ACCORD INCLUSION/EXCLUSION SUMMARY

Participant ID: MASKID [affix ID label here]

Acrostic *

Data Entered By

Date of Visit: ___ / ___ / ___ (Month, Day, Year) VISIT

Form Completed by *

Date Entered

Participant Name

(Last Name) (First Name) (MI)

Type of pre-screening performed: (check all that apply)
- CHARTREV 1 ☐ Chart review
- TELEINT 1 ☐ Telephone interview (mailings, media responses, etc.)
- REFERRAL 1 ☐ Referral
- 1 ☐ Other OTHTYPE

Screening Informed Consent

Has the participant signed a screening informed consent for the ACCORD Trial? X1CONSNT

- 1 ☐ Yes →
- 2 ☐ Not required → Continue with screening.
- 3 ☐ No → Stop and have participant read and sign screening informed consent now. If the patient will not consent, check here → 1 ☐ *(Ineligible)* *

Part I. General Inclusion Criteria:	Source Documentation Notes (not for data entry)
1. Diagnosis of Type 2 Diabetes (by 1997 ADA criteria) of > 3 months duration. X1DIAB 1 ☐ Yes 2 ☐ No ***(Ineligible)***	Year of Diagnosis ☐☐☐☐
2. Stable diabetes treatment therapy > 3 months. 1 ☐ Yes 2 ☐ No ***(Ineligible)*** *	
3. Participant gender: 1 ☐ Female 2 ☐ Male GENDER	
4. Participant Age 1 DOB: ___ / ___ / ___ (Month, Day, Year)	Age: ☐☐
5. Is this participant of Spanish, Hispanic, or Latino origin? 2 1 ☐ Yes → 1 ☐ Puerto Rican; 1 ☐ Mexican, Mexican American, Chicano; 1 ☐ Cuban; 1 ☐ Other Spanish/Hispanic/Latino 2 ☐ No	

*** Variables not available in Public Use Data Set**
1 Baseline age: available in Analysis Data set: ACCORD_Key
2 Race Class: available in Analysis Data set: ACCORD_Key

Acrostic						

Part I. General Inclusion Criteria (continued):	Source Documentation Notes (not for data entry)
6. What is the participant's race/ethnicity?	
* 1☐ White, Caucasian	* 1☐ Black, African American/Canadian
* 1☐ American Indian/Alaska Native	* ☐ Native Hawaiian/ Other Pacific Islander
* 1☐ First Nation (Aboriginal Canadian)	* 1☐ French Canadian
* 1☐ Asian (specify) ➔	*
* 1☐ Other Race (specify) ➔	*

Clinical Cardiovascular Disease History			Source Documentation Notes (not for data entry)
7. CVD History (most recent must be > 3 months ago)			
Myocardial Infarction X2MI	1☐ Yes	2☐ No	
Stroke X2STROKE	1☐ Yes	2☐ No	
Angina and/or ischemic changes (ECG) on Graded Exercise Tolerance Test or positive imaging X2ANGINA	1☐ Yes	2☐ No	
Coronary Revascularization Procedures			
CABG CABG	1☐ Yes	2☐ No	
PTCI/PTCA/Atherectomy (with or without stenting) PTCI	1☐ Yes	2☐ No	
Other revascularization procedures			
Carotid Artery Revascularization 3	1☐ Yes	2☐ No	
Peripheral Artery Revascularization 3	1☐ Yes	2☐ No	
AAA Repair 3	1☐ Yes	2☐ No	
Other (specify)➔ OREVASC *	1☐ Yes	2☐ No	

8. Total number of *clinical CVD events* marked 'Yes' in Clinical Cardiovascular Disease History ☐

Part I. General Inclusion Criteria (continued):		Source Documentation Notes (not for data entry)
9. Does this participant have a history of clinical CVD events?		
1☐ Yes ➔ CVDHIST	Is participant ≥ 40 years old? 4 1☐ Yes 2☐ No ***(Ineligible)***	
2☐ No ➔	Is participant ≥ 55 years old? 4 1☐ Yes 2☐ No ***(Ineligible)***	

*** Variables not available in Public Use Data Set**
3 Combined with "other"
4 Available in Analysis Date Set: ACCORD_Key

Acrostic

Part I. General Inclusion Criteria (continued):	Source Documentation Notes (not for data entry)
10. Current Therapy and Qualifying HbA1c within the last 3 months	

Qualifying HbA1c: X2QHBA1C %

Date of HbA1c: * Month / Day / Year

How many oral agents is the participant taking? (If >3, then participant is ***Ineligible***) X2ORAL

11. Complete eligibility table below. NOTE: Eligible participants should match description for only one row. X2CURTHP

1 ☐ Patient not on insulin AND on 0, 1, or 2 oral agents ➔ 2 ☐ Patient on ≤1u/kg insulin AND on 0 or 1 oral agent ➔	Is HbA1c between 7.5% and 11.0% inclusive? X2HBAC11 1 ☐ Yes 2 ☐ No ***(Ineligible)***
3 ☐ Patient not on insulin AND 3 oral agents ➔ 4 ☐ Patient on ≤1 u/kg insulin AND 2 oral agents ➔ 5 ☐ Patient on >1 u/kg insulin AND 0 oral agents ➔	Is HbA1c between 7.5% and 9.0% inclusive? X2HBAC9 1 ☐ Yes 2 ☐ No ***(Ineligible)***
6 ☐ Patient on >1 u/kg insulin AND 1 or more oral agents, OR ≤1 u/kg insulin AND 3 or more oral agents ➔	***(Ineligible)***

Part II. Subclinical Cardiovascular Disease: history of cardiovascular events	Source Documentation Notes (not for data entry)
12. Micro or Macro Albuminuria (within past 2 years): 1 ☐ Yes 2 ☐ No 3 ☐ Not Available X3MALB	
13. LVH by ECG or Echocardiogram (within past 2 years): 1 ☐ Yes 2 ☐ No 3 ☐ Not Available X3LVH	
14. Low ABI (< 0.9) (within past 2 years): 5 1 ☐ Yes 2 ☐ No 3 ☐ Not Available	Ankle Systolic: ☐☐☐ Brachial Systolic: ☐☐☐ AB Index: ☐.☐☐
15. ≥50% stenosis of coronary, carotid, or lower extremity artery (within past 2 years) X3STEN 1 ☐ Yes 2 ☐ No 3 ☐ Not Available	
16. **Total number of *subclinical CVD factors* checked 'Yes" in Part II:** ☐	

*** Variables not available in Public Use Data Set**
5 Combined with variable X3STEN

Acrostic | | | | | |

Part III. Cardiovascular Disease: *other risk factors*	Source Documentation Notes (not for data entry)
17. On lipid lowering medication currently or untreated LDL-C > 130 mg/dL (3.38 mmol/L) (within past 2 years). 1 ☐ Yes 2 ☐ No **X4LLMEDS**	LDL-c ___ mg/dL or ___.___ mmol/L Date: __ __/__ __ __ __ (month and year of most recent result) Therapy:
18. Low HDL-C (within past 2 years): **X4GENDER** 1 ☐ Female → HDL-c < 50 mg/dL (1.29 mmol/L)? 1 ☐ Yes 2 ☐ No **X4HDLF** 2 ☐ Male → HDL-c < 40 mg/dL (1.04 mmol/L)? 1 ☐ Yes 2 ☐ No **X4HDLM**	HDL-c ___ mg/dL or ___.___ mmol/L Date: __ __/__ __ __ __ (month and year of most recent result) Therapy:
19. High Blood Pressure Is the participant currently on BP medications? **X4BPMEDS** 1 ☐ Yes 2 ☐ No → Not on BP medication AND most recent BP (within past 2 years): SBP $\geq$ 140 mmHg **X4NOTMED** **OR** DBP $\geq$ 95 mmHg 1 ☐ Yes 2 ☐ No	SBP ___ mmHg DBP ___ mmHg Date: __ __/__ __ __ __ (month and year of most recent result) Therapy:
20. Current cigarette smoker **X4SMOKE** 1 ☐ Yes 2 ☐ No	
21. BMI > 32 kg/m² (within past 2 years): **X4BMI** 1 ☐ Yes 2 ☐ No	Height ___.__ Weight ___ __ BMI __.__
22. **Total number of cardiovascular *risk factors* checked in Part III:** ☐	

Part IV. Summary of Eligibility Inclusion Criteria		
23. Does this participant meet the general inclusion criteria?	1 ☐ Yes (continue screening)	2 ☐ No ***(Ineligible)***
24. Does this participant have either *clinical CVD* (Q8) or at least one *subclinical CVD factor* (Q16) or at least *two other CVD risk factors* (Q22)?	1 ☐ Yes (continue screening)	2 ☐ No ***(Ineligible)***

*** Variables not available in Public Use Data Set**

Acrostic						

Part V. General Exclusion Criteria: ***Answer must be 'NO' to each question.***	***If response is 'YES' to any item, then the participant is ineligible.***	
Does this participant have any of the following:		
* 25. History of hypoglycemic coma or any seizure within past 12 months?	1☐ Yes	2☐ No
* 26. Hypoglycemia requiring 3rd party assistance in last 3 months with concomitant glucose <60 mg/dl (3.3 mmol/L)?	1☐ Yes	2☐ No
* 27. History consistent with Type I diabetes?	1☐ Yes	2☐ No
* 28. Any ongoing medical therapy (e.g., corticosteroids, protease inhibitors, etc.) known to have adverse interaction with the glycemic interventions?	1☐ Yes	2☐ No
* 29. Cardiovascular event or procedure or unstable angina within the last 3 months?	1☐ Yes	2☐ No
* 30. Current symptomatic CHF, history of NYHA Class III or IV CHF, or ejection fraction <25% (by any method)?	1☐ Yes	2☐ No
* 31. Any medical condition likely to limit survival to less than 3 years or a malignancy (other than non-melanoma skin cancer) within the last 2 years?	1☐ Yes	2☐ No
* 32. A history of any organ transplant?	1☐ Yes	2☐ No
* 33. Weight loss >10% of body weight in last 6 months?	1☐ Yes	2☐ No
* 34. BMI $\geq$ 45 kg/m^2?	1☐ Yes	2☐ No
* 35. Most recently measured Serum Creatinine > 1.5 mg/dL (>132 mmol/L) (must be measured within two months of randomization)?	1☐ Yes	2☐ No
* 36. Medical condition that requires recurrent phlebotomy or transfusion?	1☐ Yes	2☐ No
* 37. Transaminase >2 times upper limit of normal or active liver disease within the past 2 years?	1☐ Yes	2☐ No
* 38. Is unwilling to do capillary blood glucose self-monitoring at least 2 times/day or is unwilling to inject insulin?	1☐ Yes	2☐ No
* 39. Any factors likely to limit adherence to interventions (SEE MOP for examples)?	1☐ Yes	2☐ No
* 40. Currently participating in another clinical trial?	1☐ Yes	2☐ No
* 41. Pregnant or trying to get pregnant, or of child-bearing potential and not actively using birth control?	1☐ Yes	2☐ No
* 42. Is a member of the participant's household currently enrolled in ACCORD?	1☐ Yes	2☐ No
* 43. Any other condition or circumstance that would necessitate exclusion from this study?	1☐ Yes	2☐ No
If yes, specify →		

