TODAY Form VISIT, Clinical Visit Inventory

☐☐–☐☐☐☐☐ RELEASEID   ☐☐☐ MVISIT
Release Participant ID   **Release Visit Number**

1. Days since randomization	☐☐☐☐	DAYS

Instructions: This form is completed for all participants at all scheduled visits after the Baseline visit (M02, M04, etc…).

Physical Exam Measurements

2. Seated arm blood pressure

    a. Systolic Blood Pressure   ☐☐☐ mmHg   SBP

    b. Diastolic Blood Pressure   ☐☐☐ mmHg   DBP

    c. Was TODAY BP cuff CAS 740-1 MAXNIBP used?   ☐₁ Yes   ☐₀ No   BPCUFF

3. Anthropometrics

    a. BMI   ☐₁ ≤28.0000   ☐☐.☐☐☐☐   ☐₃ >46.0000   BMI

    b. BMI Percentile   ☐₁ ≤98.5   ☐☐.☐   ☐₃ >99.5   BMIPCT

    c. BMI Z-score   ☐₁ ≤1.8000   ☐☐.☐☐☐☐   ☐₃ >2.7000   BMIZ

       i. Was TODAY Seca Scale 882 used to collect weight?   ☐ Yes₁   ☐ No₀   SECA

Complete d. and e. (waist circumference and abdominal height) only at M06 and M24 visits.

    d. Waist circumference   ☐₁ ≤95.0 cm   ☐☐☐.☐ cm   ☐₃ >130.0 cm   WASTCIRC

    e. Abdominal height   ☐₁ ≤21.0 cm   ☐☐☐.☐ cm   ☐₃ >30.0 cm   ABDHGHT

Concomitant Medications

4. Has the participant had any of the following medications, treatments, or procedures since the last visit?   ☐₁ Yes   ☐₀ No   MEDS

       If YES, continue. If NO, skip to question 5

    a. Antihypertensives (study and non-study drug)?   ☐₁ Yes   ☐₀ No   ANTIHYP

    b. Lipid lowering medications (study and non-study drug)?   ☐₁ Yes   ☐₀ No   LIPLOW

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c. Diabetes medication (other than study medication or insulin)?	☐ Yes₁ ☐ No₀	DIABMED
d. Steroids?	☐ Yes₁ ☐ No₀	STER
e. Weight loss treatments?	☐ Yes₁ ☐ No₀	WHTSUP
f. Other prescription medications?	☐ Yes₁ ☐ No₀	OTHERRX

Interval History

5. Outside the TODAY study, since the last clinic visit, how many times has the participant:

a. Called a health care provider for a specific medical issue/concern? ☐☐ time(s)   JCALLHCP

b. Had a regularly scheduled outpatient visit(s)? ☐☐ time(s)   JSCHEDOV

c. Had urgent care visit(s) (i.e. doctor's office, clinic, not to emergency room)? ☐☐ time(s)   JUCARE

d. Had an emergency room visit? ☐☐ time(s)   JERVISIT

e. Had an overnight hospital stay? ☐☐ time(s)   JINPATNT

6. Since the last clinic visit, how many days has the participant missed from school, work, or household activities, due to illness, injury, or medical care? Include visits related to his/her diabetes. ***DO NOT*** *include scheduled TODAY visits.* Round to nearest half day.

a. School ☐☐.☐ day (s)   JLSTSCH1

b. Work ☐☐.☐ day (s)   JLSTWRK1

c. Household activities ☐☐.☐ day (s)   JLSTHOU1

7. Since the last clinic visit, how many days has the participant missed from school, work, or household activities while attending scheduled TODAY visits, including TLP visits? Round to nearest half day.

a. School ☐☐.☐ day (s)   JLSTSCH2

b. Work ☐☐.☐ day (s)   JLSTWRK2

c. Household activities ☐☐.☐ day (s)   JLSTHOU2

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8. Is the participant in school?	☐₁ Yes ☐₀ No	JSTUDENT
If YES,		
a. What grade?	☐☐ grade	JGRADE
9. Is the participant employed outside the home?	☐₁ Yes ☐₀ No	JEMPLOY
If YES,		
a. How many hours per week?	☐☐ hours/week	JHRWKS
10. Is the participant in a formal weight loss program outside of TODAY? *(Examples are programs such as Weight Watchers or Jenny Craig.)*	☐₁ Yes ☐₀ No	JWTLOSS

Study Medication Status

11. Was the participant supposed to have taken study medication since the last visit?	☐₁ Yes ☐₀ No	JMEDS
If YES, continue. If NO, skip to question 12.		
a. Number of pills taken since the last visit?	☐☐☐ pills	JRXNMBR
b. Number of pills taken from late returns?	☐☐☐ pills	JLATENBR
12. Has the participant missed any doses of study medication?	☐₁ Yes ☐₀ No	JMISSRX

If YES,

What has gotten in the way with taking study medication as prescribed?

Check All That Apply

a. Permanently discontinued study medication	☐₁	JDISCRX
b. Temporarily stopped study medication due to intercurrent illness or other protocol-specified break	☐₁	JTEMPBRK
c. Forgets to take pills in general	☐₁	JFORGET
d. Tends to forget to take a particular dose	☐₁	JMISSDOS
If YES, Which dose?	☐₁ Morning ☐₂ Evening	JMISSPEC
e. GI reaction to pills	☐₁	JGIREACT

☐☐–☐☐☐☐☐ RELEASEID ☐☐☐ MVISIT
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f. Believes pills cause weight gain or edema	☐ 1	JWGHTGN
g. Disruption of regular routine due to new personal or family issues	☐ 1	JDISRPT
h. Depressed mood or other psychiatric issue	☐ 1	JDEPRSS
i. Lost/misplaced pills	☐ 1	JLOSTRX
j. Size of pill is a problem	☐ 1	JSIZERX
k. Lack of family support to remember pills	☐ 1	JLACKSUP
l. Sometimes spends a few days away from home	☐ 1	JAWAY
m. No specific reason given	☐ 1	JNOSPEC

13. What strategies has participant used to help remember to take study medication as prescribed?

Check All That Apply

a. Taking pills at scheduled time	☐ 1	JSCHEDTM
b. Taking pills at the same time as other activity (e.g., brushing teeth)	☐ 1	JSCHDACT
c. Reminder device	☐ 1	JREMIND
d. Family help with remembering pills	☐ 1	JFAMILY
e. Change in type and/or frequency of TODAY staff communication	☐ 1	JCHGTYP
f. No strategy used	☐ 1	JNOSTRAT