

-

Participant ID

Nickname

RISE **RUNEND.2**

July 2014

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

1. Study Visit Number <b>VISIT</b>	<input type="text"/> REN
2. Visit date (mm/dd/yyyy) <b>Replaced with DAYSRAND</b>	<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. Run-in start date (mm/dd/yyyy) <b>Available on RUNSTART form</b>	<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. Total weeks of run-in <b>REWEEKS</b> → <b>Must be ≥3 weeks and ≤4 weeks for randomization</b>	<input type="text"/>
5. Staff ID	<input type="text"/> <input type="text"/> <input type="text"/>

**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**  1 Yes  2 No  
→ **If YES, participant is ineligible.**

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

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**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

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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** 1 0% 2 1 - 49% 3 50 - 79%

b. Calculated medication adherence

**REINJCTADHR** 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 No15. Did the participant meet adherence criteria for taking medication as prescribed (**at least 80% adherence to both**)?**READHERE** 1 Yes 2 No