Part VI. Lipid and BP Trial Eligibility: ***Response must be 'Yes' to one or both questions.***		
44. Is this participant eligible for the Blood Pressure trial?	1☐ Yes	2☐ No
45. Is this participant eligible for the Lipid (fibrate) trial?	1☐ Yes	2☐ No

Part VII. Randomization Consent		
46. Has the participant signed a [randomization] informed consent for the ACCORD Trial? X5RCNSNT	1☐ Yes →	Continue with screening, randomize if eligible.
	2☐ No →	* If patient does not consent to randomization, then check here → 1☐ ***(Ineligible)***

*** Variables not available in Public Use Data Set**

ACCORD BLOOD PRESSURE TRIAL SCREENING FORM

Participant ID: MASKID [affix ID label here]

Acrostic: *

Data Entered By

Date of Visit: ___ / ___ / ___ (Month, Day, Year) VISIT

Form Completed by: *

Date Entered

Sitting Blood Pressures and Heart Rate

1. Check here if measurement not performed using the study automated BP device: 1☐ *

	2. Systolic BP	3. Diastolic BP	4. Heart Rate
First Measure	___ mmHg	___ mmHg	___ bpm
Second Measure	___ mmHg	___ mmHg	___ bpm
Third Measure	___ mmHg	___ mmHg	___ bpm
Average of Three	B1SYS1 mmHg	B1DIAS1 mmHg	B1HEART bpm

Current BP Medications (source documentation only)

Name of Medication	Dose	Frequency	Notes

Blood Pressure Trial Inclusion/Exclusion Check

5. Is there evidence of significant proteinuria within the past year? (see instructions on reverse) B1SIGPRO
   - 1☐ Yes → STOP *(participant is **ineligible**)*
   - 2☐ No → *(continue screening)*

6. How many anti-hypertensive medications is the participant currently taking? B1ANTIHP

- ☐ 4 or more → Stop here, patient is currently ***ineligible*** for blood pressure trial.
- ☐ 3 → Is SBP ≥ 130 and ≤ 160 mmHg? B1MEDS3
  - 1☐ Yes → Participant is eligible for randomization in BP trial.
  - 2☐ No → Participant is currently ***ineligible*** for randomization in BP trial.
- ☐ 2 → Is SBP ≥ 130 and ≤ 170 mmHg? B1MEDS2
  - 1☐ Yes → Participant is eligible for randomization in BP trial.
  - 2☐ No → Participant is currently ***ineligible*** for randomization in BP trial.
- ☐ 1 → Is SBP ≥130 and ≤ 180 mmHg? B1MEDS1
  - 1☐ Yes → Participant is eligible for randomization in BP trial.
  - 2☐ No → Participant is currently ***ineligible*** for randomization in BP trial.
- ☐ 0 → Is there a prior SBP ≥ 130 mmHg for Blood Pressure Trial screening (see instructions on reverse)? B1MEDS0
  - 1☐ Yes →

Date of prior SBP:	SBP Value	SBP Source	Is today's SBP ≥ 130 and ≤ 180 mmHg? *
* ___ / ___ / ___ (Month, Day, Year)	* ___ mmHg	1☐ Chart * 2☐ Screening Visit	1☐ Yes → eligible 2☐ No → ***ineligible***

  - 2☐ No → Participant is currently ***ineligible*** for randomization in BP trial (see instructions on reverse).

7. Is this participant eligible for the blood pressure trial? 1☐ Yes 2☐ No 3☐ Not at this time

*** Variables not available in Public Use Data Set**

ACCORD LIPID TRIAL SCREENING FORM

Participant ID MASKID [affix ID label here]

Acrostic *

Data Entered By

Date of Visit ___ / ___ / ___ VISIT (Month, Day, Year)

Form Completed by *

Date Entered

Fasting Serum LDL

NOTE: All fasting serum lipid values used to determine eligibility must be from the same sample. The date of sample must be within one year of the screening date.

1. Eligibility LDL-cholesterol value: LDLMG mg/dL or * mmol/L   Date of sample: * month / day / year

2. Is the participant currently being treated with lipid lowering agent(s)? LLAGENTS

1 ☐ Yes →

Use the chart below to indicate the adjusted interval for Lipid Trial eligibility. If the participant takes more than one lipid lowering medication, see instructions on reverse for calculating LDL-c cut points. Mark all rows that apply.

Lipid-Lowering Agent	Dose	Expected Percent Reduction	Observed LDL-c must be between these two values (inclusive): mg/dL	mmol/L	Mark row(s) used for eligibility
Atorvastatin (Lipitor)	2.5 mg	25	[45,135]	[1.16,3.49]	1 ☐ *
Atorvastatin (Lipitor)	5 mg	29	[43, 128]	[1.10, 3.30]	1 ☐ *
Atorvastatin (Lipitor)	10 mg	39	[37, 110]	[0.95, 2.84]	1 ☐ *
Atorvastatin (Lipitor)	20 mg	43	[34, 103]	[0.88, 2.65]	1 ☐ *
Atorvastatin (Lipitor)	40 mg	50	[30, 90]	[0.78, 2.33]	1 ☐ *
Atorvastatin (Lipitor)	80 mg	60	[24, 72]	[0.62, 1.86]	1 ☐ *
Simvastatin (Zocor)	5 mg	26	[44, 133]	[1.15, 3.44]	1 ☐ *
Simvastatin (Zocor)	10 mg	30	[42, 126]	[1.09, 3.26]	1 ☐ *
Simvastatin (Zocor)	20 mg	38	[37, 112]	[0.96, 2.89]	1 ☐ *
Simvastatin (Zocor)	40 mg	41	[35, 106]	[0.92, 2.75]	1 ☐ *
Simvastatin (Zocor)	80 mg	47	[32, 95]	[0.82, 2.47]	1 ☐ *
Lovastatin (Mevacor)	10 mg	18	[49,148]	[1.27, 3.82]	1 ☐ *
Lovastatin (Mevacor)	20 mg	24	[46, 137]	[1.18, 3.54]	1 ☐ *
Lovastatin (Mevacor)	40 mg	30	[42, 126]	[1.09, 3.26]	1 ☐ *
Lovastatin (Mevacor)	80 mg	40	[36, 108]	[0.93, 2.79]	1 ☐ *
Pravastatin (Pravachol)	10 mg	22	[47, 104]	[1.21, 3.63]	1 ☐ *
Pravastatin (Pravachol)	20 mg	32	[41, 122]	[1.06, 3.17]	1 ☐ *
Pravastatin (Pravachol)	40 mg	34	[40, 119]	[1.02, 3.07]	1 ☐ *
Fluvastatin (Lescol)	20 mg	22	[47, 140]	[1.21, 3.63]	1 ☐ *
Fluvastatin (Lescol)	40 mg	24	[46, 137]	[1.18, 3.54]	1 ☐ *
Ezetimibe (Zetia)	10 mg	17	[50, 149]	[1.29, 3.86]	1 ☐ *
Fenofibrate	any	5	[57, 171]	[1.47, 4.42]	1 ☐ *
Niacin	any	10	[54, 162]	[1.40, 4.19]	1 ☐ *
Other agent (see instructions) *	**Dose (mg)** *	**% Reduc** *	**LDL-c ≥** *	**LDL-c ≤** * 1 ☐ mg/dL 2 ☐ mmol/L *	1 ☐ *

Is the participant's (on-treatment) observed fasting LDL-c (from question #1) ≥ the lower critical value and ≤ the upper critical value from the chart above based on his/her current lipid-lowering therapy? * 1 ☐ Yes 2 ☐ No ***(ineligible)***

2 ☐ No → Is the participant's fasting LDL-c ≤ 180 mg/dL (≤ 4.65 mmol/L) and ≥ 60 mg/dL (≥ 1.55 mmol/L)? * 1 ☐ Yes 2 ☐ No ***(ineligible)***

*** Variables not available in Public Use Data Set**

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Fasting Serum HDL and Triglycerides

3. Is the participant:
   (a) Not on lipid lowering medication for hyperlipidemia with fasting triglyceride level < 750 mg/dL (8.47 mmol/L)?
   OR
   (b) On lipid lowering medication with fasting triglyceride level < 400 mg/dL (4.52 mmol/L)? — 1☐ Yes * 2☐ No ***(ineligible)***

4. Is the participant's HDL-cholesterol
   (a) < 50 mg/dL (1.29 mmol/L)?
   OR
   (b) Is the participant female or African American and has a HDL-cholesterol < 55 mg/dL (1.42 mmol/L)? — 1☐ Yes * 2☐ No ***(ineligible)***

Lipid Trial Exclusion Check

(An answer of "Yes" to any of these questions makes the participant ineligible for the Lipid Trial.)

