Restoring Insulin Secretion Study
RUNSTART: Start of Run-in Visit Inventory

1.	Study Visit Number VISIT	RST
2.	Visit date (mm/dd/yyyy) Replaced with DAYSRAND	__ __ / __ __ / __ __ __ __
3.	Staff ID	__ __ __

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

Diabetes Management

4. Has the participant used any diabetes medication (other than metformin for pediatric participants) since the last visit? RSDIAMED — ☐1 Yes ☐2 No

   → ***If YES, participant is ineligible.***

5. **If PEDIATRIC**, is the participant on metformin? RSMET — ☐1 Yes ☐2 No

   a. **If YES**, what is the current dose? RSMETDOSE — __ __ __ __ mg/day

6. Is the participant taking any other new medications since screening? RSNEWMED — ☐1 Yes ☐2 No

   a. **If YES**, are any of the new medications exclusionary (MOP v.1 Appendix 14.1.1)? RSMEDEXCL — ☐1 Yes ☐2 No

7. Was the participant diagnosed with any new illness since screening? RSNEWILL — ☐1 Yes ☐2 No

   a. **If YES**, are any of the new illnesses exclusionary (MOP v.1 Appendix 14.1.2)? RSILLEXCL — ☐1 Yes ☐2 No

Serious Adverse Events

8. Since the screening 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

9. Since the screening visit, did the participant experience any of the following?

	Yes	No
a. Episode(s) of low blood sugar? RSLOWBS	☐1	☐2
If YES		
i. Was this repeated mild hypoglycemia? (blood glucose <70 more than twice/week or 5 times/month) RSMILDHYP	☐1	☐2
ii. How many episodes of mild hypoglycemia have occurred since the last clinic visit? RSHYPONUM	☐☐ time(s)	
b. Skin rashes? RSSKINRASH	☐1	☐2
c. Frequent stomach pains, bloating, nausea, vomiting, diarrhea, or loss of appetite? RSSTOMACH	☐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)? RSSYMP	☐1	☐2
e. Other clinically important symptoms? RSOTHER	☐1	☐2

If "Other,"

i. Specify: ☐

Medication Dispensing

10. Was run-in metformin placebo dispensed? RSMETPLDISP ☐1 Yes ☐2 No

11. **Pediatric Study Only:** Was run-in active metformin dispensed? RSMETACDISP ☐1 Yes ☐2 No

12. **Adult Study Only:** Was run-in injection placebo dispensed? RSINJCTDISP ☐1 Yes ☐2 No