Question	Yes	No	
5. Does the participant have any of the following contraindications:			
Current treatment with cyclosporine or other immunosuppressive therapy?	1☐ Yes	2☐ No	*
Known allergy, hypersensitivity, or intolerance of statins or fibrates?	1☐ Yes	2☐ No	*
6. Is the participant currently on one or more prescribed lipid lowering agents that he/she is unwilling to change or is inappropriate to change to study medications?	1☐ Yes	2☐ No	*
7. Does the participant have a condition that requires regular use of erythromycin, clarithromycin, azole antifungals, protease inhibitors, or other prohibited medications?	1☐ Yes	2☐ No	*
8. Does the participant have a known untreated or inadequately treated secondary cause of hyperlipidemia (e.g., hypothyroidism, nephrotic syndrome, etc.)?	1☐ Yes	2☐ No	*
9. Does the participant have a history of pancreatitis?	1☐ Yes	2☐ No	*
10. Does the participant have documented previous occurrence of myositis or myopathy?	1☐ Yes	2☐ No	*
11. Does the participant have pre-existing gall bladder disease without cholecystectomy?	1☐ Yes	2☐ No	*
12. Is the participant a woman who is breast feeding, pregnant or trying to get pregnant, or of child-bearing potential and not actively using birth control?	1☐ Yes	2☐ No	*

13. Is this participant eligible for the Lipid Trial? 1☐ Yes 2☐ No

*** Variables not available in Public Use Data Set**

ACCORD BASELINE HISTORY AND PHYSICAL EXAM FORM

Participant ID	MASKID [affix ID label here]	Acrostic *	Data Entered By
Date of Visit * (Month / Day / Year)	Visit Code VISIT	Form Completed by *	Date Entered

FORM MUST BE COMPLETED PRIOR TO RANDOMIZATION

Demographics

1. What is the participant's date of birth? 1 ___/___/___ (Month, Day, Year) ___ years old
2. Does the participant live with one or more other adults? LIVEALON 1☐ Yes 2☐ No
3. What is the participant's highest level of education? EDU
   1☐ Less than high school graduate 2☐ High school grad (or GED) 3☐ Some college or technical school
   4☐ College graduate or more

Disease Histories

4. Year of Diabetes Diagnosis: YRSDIAB 2☐ Unknown*
5. Year of Hyperlipidemia Diagnosis: YRSLIPI 1☐ N/A 2☐ Unknown*
6. Year of Hypertension Diagnosis: YRSTENS 1☐ N/A 2☐ Unknown*

Other Histories

7. Has the participant ever had an amputation due to diabetes*? 1☐ Yes 2☐ No
8. Has the participant ever been told by a physician that he/she has:

A foot ulcer requiring antibiotics ULCER	1☐ Yes	2☐ No	3☐ Unknown
Protein in his/her urine PROTEIN	1☐ Yes	2☐ No	3☐ Unknown
Heart failure/CHF HARTFAIL	1☐ Yes	2☐ No	3☐ Unknown
Neuropathy/nerve problems NEUROPAT	1☐ Yes	2☐ No	3☐ Unknown
Depression DEPRESSN	1☐ Yes	2☐ No	3☐ Unknown
Eye disease (including cataracts, proliferative diabetic retinopathy, diabetic macular edema, ischemia of the macula and hypertensive retinopathy) EYEDISEA	1☐ Yes	2☐ No	3☐ Unknown

Ask questions 9-13 verbatim.

Family History

9. "Is there a history of any of the following conditions in a brother, sister, or parent?"
   Heart Disease, Heart Attack, or Stroke (before age 55 for father/brother, 65 for mother/sister) HISTHART 1☐ Yes, at an early age 2☐ Yes, age unknown 3☐ No 4☐ Unknown

* Variables not available in Public Use Data Set
1 Baseline Age: available in Analysis Data Set: ACCORD_Key

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Health Habits

10. "Have you smoked any cigarettes in the last 30 days?" **CIGARETT**

1 ☐ Yes

2 ☐ No → "Have you smoked more than 100 cigarettes during your lifetime?" **SMOKELIF**

1 ☐ Yes → "When did you quit smoking cigarettes?" [ ][ ] Month **QUITYRS**[2] [ ][ ][ ][ ] Year

2 ☐ No

11. "How many alcoholic drinks do you consume in a typical week?"
("A drink" is a 12 oz. Beer, 6 oz. glass of wine, or 1.5 oz. liquor.) **ALCOHOL** [ ][ ] number of drinks

Insurance Status

12. "Which of the following best describes your current type of insurance coverage?" (mark all that apply)

1 ☐ Medicare **INS_COVER**[3] 1 ☐ Medicaid 1 ☐ VA 1 ☐ Tricare/CHAMPVA 1 ☐ Provincial Health Insurance Plan

1 ☐ Private/Commercial 1 ☐ HMO 1 ☐ Don't Know 1 ☐ Uninsured **DK_UNINS**[4]

13. "Do you have full or partial drug benefits under your insurance or Provincial health plan?" **DRUGBENE**

1 ☐ Yes 2 ☐ No 3 ☐ Don't Know 4 ☐ Uninsured

2 Combined with quitmos to include year and months
3 Changed to include all types of insurance
4 Combines "don't know" and "uninsured" responses

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14. **Participant Weight:**	WT_KG[5] .	Measurement recorded in:	1 ☐ pounds	2 ☐ kilograms
15. **Participant Height:**	HT_CM[5] .	Measurement recorded in:	1 ☐ inches	2 ☐ centimeters
16. **Waist Circumference:**	WAIST_CM[5] .	Measurement recorded in:	1 ☐ inches	2 ☐ centimeters

Sitting Blood Pressures and Heart Rate

COMPLETE BLOOD PRESSURE INFORMATION FOR LIPID TRIAL PARTICIPANTS ONLY ON THIS FORM. For BP trial participants, mark "N/A" here and complete blood pressure information on the BLOOD PRESSURE MANAGEMENT FORM.

17. **Systolic BP** (Average of 3)	18. **Diastolic BP** (Average of 3)	19. **Heart Rate** (Average of 3)
6 mmHg 1 ☐ N/A	6 mmHg 1 ☐ N/A	6 bpm 1 ☐ N/A

Corrected Visual Acuity

20. **Right Eye**	21. **Left Eye**
(a) Blindness * 1 ☐ Yes 2 ☐ No	(a) Blindness * 1 ☐ Yes 2 ☐ No
If Yes, Go to Left Eye (Question 21)	*If Yes, Go to Eye Disease History (Question 22)*
(b) Visual Acuity Score SCRRIGHT (0 – 100)	(b) Visual Acuity Score SCRLEFT (0 – 100)
(c) Snellen Fraction 20 / *	(c) Snellen Fraction 20 / *

If visual acuity (Snellen fraction) is worse than 20/40, refer participant to his/her ophthalmologist (remember to send OPHTHALMOLOGIST EXAM FORM with participant).

Eye Disease History

22. Has the participant ever had eye surgery, including laser photocoagulation? EYESURG
1 ☐ Yes ➔ Please indicate type below.
2 ☐ No

Right Eye	Left Eye
1 ☐ Cataract removal	1 ☐ Cataract removal
1 ☐ Retinal laser photocoagulation for diabetic retinopathy	1 ☐ Retinal laser photocoagulation for diabetic retinopathy
1 ☐ Yag laser for cataract capsule	1 ☐ Yag laser for cataract capsule
1 ☐ Vitrectomy for diabetic retinopathy	1 ☐ Vitrectomy for diabetic retinopathy
1 ☐ Other * REOTHR	1 ☐ Other * LEOTHR

RECAT_YAG, RERET_VIT, LECAT_YAG, LERET_VIT

23. Has the participant experienced any of the following vision problems?

(a) Retinopathy RETPATHY 1 ☐ Yes ➔ Indicate Eye ➔ 1 ☐ Left LRTPATHY 1 ☐ Right RRTPATHY
2 ☐ No

(b) Vision Loss VISLOSS 1 ☐ Yes ➔ Indicate Eye ➔ 1 ☐ Left LE_VLOSS 1 ☐ Right RE_VLOSS
2 ☐ No

5 All units converted to metric system (kg or cm)
6 Variables available in Analysis Data set: BloodPressure
* Variables not available for Public Use Data Set

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Heart Failure Risk

24. Have you experienced any of the following problems since ***[date of last events ascertainment]***?

(a) Swelling of your feet, ankles, or legs **HFRSWELL**
- 1 ☐ Yes →
  - 1 ☐ New or worsened
  - 2 ☐ Unchanged or improved
  - **HFRSWECH**
- 2 ☐ No
- 3 ☐ Unknown

(b) Shortness of breath while lying, sitting or with minimal exertion? **HFRSHORT**
- 1 ☐ Yes →
  - 1 ☐ New or worsened
  - 2 ☐ Unchanged or improved
  - **HFRSHOCH**
- 2 ☐ No
- 3 ☐ Unknown

(c) The need to pass urine three or more times per night? **HFRURINE**
- 1 ☐ Yes →
  - 1 ☐ New or worsened
  - 2 ☐ Unchanged or improved
  - **HFRURICH**
- 2 ☐ No
- 3 ☐ Unknown

Edema Exam

25. **Right Foot**	26. **Left Foot**
Grade Pre-tibial edema based on today's vist. (mark one only) **RPTDESC**	Grade Pre-tibial edema based on today's vist. (mark one only) **LPTDESC**
1 ☐ 1+ 2 ☐ 2+	1 ☐ 1+ 2 ☐ 2+
3 ☐ 3+ 4 ☐ 4+	3 ☐ 3+ 4 ☐ 4+
5 ☐ None 6 ☐ N/A	5 ☐ None 6 ☐ N/A

Chest Exam

27. **Complete only if any of the responses to 24 (a), (b), or (c) is 'Yes' or if edema was found on today's exam (grade of 1+ or greater).CHEST_EXAM[7]**

Auscultation of lungs:	1 ☐ No rales	2 ☐ Basilar rales only	3 ☐ Rales greater than basilar
Third heart sound present?	1 ☐ Yes	2 ☐ No	

7 Changed to combine two questions into yes/no response

Acrostic						

Foot Exam

28. Right Foot

Amputation History: Document amputation history and assess foot characteristics as outlined below.

Has participant ever had amputation of a lower extremity on the right side? FAMPHIS[8]

1 ☐ Yes (complete box for amputation description)   2 ☐ No (skip to part (a) below)

Amputation Description (mark one only) *

1 ☐ Toe   2 ☐ Ray (metatarsal)
3 ☐ Forefoot   4 ☐ Foot
5 ☐ Below knee   6 ☐ Above knee

Stop here, *do not* complete (a) – (e) below.

(a) Appearance: FAPPEAR[8]

0 ☐ Normal
1 ☐ Abnormal *(complete table below, mark all that apply)*

1 ☐ Deformities FDEFORM[8]   1 ☐ Infection FINFECT[8]
1 ☐ Dry skin, call FDRYSKI[8]   1 ☐ Fissur FFISSUR[8]
1 ☐ Other (specify below) FOTHER[8]

*

(b) Ulceration FULCER[8]

0 ☐ Absent   1 ☐ Present

(c) Ankle Reflexes FANKLE[8]

0 ☐ Present   0.5 ☐ Present/Reinforcement
1 ☐ Absent

(d) Vibration (perception at great toe) FVIBRAT[8]

0 ☐ Present (≤10 sec)   0.5 ☐ Reduced (>10 sec)
1 ☐ Absent

(e) 10 gm Filament (number of applications detected) FFILAM[8]

0 ☐ Present (≥ 8)   0.5 ☐ Reduced (1-7)   1 ☐ Absent

29. Left Foot

Amputation History: Document amputation history and assess foot characteristics as outlined below.

Has participant ever had amputation of a lower extremity on the left side?

1 ☐ Yes (complete box for amputation description)   2 ☐ No (skip to part (a) below)

Amputation Description (mark one only)

1 ☐ Toe   2 ☐ Ray (metatarsal)
3 ☐ Forefoot   4 ☐ Foot
5 ☐ Below knee   6 ☐ Above knee

Stop here, *do not* complete (a) – (e) below.

(a) Appearance

0 ☐ Normal
1 ☐ Abnormal *(complete table below, mark all that apply)*

1 ☐ Deformities   1 ☐ Infection
1 ☐ Dry skin, callus   1 ☐ Fissure
1 ☐ Other (specify below)

(b) Ulceration

0 ☐ Absent   1 ☐ Present

(c) Ankle Reflexes

0 ☐ Present   0.5 ☐ Present/Reinforcement
1 ☐ Absent

(d) Vibration (perception at great toe)

0 ☐ Present (≤10 sec)   0.5 ☐ Reduced (>10 sec)
1 ☐ Absent

(e) 10 gm Filament (number of applications detected)

0 ☐ Present (≥ 8)   0.5 ☐ Reduced (1-7)   1 ☐ Absent

MNSISCOR[9]

* Variables not available for Public Use Data Set
8 All right and left foot exam variables combined
9 Created value to score foot exam

Acrostic						

Concomitant Medications

30. Indicate all medications that the participant is taking ***on a regular basis prior to randomization*** by marking the appropriate boxes.

If participant is not taking any medications on a regular basis, check here: 1 ☐

Antihypertensive Agents

1 ☐ Loop diuretics	1 ☐ Thiazide diuretics	1 ☐ K-sparing diuretic agents
1 ☐ Potassium supplements	1 ☐ Angiotensin type 2 antagonists (ARB)	1 ☐ ACE inhibitors
1 ☐ Any dihydropyridine calcium-channel blocker (CCB)	1 ☐ Any non-dihydropyridine calcium-channel blocker (CCB)	1 ☐ Peripheral alpha-blockers
1 ☐ Central alpha-adrenergic agonists	1 ☐ Beta-blockers	1 ☐ Vasodilators
1 ☐ Reserpine	1 ☐ Other antihypertensive agents	

Cardiovascular Drugs

1 ☐ Digitalis preparations	1 ☐ Anti-arrhythmics	1 ☐ Nitrates
1 ☐ Other cardiovascular drugs		

Diabetes Treatments

1 ☐ Sulfonylureas	1 ☐ Biguanides	1 ☐ Meglitinides
1 ☐ Alpha-glucosidase inhibitors	1 ☐ Glargine, NPH, UL or L Insulins	1 ☐ Thiazolidinediones
1 ☐ Regular Insulins	1 ☐ Lispro or Aspart Insulins	1 ☐ Other Diabetes Treatments

Lipid-lowering Drugs

1 ☐ Bile-acid sequestrants	1 ☐ HMG CoA reductace inhibitors (statins)	1 ☐ Fibrates
1 ☐ Other lipid-lowering drugs	1 ☐ Cholesterol absorption inhibitors	1 ☐ Niacin and nicotinic acid

Miscellaneous Prescribed Therapies

1 ☐ Oral anticoagulants (warfarin, coumadin, anisindione)	1 ☐ Non-steroidal anti-inflammatory agents (excluding aspirin)	1 ☐ Inhibitors of platelet aggregation (except aspirin)
1 ☐ Cox-2 inhibitors	1 ☐ Heparins	1 ☐ Aspirin
1 ☐ Progestins	1 ☐ Estrogens (excluding vaginal creams)	1 ☐ Thyroid agents
1 ☐ Oral asthma drugs (except steroids)	1 ☐ Inhaled steroids for asthma	1 ☐ Oral steroids
1 ☐ Any antidepressant	1 ☐ Any antipsychotic	1 ☐ Weight loss drugs
1 ☐ Erectile dysfunction drugs	1 ☐ Any other (prescribed) medication not listed above	

Miscellaneous Non-prescribed Therapies

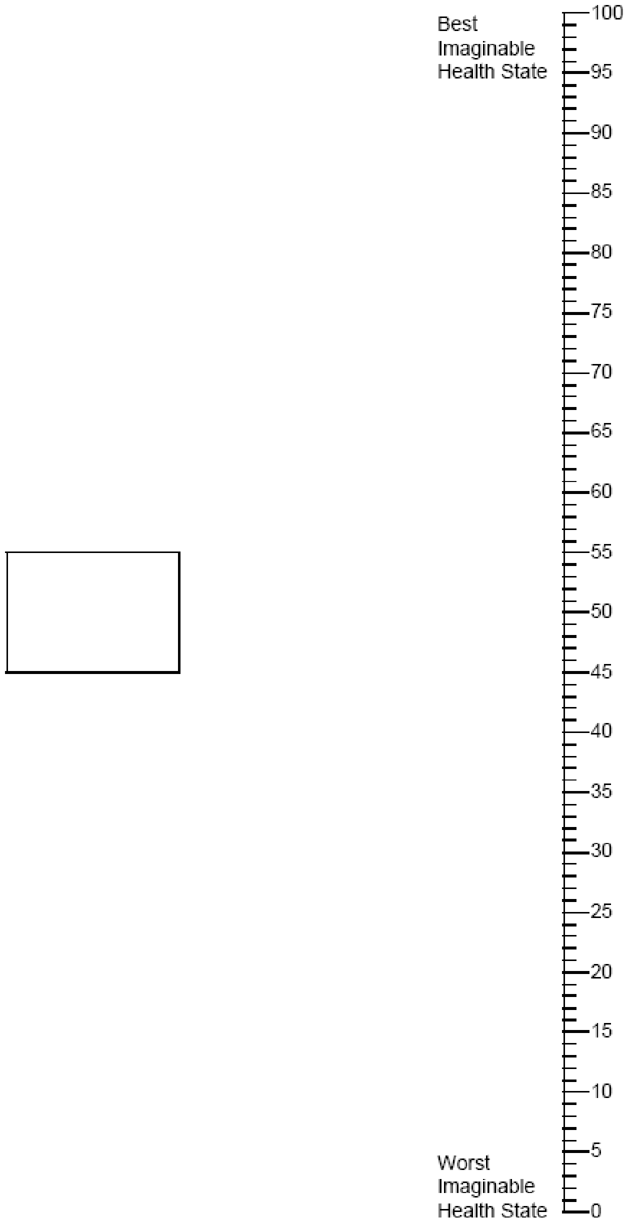
1 ☐ Vitamins and/or nutritional supplements	1 ☐ Over-the-counter medications	1 ☐ Herbal/alternative medication therapies

Acrostic						

TO BE COMPLETED BY THE PARTICIPANT PRIOR TO RANDOMIZATION

Feeling Thermometer: To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

We would like for you to indicate on this scale, in your opinion, how good or bad your own health is **TODAY**. Please do this by drawing a line from the the center of the box below to whichever point on the scale indicates how good or bad your current health state is.



Score FEELING

ACCORD *INTENSIVE* GLYCEMIA MANAGEMENT FORM

Participant ID **MASKID** [affix ID label here]

Acrostic *

Data Entered By

Date of Visit * Month / Day / Year

Visit Code **VISIT**

Form Completed by *

Date Entered

What is this participant's current Glycemia Trial status? (see instructions on reverse for definitions of terms). *

1 ☐ Active Participant   2 ☐ Inactive Participant (Complete **Parts I and II** only)

Part I. Contact Type

Indicate below the setting of this participant contact. **G1CONTCT**

1 ☐ Phone/Fax/Email →

Who initiated this contact? 1 ☐ Study Center 2 ☐ Participant *

What was the reason for this contact? *

1 ☐ Protocol-required phone visit   2 ☐ Hypoglycemia   3 ☐ PRN call for meds change (skip **Part II** unless responding to hypos)

4 Other → (specify) *

Was the contact completed as planned? *

1 ☐ Yes

2 ☐ No → Specify Problem(s) *

2 ☐ In person visit (in clinic) →

Indicate below the time spent addressing each of the following to the participant during today's visit.

Nutrition Education **G1NUTRIT** min

General Diabetes Education (other than Nutrition) **G1DIABED** min

Part II. Glucose Diary

Review the participant's glucose diary.

1. Since the last call or visit, how many times per week, on average, has the participant checked his/her blood sugar? **G1CHECK** times per week
2. How many hypoglycemic episodes (SMBG <70 mg/dL or <3.9 mmol/L) did the participant have **in the last 7 days**? **G17DAYS** ('00' if none)
3. How many times since the last call or visit was the participant's hypoglycemia so severe that it required him/her to be hospitalized?* ('00' if none)
4. How many times since the last call or visit was the participant's hypoglycemia so severe that it caused him/her to visit the emergency room or required attention from emergency personnel without admission to the hospital?* ('00' if none)
5. How many times since the last call or visit was the participant's hypoglycemia so severe that it required him/her to need assistance from medical personnel (but not attention from emergency personnel, an ER visit or hospitalization)?* ('00' if none)

G1_REPORT (questions 3–5)

6. How many times since the last call or visit was the participant's hypoglycemia so severe that it required him/her to need assistance from another person (but not attention from medical or emergency personnel, an ER visit or hospitalization)?* **G1OTHPER** ('00' if none)
7. Did any of the above hypoglycemic episodes (recorded in questions 3, 4, 5 or 6) occur without warning symptoms? **G1WARN** 1 ☐ Yes 2 ☐ No 3 ☐ N/A
8. Did any hypoglycemic episodes since the last call or visit occur when the participant was asleep? **G1ASLEEP** 1 ☐ Yes 2 ☐ No 3 ☐ N/A

*If number of events is greater than 0, complete an **ACCORD Severe Hypog**

* Variables not available in Public Use Data Set

Acrostic

Part II Glucose Diary (continued)

9. Since the last visit or call, how many times per week, on average,did the participant report having minor, but uncomfortable symptoms suggesting hypoglycemia? G1MHYPO

1 ☐ None

2 ☐ Less than one per week

3 One or more per week → How many times per week? *

Part III. HbA1c Monitoring

If this is a protocol-required phone visit ***go to Part III-B.*** *If you are using the protocol-required phone visit to respond to a* ***recently received Central Lab Hba1c, then complete Q10b and Q10c, and follow the algorithm.***
If this a PRN contact to address Side Effects ***go to Part IV***

10a. Most recent POC HbA1c: (including today's visit) * Source: 1 ☐ Bayer DCA 2 ☐ Local Lab * Date of measurement * Month / Day / Year

10b. Most recent central lab HbA1c within the past 30 days: * Date of measurement * Month / Day / Year

(If > 30 days prior to today, skip this field.)

10c. Identify the HbA1c range on which today's therapy decision is based. *

1 ☐ HbA1c* ≥ 6.0% → **Go to Part III-A**
2 ☐ HbA1c* < 6.0% → **Go to Part III-B**

*POC values should be adjusted for any systematic difference

Part III-A. *Complete if the HbA1c range in question 10c ≥6.0%, otherwise* ***go to Part III-B***

11. Was medical therapy intensified? *

1 ☐ Yes (go to **Part V**)

2 ☐ No → If no, why was therapy not intensified? (check all that apply)

1 ☐ Participant refused *
1 ☐ Previous intolerance *
1 ☐ Participant concern due to recurrent Hypoglycemic symptoms *
1 ☐ Addressed adherence problem *
1 ☐ Caregiver concern due to recurrent Hypoglycemic symptoms *
1 ☐ Severe hypoglycemia requir *
1 ☐ 25% or more of SMBG readings <70 mg/dL (3.9 mmol/L) (previous 2 weeks) *
1 ☐ Adverse experience (specify) → * *
1 ☐ Other → * *

(Go to **Part IV**)

* Variables not available in Public Use Data Set

Acrostic | | | | | |

Part III. HbA1c Monitoring continued)

Part III-B. *Complete if the HbA1c range in question 10c < 6.0% or if this a protocol-required phone visit.*

12. Since the last change in anti-hyperglycemic medications, were 50% or more of SMBG readings over a 4 day period outside the target range? [>100 mg/dL ac (5.6 mmol/L), >140mg/dL pc (7.8 mmol/L)] *

- 1 ☐ Yes → Was therapy intensified? *
  - 1 ☐ Yes (go to **Part V**)
  - 2 ☐ No → If no, why was therapy not intensified? (check all that apply)
    - 1 ☐ Patient refused *
    - 1 ☐ Previous intolerance *
    - 1 ☐ Participant concern due to recurrent Hypoglycemic symptoms *
    - 1 ☐ Addressed adherence pro *
    - 1 ☐ Caregiver concern due to recurrent Hypoglycemic symptoms *
    - 1 ☐ Severe hypoglycemia re assistance *
    - 1 ☐ 25% or more of SMBG readings <70 mg/dL (3.9 mmol/L) (previous 2 weeks *
    - 1 ☐ Adverse experience (specify) → * *
    - 1 ☐ Other → * *

    (Go to **Part IV**)
- 2 ☐ No (go to **Part IV**)

Part IV. Non-Protocol adjustments to Glycemic Therapy

13. Were pharmacologic changes in therapy made at this visit? *

- 1 ☐ Yes → Why were changes made? (check all that apply)
  - 1 ☐ Participant requested ch *
  - 1 ☐ Participant not adherent to prior therapy *
  - 1 ☐ Side Effects *
  - 1 ☐ Participant made dietary / lifestyle changes *
  - 1 ☐ Weight Gain *
  - 1 ☐ Adverse Experience *
  - 1 ☐ Weight Loss *
  - 1 ☐ SMBG readings were too high *
  - 1 ☐ Other Doctor's request *
  - 1 ☐ SMBG readings were too low *
  - 1 ☐ Hypoglycemia/Hypoglycemic symptoms *
  - 1 ☐ SMBG readings were too variable *
  - 1 ☐ Medication added/increased because of reduction/removal of another med. *
  - 1 ☐ Other (specify) → * *

  (Go to **Part V**)
- 2 ☐ No → Go to **Part V**

Part V. Non-Insulin Medications

14. Was the participant on non-insulin therapy at visit entry? *

- 1 ☐ Yes → Were changes made at this visit? *
  - 1 ☐ Yes → Please complete the ***Glycemia Medications Log***.
  - 2 ☐ No → Please verify current medications,complete adherence information and indicate "No Change" in therapies on the ***Glycemia Medications Log.***
- 2 ☐ No → Was any non-insulin therapy initiated at this visit? *
  - 1 Yes → Please complete the ***Glycemia Medications Log***.
  - 2 No

* Variables not available in Public Use Data Set

Acrostic | | | | | |

Part VI. Insulin Therapy Record

15. Is the participant on injected or inhaled insulin at either visit entry or exit or both? G2ANYINS
1 ☐ Yes
2 ☐ No → (**STOP HERE**, *End of* **Glycemia Form**)

16. If this is a phone visit **AND** there is no change in insulin therapy today, check here 1 ☐ and **STOP**. Otherwise complete insulin therapy record below. G3PHONE

Part VI-A. Visit Entry

17. How many times per day was the participant prescribed to take insulin at visit entry? (if none enter "0") G2PRSCBIN *f none,go to* ***Part VI-B***)

18. How often does the participant:

Self-adjust his/her insulin?	1 ☐ Regularly	2 ☐ Irregularly	3 ☐ Never	G2HWOFSA
Use CHO/Insulin ratio?	1 ☐ Regularly	2 ☐ Irregularly	3 ☐ Never	G2HWOFCH
Use an insulin pen?	1 ☐ Regularly	2 ☐ Irregularly	3 ☐ Never	G2HWOFIP

19. How often does th[illegible] ke his/her insulin injections/ inhalations as prescribed for:

Basal (backgroun[illegible] G2HWOFBA	1 ☐ All (80-100%)	2 ☐ Some (1-79%)	3 ☐ None (0%)	8 ☐ > Prescribed (>100%)	4 ☐ N/A
Injected Bolus (pre[illegible] G2HWOFBO	1 ☐ All (80-100%)	2 ☐ Some (1-79%)	3 ☐ None (0%)	8 ☐ > Prescribed (>100%)	4 ☐ N/A
Inhaled Bolus Insulin? *	1 ☐ All (80-100%)	2 ☐ Some (1-79%)	3 ☐ None (0%)	8 ☐ > Prescribed (>100%)	4 ☐ N/A

Injected Insulins

20. Basal Insulin (check all that apply)
- 1 ☐ NPH G2AVENPH
- 1 ☐ Lente
- 1 ☐ UltraLente
- 1 ☐ Glargine G2AVEGLA
- Insulin Pump G2AVEINP
- 1 ☐ Levemir G2AVELEV
- 1 ☐ No Basal G2AVENOB

21. Total Basal Insulin/Day G2AVEBA

22. Bolus Insulin (check all that apply)
- 1 ☐ Regular G2AVEREG
- 1 ☐ Aspart G2AVEASP
- 1 ☐ No Bolus G2AVENBO
- 1 ☐ Glulisine
- 1 ☐ Lispro
- G2AVEOTB

23. Total Bolus Insulin/Day G2AVEBOL

24. Premixed Insulin (check all that apply)
- 1 ☐ 70/30 G2AVEPRE
- 1 ☐ 75/25 *
- 1 ☐ 50/50 *
- 1 ☐ Other (specify) → *
- G2AVEOTH
- 1 ☐ No Premixed G2AVENPRE

25. Total Premixed Insulin/Day G2AVEPBA

26. Total Injected Insulins/Day G2AVETID

Other Insulins

1 ☐ Exubera (inhaled) *

27. Total Other Insulin/Day * mg

28. Were there any changes in the insulin regimen? G2NOCHIN
- 1 ☐ Yes → Complete all sections of **Part VI-B** on the next page.
- 2 ☐ Yes, but changes in time distribution of insulin only → (**STOP HERE**, *End of* **Glycemia Form**)
- 3 ☐ No → (**STOP HERE**, *End of* **Glycemia Form**)

*** Variables not available in Public Use Data Set**

Acrostic

Part VI-B. Visit Exit

29. How many times per day will the participant be taking insulin at visit exit? G2AVXNIN (...ne, END of **Glycemia Form**)

Injected Insulins

30. Basal Insulin (check all that apply)
- 1 ☐ NPH G2AVXNPH
- 1 ☐ Insulin Pump G2AVXINP
- * 1 ☐ Lente
- 1 ☐ Levemir G2AVXLEV
- * 1 ☐ Ultralente
- 1 ☐ No Basal G2AVXNOB
- 1 ☐ Glargine G2AVXGLA

31. Total Basal Insulin/Day G2AVXBA

32. Bolus Insulin (check all that apply)
- 1 ☐ Regular G2AVXREG
- 1 ☐ Glulisine
- 1 ☐ Aspart G2AVXASP
- 1 ☐ Lispro
- 1 ☐ No Bolus G2AVXNBO
- G2AVXOTB

33. Total Bolus Insulin/Day G2AVXBOL

34. Premixed Insulin (check all that apply)
- 1 ☐ 70/30 G2AVXPRE
- 1 ☐ No Premixed G2AVXNPRE
- 1 ☐ 75/25 *
- 1 ☐ 50/50 *
- 1 ☐ Other (specify) → G2AVXOTH

35. Total Premixed Insulin/Day G2AVXPBA

36. Total Injected Insulins/Day G2AVXTID

Other Insulins

1 ☐ Exubera (inhaled) *

37. Total Other Insulin/Day * mg

* Variables not available in Public Use Data Set

ACCORD *STANDARD* GLYCEMIA MANAGEMENT FORM

Participant ID	MASKID [affix ID label here]	Acrostic	*	Data Entered By
Date of Visit	* / / (Month Day Year)	Visit Code	VISIT	Date Entered
		Form Completed by	*	

What is this participant's current Glycemia Trial status? (see instructions on reverse for definitions of terms). *

1 ☐ Active Participant 2 ☐ Inactive Participant (Complete **Parts I and II** only)

Part I. Contact Type

Indicate below the setting of this participant contact. G1CONTCT

1 ☐ Phone/Fax/Email →

Who initiated this contact? 1 ☐ Study Center 2 ☐ Participant *

What was the reason for this contact? *

1 ☐ Protocol-required phone visit 2 ☐ Hypoglycemia 3 ☐ PRN call for meds change (skip **Part II** unless responding to hypos)

4 ☐ Other → (specify) *

Was the contact completed as planned? *

1 ☐ Yes

2 ☐ No → Specify Problem(s) *

2 ☐ In person visit (in clinic) →

Indicate below the time spent addressing each of the following to the participant during today's visit.

Nutrition Education G1NUTRIT

General Diabetes Education (other than Nutrition) G1DIABED min

Part II. Glucose Diary

Review the participant's glucose diary.

1. Since the last call or visit, how many times per week, on average, has the participant checked his/her blood sugar? G1CHECK ☐☐ times per week
2. How many hypoglycemic episodes (SMBG <70 mg/dL or <3.9 mmol/L) did the participant have **in the last 7 days**? G17DAYS ☐☐ ('00' if none)
3. How many times since the last call or visit was the participant's hypoglycemia so severe that it required him/her to be hospitalized?* ☐☐ ('00' if none)
4. How many times since the last call or visit was the participant's hypoglycemia so severe that it caused him/her to visit the emergency room or required attention from emergency personnel without admission to the hospital?* G1_REPORT ('00' if none)
5. How many times since the last call or visit was the participant's hypoglycemia so severe that it required him/her to need assistance from medical personnel (but not attention from emergency personnel, an ER visit or hospitalization)?* ☐☐ ('00' if none)
6. How many times since the last call or visit was the participant's hypoglycemia so severe that it required him/her to need assistance from another person (but not attention from medical or emergency personnel, an ER visit or hospitalization)? G1OTHPER ('00' if none)
7. Did any of the above hypoglycemic episodes (recorded in questions 3, 4, 5, or 6) occur without warning symptoms? G1WARN 1 ☐ Yes 2 ☐ No 3 ☐ N/A
8. Did any hypoglycemic episodes since the last call or visit occur when the participant was asleep? G1ASLEEP 1 ☐ Yes 2 ☐ No 3 ☐ N/A

* If number of events is greater than 0, complete an **ACCORD Severe Hypoglycemia Action Form** for each distinct event.

* Variables not available in Public Use Data Set

	Acrostic

Part II Glucose Diary (continued)

9. Since the last visit or call, how many times per week, on average,did the participant report having minor, but uncomfortable symptoms suggesting hypoglycemia?

G1MHYPO

1 ☐ None

2 ☐ Less than one per week

3 ☐ One or more per week → How many times per week? [ ][ ] *

Part III. HbA1c Monitoring

If this a PRN contact to address Side Effects ***go to Part IV***

10a. Most recent POC HbA1c: * [ ][ ].[ ] %

Source: 1 ☐ Bayer DCA 2 ☐ Local Lab *

Date of measurement * [ ][ ] / [ ][ ] / [ ][ ] Month Day Year

10b. Most recent central lab HbA1c: * [ ][ ].[ ] %

Date of measurement * [ ][ ] / [ ][ ] / [ ][ ] Month Day Year

11. Was there an episode of severe hypoglycemia, any adverse effects of anti-hyperglycemic drugs, symptomatic hypoglycemia more than once per week, or > 50% of SMBGs below 90 mg/dL (5.0 mmol/L)? *

1 ☐ Yes → The protocol requires **a decrease** in therapy. Was therapy reduced? *

- 1 ☐ Yes → Go to **Part V**
- 2 ☐ No → If no, why was therapy not decreased? *
  - 1 ☐ Participant refused
  - 2 ☐ Other → * ____________
  - (Go to **Part IV**)

2 ☐ No

12. Have changes to glycemic management been made at a prior visit in response to the more recent of the HbA1c values in question 10 above? *

1 ☐ Yes → **Visit Code** * [ ][ ] (Go to **Part IV**)

2 ☐ No → **Indicate the HbA1c range that you are basing today's therapy decision on.** *

- 1 ☐ **HbA1c* ≤ 6.5%**→ Go to **Part III-A**
- 2 ☐ **HbA1c* is 6.6% to 6.9%** → Go to **Part III-B**
- 3 ☐ **HbA1c* 7.0%to 7.9%** → Go to **Part IV**
- 4 ☐ **HbA1c* ≥ 8.0%** → Go to **Part III-C**

*POC values should be adjusted for any systematic difference

Part III-A. Complete if HbA1c range in question 12 is ≤ 6.5%.

13. Is the participant on insulin or secretagogue, or has there been any symptomatic hypoglycemia or > 1 SMBG reading below 90 mg/dL (5.0 mmol/L) since the last visit? *

1 ☐ Yes → The protocol requires **a decrease** in therapy. Was pharmacologic therapy reduced? *

- 1 ☐ Yes → Go to **Part V**
- 2 ☐ No → If no, why was therapy not decreased?
  - 1 ☐ Participant refused *
  - 2 ☐ Other → * ____________
  - (Go to **Part IV**)

2 ☐ No

(Go to **Part IV**)

*** Variables not available in Public Use Data Set**

Acrostic | | | | | |

Part III-B. Complete if HbA1c range in question 12 is 6.6% to 6.9%.

14. Was the central lab HbA1c < 6.9% at the previous measurement (i.e. on 2 consecutive occasions)? *

1 ☐ Yes → Is the participant on insulin or a secretagogue or has there been any syptomatic hypoglycemia or > 1 SMBG reading below 90 mg/dL (5.0 mmol/L) since the last visit? *

- 1 ☐ Yes → The protocol requires **a decrease** in therapy. Was pharmacologic therapy reduced? *
  - 1 ☐ Yes → Go to **Part V**
  - 2 ☐ No → If no, why was therapy not decreased?
    - 1 ☐ Participant refused *
    - 2 ☐ Other → ______ *
    - (Go to **Part IV)**
- 2 ☐ No (Go to **Part IV)**

2 ☐ No (Go to **Part IV)**

Part III-C. Complete if HbA1c range in question 12 is > 8.0%.

15. The protocol requires an **increase** in therapy. Was medical therapy intensified?

1 ☐ Yes (go to **Part V**) *

2 ☐ No → If no, why was therapy not intensified? (check all that apply)

- 1 ☐ Participant refused *
- 1 ☐ Participant concern due to recurrent hypoglycemic symptoms *
- 1 ☐ Caregiver concern due to recurrent hypoglycemic symptoms *
- 1 ☐ Previous ir *
- 1 ☐ Addressed adherence problem *
- 1 ☐ Severe hypoglycemia requiring assistance *
- 1 ☐ One or more SMBG readings <90 mg/dL (5.0 mmol/L) (previous 2 week: *
- 1 ☐ Adverse experience (specify) → ______ * *
- 1 ☐ Other (specify) → ______ * *

(Go to **Part IV**)

Part IV. Non-Protocol adjustments in Glycemic Therapy

16. Were pharmacologic changes in therapy made at this visit? *

1 ☐ Yes → Why were changes made? (check all that apply)

- 1 ☐ Participant requ *
- 1 ☐ Side Effects *
- 1 ☐ Weight Gain *
- 1 ☐ Weight Loss *
- 1 ☐ Other Doctor's request *
- 1 ☐ Hypoglycemia/Hypoglycemic symptoms *
- 1 ☐ Participant not adherent to prior therapy *
- 1 ☐ Participant made dietary / lifestyle changes *
- 1 ☐ Adverse Experience *
- 1 ☐ SMBG readings were too high *
- 1 ☐ SMBG readings were too low *
- 1 ☐ SMBG readings were too variable *
- 1 ☐ Medication added/increased because of reduction/removal of another med. *
- 1 ☐ Other (specify)→ ______ * *

(Go to **Part V**)

2 ☐ No → Go to **Part V**

*** Variables not available in Public Use Data Set**

Acrostic

Part V. Non- Insulin Medications

17. Was the participant on non-insulin therapy at visit entry? *

1 ☐ Yes → Were changes made at this visit? *

- 1 ☐ Yes → Please complete the ***Glycemia Medications Log***.
- 2 ☐ No → Please verify current medications,complete adherence information and indicate "No Change" in therapies on the ***Glycemia Medications Log.***

2 ☐ No → Was non-insulin therapy initiated at this visit? *

- 1 ☐ Yes → Please complete the ***Glycemia Medications Log***.
- 2 ☐ No

Part VI. Insulin Therapy Record

18. Is the participant on injected or inhaled insulin at either visit entry or exit or both? G2ANYINS

- 1 ☐ Yes
- 2 ☐ No → (***STOP HERE***, *End of* ***Glycemia Form***)

Part VI-A. Visit Entry

19. How many times per day was the participant prescribed to take insulin at visit entry? G2PRSCBIN (*if none,go to* ***Part VI-B***)

20. How often does the participant:

Self-adjust his/her insulin? G2HWOFSA	1 ☐ Regularly	2 ☐ Irregularly	3 ☐ Never
Use CHO/Insulin G2HWOFCH	1 ☐ Regularly	2 ☐ Irregularly	3 ☐ Never
Use an insulin pen G2HWOFIP	1 ☐ Regularly	2 ☐ Irregularly	3 ☐ Never

21. How often does the participant take his/her insulin injections / inhalations as prescribed for:

Basal (background) G2HWOFBA	1 ☐ All (80-100%)	2 ☐ Some (1-79%)	3 ☐ None (0%)	8 ☐ > Prescribed (>100%)	4 ☐ N/A
Injected Bolus (prandial) G2HWOFBO	☐ All (80-100%)	2 ☐ Some (1-79%)	3 ☐ None (0%)	8 ☐ > Prescribed (>100%)	4 ☐ N/A
Inhaled Bolus Insulin? *	1 ☐ All (80-100%)	2 ☐ Some (1-79%)	3 ☐ None (0%)	8 ☐ > Prescribed (>100%)	4 ☐ N/A

Injected Insulins

22. Basal Insulin (check all that apply)

- 1 ☐ NPH G2AVENPH
- 1 ☐ Lente
- 1 ☐ Ultralente
- 1 ☐ Insulin Pump G2AVEINP
- 1 ☐ Levemir G2AVELEV
- 1 ☐ No Basal G2AVENOB
- 1 ☐ Glargine G2AVEGLA

23. Total Basal Insulin/Day G2AVEBA

24. Bolus Insulin (check all that apply)

- 1 ☐ Regular G2AVEREG
- 1 ☐ Aspart G2AVEASP
- 1 ☐ No Bolus G2AVENBO
- 1 ☐ Glulisine
- 1 ☐ Lispro
G2AVEOTB

25. Total Bolus Insulin/Day G2AVEBOL

26. Premixed Insulin (check all that apply) G2AVEPRE

- 1 ☐ 70/30
- 1 ☐ 75/25 *
- 1 ☐ 50/50 *
- 1 ☐ Other (specify) → G2AVEOTH
- 1 ☐ No Premixed G2AVENPRE

27. Total Premixed Insulin/Day G2AVEPBA

28. Total Injected Insulins/Day G2AVETID

* Variables not available in Public Use Data Set

Acrostic

Other Insulins

1 ☐ Exubera (inhaled) *

29. Total Other Insulin/Day * mg

30. Were there any changes in the insulin regimen? G2NOCHIN
    - 1 ☐ Yes → Complete all sections of **Part VI-B** on the next page.
    - 2 ☐ Yes, but changes in time distribution of insulin only → *(**STOP HERE**, End of **Glycemia Form**)*
    - 3 ☐ No → *(**STOP HERE**, End of **Glycemia Form**)*

Part VI-B. Visit Exit

31. How many times per day will the participant be taking insulin at visit exit? G2AVXNIN *none, End of **Glycemia Form**)*

Injected Insulins

32. Basal Insulin (check all that apply)
    - 1 ☐ NPH G2AVXNPH
    - 1 ☐ Lente
    - 1 ☐ Ultralente
    - 1 ☐ Glargine G2AVXGLA
    - Insulin Pump G2AVXINP
    - 1 ☐ Levemir G2AVXLEV
    - 1 ☐ No Basal G2AVXNOB

33. Total Basal Insulin/Day G2AVXBA

34. Bolus Insulin (check all that apply)
    - 1 ☐ Regular G2AVXREG
    - 1 ☐ Aspart G2AVXASP
    - 1 ☐ No Bolus G2AVXNBO
    - 1 ☐ Glulisine
    - 1 ☐ Lispro
    - G2AVXOTB

35. Total Bolus Insulin/Day G2AVXBOL

36. Premixed Insulin (check all that apply)
    - 1 ☐ 70/30 G2AVXPRE
    - 1 ☐ 75/25
    - 1 ☐ 50/50
    - 1 ☐ Other (specify) → G2AVXOTH
    - 1 ☐ No Premixed G2AVXNPRE

37. Total Premixed Insulin/Day G2AVXPBA

38. Total Injected Insulins/Day G2AVXTID

Other Insulins

1 ☐ Exubera (inhaled) *

39. Total Other Insulin/Day * mg

* Variables not available in Public Use Data Set

ACCORD GLYCEMIA MEDICATIONS LOG

Participant ID MASKID [affix ID label here]

Acrostic *

Data Entered By

Date of Visit * / / (Month Day Year)

Visit Code VISIT

Form Completed by *

Date Entered

Last Reported Visit Code

XORALGMED

Non-Insulin Medications

Medication Name	Last Reported Dosage	Adherence (percentage of the time)	Action Taken at this visit	Adjustments Dosage	Study meds adjusted due to side effects?
ORAL_GMED Date Last Reported Month / Day / Year	* mg * /Day	COMP 1 ☐ All or almost all (80-100%) 2 ☐ Some (1% to 79%) 3 ☐ None (0%) 4 ☐ > Prescribed (>100%)	ACTION 1 ☐ No change 2 ☐ Discontinued 3 ☐ Dose Modified 4 ☐ New Medication	* mg * /Day	1 ☐ Yes*, due to ADJUST 1 ☐ Hypos HYPO 1 ☐ Other OTHER
Date Last Reported Month / Day / Year	mg /Day	1 ☐ All or almost all (80-100%) 2 ☐ Some (1% to 79%) 3 ☐ None (0%) 4 ☐ > Prescribed (>100%)	1 ☐ No change 2 ☐ Discontinued 3 ☐ Dose Modified 4 ☐ New Medication	mg /Day	1 ☐ Yes*, due to 1 ☐ Hypos 1 ☐ Other
Date Last Reported Month / Day / Year	mg /Day	1 ☐ All or almost all (80-100%) 2 ☐ Some (1% to 79%) 3 ☐ None (0%) 4 ☐ > Prescribed (>100%)	1 ☐ No change 2 ☐ Discontinued 3 ☐ Dose Modified 4 ☐ New Medication	mg /Day	1 ☐ Yes*, due to 1 ☐ Hypos 1 ☐ Other
Date Last Reported Month / Day / Year	mg /Day	1 ☐ All or almost all (80-100%) 2 ☐ Some (1% to 79%) 3 ☐ None (0%) 4 ☐ > Prescribed (>100%)	1 ☐ No change 2 ☐ Discontinued 3 ☐ Dose Modified 4 ☐ New Medication	mg /Day	1 ☐ Yes*, due to 1 ☐ Hypos 1 ☐ Other
Date Last Reported Month / Day / Year	mg /Day	1 ☐ All or almost all (80-100%) 2 ☐ Some (1% to 79%) 3 ☐ None (0%) 4 ☐ > Prescribed (>100%)	1 ☐ No change 2 ☐ Discontinued 3 ☐ Dose Modified 4 ☐ New Medication	mg /Day	1 ☐ Yes*, due to 1 ☐ Hypos 1 ☐ Other

Total Number of Pages Completed *

*If the investigator feels the adverse experience is serious, a Serious Adverse Experience form must be completed within 24 hours of event notification. A serious adverse experience (SAE) is defined as any adverse experience that is significantly life threatening and/or results in death, permanent disability, hospitalization or prolongation of hospitalization, myositis/myopathy, or hepatitis.

*** Variables not available in Public Use Data Set**

ACCORD *INTENSIVE* BLOOD PRESSURE MANAGEMENT FORM

Participant ID MASKID [affix ID label here]

Acrostic *

Data Entered By

Date Entered

Date of Visit * / / Month Day Year

Visit Code VISIT

Form Completed by *

Part I. Sitting Blood Pressures and Heart Rate

1. Check here if measurement not performed using study automated BP device: 1 ☐ NOTDEV

	2. **Systolic BP**	3. **Diastolic BP**	4. **Heart Rate**
First Measure	mmHg	mmHg	bpm
Second Measure	mmHg	mmHg	bpm
Third Measure	mmHg	mmHg	bpm
Average of Three	1 mmHg	1 mmHg	1 bpm

Part II. Treatment Algorithm

5. What is the current SBP? CURRSBP	**Protocol determined action (enter in Part III)**
1 ☐ ≥ 120 mmHg Ð	
Is this a milepost visit? MILEPST (*Milepost visits are F04, F08, F12, F16, F20, F24, F36, F48, F60, F72, F84 ,and F96)* 1 ☐ Yes →	Add medication
2 ☐ No →	Add medication or increase dose
2 ☐ < 120 mmHg →	No Action Required

Part III. Treatment Changes

6. Were protocol determined changes in participant therapy indicated at this visit? *(Please complete the **BP Medications Log**)*

INDPC

1 ☐ Yes, add medication ***(Milepost Visits)*** →

Was a medication added? MEDADD
1 ☐ Yes
2 ☐ No →
*(If no, must complete **BP Milepost Exemption Form**)*

2 ☐ Yes, add medication or increase dose →

3 ☐ No, no change required

Were changes made? MEDCHG
1 ☐ Yes
2 ☐ No →

Specify reason(s) that changes were not made (check all that apply):

1 ☐ Particip PARTREF

1 ☐ Previous intolei PREVINT

1 ☐ Blood pressure too low (Orthostatic Hypotension)

1 ☐ Addressed adherence problem ADDADH

1 ☐ Adverse experience* (specify) → ADVEXP *

1 ☐ Other (specify) → OTHER *

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* Variables not available in Public Use Data Set
1 Available in Analysis Data Set: BloodPressure

ACCORD STANDARD BLOOD PRESSURE MANAGEMENT FORM

Participant ID: MASKID [affix ID label here]

Acrostic: *

Data Entered By

Date Entered

Date of Visit: * Month / Day / Year

Visit Code: VISIT

Form Completed by: *

Part I. Sitting Blood Pressures and Heart Rate

1. Check here if measurement not performed using study automated BP device: 1 ☐ NOTDEV

	2. Systolic BP	3. Diastolic BP	4. Heart Rate
First Measure	mmHg	mmHg	bpm
Second Measure	mmHg	mmHg	bpm
Third Measure	mmHg	mmHg	bpm
Average of Three	1 mmHg	1 mmHg	1 bpm

Part II. Treatment Algorithm

5. What is the current SBP? CURRSBP	Protocol determined action (enter in Part III)
1 ☐ ≥ 160 mmHg →	Add medication or increase dose
2 ☐ 140 – 159 mmHg ↓	
Was previous SBP ≥ 140? PREV140 (If Baseline Visit answer 'No') 1 ☐ Yes →	Add medication or increase dose
2 ☐ No →	No Action Required
3 ☐ 135 – 139 mmHg →	No Action Required
4 ☐ 130 – 134 mmHg ↓	
Was previous SBP ≥ 135? PREV135 (If Baseline Visit answer 'No') 1 ☐ Yes →	No Action Required
2 ☐ No →	Remove medication or decrease dose
5 ☐ ≤ 129 mmHg →	Remove medication or decrease dose

Part III. Treatment Changes

6. Were protocol determined changes in participant therapy indicated at this visit? (Please complete the BP Medications Log)

1 ☐ Yes, add medication or increase dose → INDPC

2 ☐ Yes, remove medication or decrease dose →

3 ☐ No, no change required

Were these changes made? MEDCHG

1 ☐ Yes

2 ☐ No →

Specify reason(s) that changes were not made (check all that apply):

1 ☐ Baseline Visit

1 ☐ Participant Refusal PARTREF

1 ☐ Blood pressure too low (Orthostatic Hypotension)

1 ☐ Adverse experience* (specify) ADVEXP *

1 ☐ Other (specify) → * OTHER

1 ☐ Previous intolerance

1 ☐ Addressed adherence ADDADH

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*** Variables not available in Public Use Data Set**
1 Available in Analysis Data Set: BloodPressure

ACCORD BLOOD PRESSURE TRIAL MEDICATIONS LOG

Participant ID MASKID [affix ID label here] Acrostic * Data Entered By

Date of Visit * Month / Day / Year Visit Code VISIT Form Completed by * Date Entered

Contact Type

Indicate below the setting of this participant contact. CONTACT

1 Phone/Fax/Email 2 In person visit (in clinic)

Last Reported Visit Code XBPMEDS

Blood Pressure Medications 1 Participant is not taking antihypertensive medications

Medication Name (BP_MED)	Last Reported Dosage (TDD_ENTRY, RANGE_ENTRY)	Adherence (percentage of the time) (ADHERE)	Action Taken at this visit (ACTION)	Adjustments Dosage (TDD_EXIT, RANGE_EXIT)	Check here if study meds adjusted due to side effects (ADJUST)
Date Last Reported Month/Day/Year	mg /Day	1 All or almost all (80-100%) 2 Some (1-79%) 3 None (0%) 4 > Prescribed (100%)	1 No change 2 Discontinued 3 Dose Modified 4 New Medication	mg /Day	1 Yes*
Date Last Reported Month/Day/Year	mg /Day	1 All or almost all (80-100%) 2 Some (1-79%) 3 None (0%) 4 > Prescribed (100%)	1 No change 2 Discontinued 3 Dose Modified 4 New Medication	mg /Day	1 Yes*
Date Last Reported Month/Day/Year	mg /Day	1 All or almost all (80-100%) 2 Some (1-79%) 3 None (0%) 4 > Prescribed (100%)	1 No change 2 Discontinued 3 Dose Modified 4 New Medication	mg /Day	1 Yes*
Date Last Reported Month/Day/Year	mg /Day	1 All or almost all (80-100%) 2 Some (1-79%) 3 None (0%) 4 > Prescribed (100%)	1 No change 2 Discontinued 3 Dose Modified 4 New Medication	mg /Day	1 Yes*

** **If the investigator feels the adverse experience is serious, a Serious Adverse Experience form must be completed within 24 hours of event notification. A serious adverse experience (SAE) is defined as any adverse experience that is significantly life threatening and/or results in death, permanent disability, hospitalization or prolongation of hospitalization, myositis/myopathy, or hepatitis.*

Total Number of Pages Completed *

*** Variables not available in Public Use Data Set**

ACCORD LIPID MEDICATIONS MANAGEMENT FORM

Participant ID	MASKID [affix ID label here]	Acrostic	*	Data Entered By
Date of Visit	* / / (Month, Day, Year)	Visit Code	VISIT .	Form Completed by *	Date Entered

Contact Type

1. Indicate below the setting of this participant contact. CONTACT

1 ☐ Phone/Fax/Email 2 ☐ In person visit (in clinic)

Part I. Open Label Therapy

	Medication Name	Prescription at Visit Entry	Adherence	Prescription at Visit Exit	Study meds adjusted due to side effects?
2.	Simvastatin (Zocor)	Dose: ZTDDOSENT mg; Times/Day:	1 ☐ All or almost all (80-100%) 2 ☐ Some (1-79%) 3 ☐ None (0%) ZADHERE 4 ☐ > Prescribed (100%)	Dose: ZTDDOSEXT mg; Times/Day: 1 ☐ No Change*	ZADJUST 1 ☐ Yes* 2 ☐ No
3.	Other lipid lowering: OTHLL	Dose: * mg; Times/Day: *	1 ☐ All or almost all (80-100%) 2 ☐ Some (1-79%) 3 ☐ None (0%) LLADHERE 4 ☐ > Prescribed (100%)	Dose: * mg; Times/Day: * 1 ☐ No Change*	* 1 ☐ Yes* 2 ☐ No

4. If not on simvastatin at visit exit, please specify reason (check all that apply):

1 ☐ Participant refusal ZREFUSE

1 ☐ Previous intolerance ZPINTOL

1 ☐ On another lipid lowering drug ZOLLDRUG

1 ☐ Monitored LDL-c < 40 mg/dL ZMONITORED

1 ☐ Adverse Experience* (specify) → ZADVEXP *

1 ☐ Other (specify) → ZOTHER *

Part II. Blinded Therapy

	Medication Name	At Visit Entry: Dose	At Visit Entry: Adherence
5.	Fenofibrate or Placebo	FDOSENT 1 ☐ Full 2 ☐ Reduced 3 ☐ None	1 ☐ All or almost all (80-100%) 2 ☐ Some (1-79%) 3 ☐ None (0%) FADHERE 4 ☐ > Prescribed (100%)

6. Dose of blinded therapy at visit exit? FDOSEXT

1 ☐ Full

2 ☐ Reduced

3 ☐ None →

If not on blinded therapy, please specify reason *(check all that apply)*:

1 ☐ Participant refusal FREFUSE

1 ☐ Previous intolerance FPINTOL

1 ☐ On another lipid lowering drug FOLLDRUG

1 ☐ Baseline Visit FBASELIN

1 ☐ Adverse Experience* (specify) → FADVEXP *

1 ☐ Other (specify) → FOTHER *

**If the investigator feels the adverse experience is serious, a Serious Adverse Experience form must be completed within 24 hours of event notification. A serious adverse experience (SAE) is defined as any adverse experience that is significantly life threatening and/or results in death, permanent disability, hospitalization or prolongation of hospitalization, myositis/myopathy, or hepatitis.*

* Variables not available in Public Use Data Set

ACCORD HEALTH UTILITIES INDEX FORM

Participant ID	MASKID [affix ID label here]	Acrostic	*	Data Entered By
Date of Visit	* / / (Month Day Year)	Visit Code	VISIT	Form Completed by *	Date Entered

Instructions: This questionnaire contains a set of questions which ask about various aspects of your health. When answering these questions please think about your health and your ability to do things on a day-to-day basis, during the past 4 weeks. To define the 4 week period, please think about what the date was 4 weeks ago and recall the major events that you have experienced during this period. Please focus your answers on your overall abilities, disabilities and how you felt during the past 4 weeks.

You may feel that some of these questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar; please excuse the apparent overlap and answer each question independently.

Please read each question and consider your answers carefully. For each question, please select one answer that best describes your level of ability or disability during the past 4 weeks. Please indicate the selected answer by checking the box beside the answer.

All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities and feelings.

1. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to read ordinary newsprint? **1, 2***

1☐ a. Able to see well enough without glasses or contact lenses.

2☐ b. Able to see well enough with glasses or contact lenses.

3☐ c. Unable to see well enough even with glasses or contact lenses.

4☐ d. Unable to see at all.

2. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to recognize a friend on the other side of the street? **1, 2***

1☐ a. Able to see well enough without glasses or contact lenses.

2☐ b. Able to see well enough with glasses or contact lenses.

3☐ c. Unable to see well enough even with glasses or contact lenses.

4☐ d. Unable to see at all.

3. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a group conversation with at least three other people? **1, 2***

1☐ a. Able to hear what was said without a hearing aid.

2☐ b. Able to hear what was said with a hearing aid.

3☐ c. Unable to hear what was said even with a hearing aid.

4☐ d. Unable to hear what was said, but did not wear a hearing aid.

5☐ e. Unable to hear at all.

*** Variables not available for Public Use Data Set**
1* – Responses used to calculate HUI3Scor
2* – Responses used to calculate HUI2pf

Acrostic						

4. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a conversation with one other person in a quiet room? **1, 2***

1☐ a. Able to hear what was said without a hearing aid.

2☐ b. Able to hear what was said with a hearing aid.

3☐ c. Unable to hear what was said even with a hearing aid.

4☐ d. Unable to hear what was said, but did not wear a hearing aid.

5☐ e. Unable to hear at all.

5. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking your own language with people who do not know you? **1, 2***

1☐ a. Able to be understood completely.

2☐ b. Able to be understood partially.

3☐ c. Unable to be understood.

4☐ d. Unable to speak at all.

6. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking with people who know you well? **1, 2***

1☐ a. Able to be understood completely.

2☐ b. Able to be understood partially.

3☐ c. Unable to be understood.

4☐ d. Unable to speak at all.

7. Which one of the following best describes how you have been feeling during the past 4 weeks? **1***

1☐ a. Happy and interested in life.

2☐ b. Somewhat happy.

3☐ c. Somewhat unhappy.

4☐ d. Very unhappy.

5☐ e. So unhappy that life was not worthwhile.

8. Which one of the following best describes the pain and discomfort you have experienced during the past 4 weeks? **1***

1☐ a. Free of pain and discomfort.

2☐ b. Mild to moderate pain or discomfort that prevented no activities.

3☐ c. Moderate pain or discomfort that prevented a few activities.

4☐ d. Moderate to severe pain or discomfort that prevented some activities.

5☐ e. Severe pain or discomfort that prevented most activities.

1* – Responses used to calculate HUI3Scor
2* – Responses used to calculate HUI2pf

Acrostic | | | | | |

9. Which one of the following best describes your ability, during the past 4 weeks, to walk? (Note: Walking equipment refers to mechanical supports such as braces, a cane,crutches, or a walker.) **1, 2***

- 1 ☐ a. Able to walk around the neighborhood without difficulty, and without walking equipment.
- 2 ☐ b. Able to walk around the neighborhood with difficulty; but did not require walking equipment or the help of another person.
- 3 ☐ c. Able to walk around the neighborhood with walking equipment, but without the help of another person.
- 4 ☐ d. Able to walk only short distances with walking equipment, and required a wheelchair to get around the neighborhood.
- 5 ☐ e. Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and required a wheelchair to get around the neighborhood.
- 6 ☐ f. Unable to walk at all.

10. Which one of the following best describes your ability, during the past 4 weeks, to use your hands and fingers? (Note: Special tools refers to hooks for buttoning clothes, gripping devices for opening jar or lifting small items, and other devices to compensate for limitations of hand or fingers.) **1***

- 1 ☐ a. Full use of hands and ten fingers.
- 2 ☐ b. Limitations in the use of hand or fingers, but did not require special tools or the help of another person.
- 3 ☐ c. Limitations in the use of hands or fingers, independent with use of special tools (did not require the help of another person).
- 4 ☐ d. Limitations in the use of hands or fingers, required the help of another person for some tasks (not independent even with use of special tools).
- 5 ☐ e. Limitations in the use of hands or fingers, required the help of another person for most tasks (not independent even with use of special tools).
- 6 ☐ f. Limitations in the use of hands or fingers, required the help of another person for all tasks (not independent even with use of special tools).

11. Which one of the following best describes your ability, during the past 4 weeks, to remember things? **1, 2***

- 1 ☐ a. Able to remember most things.
- 2 ☐ b. Somewhat forgetful.
- 3 ☐ c. Very forgetful.
- 4 ☐ d. Unable to remember anything at all.

1* – Responses used to calculate HUI3Scor
2* – Responses used to calculate HUI2pf

Acrostic						

12. Which one of the following best describes your ability, during the past 4 weeks, to think and solve day to day problems? 1, 2*

- 1☐ a. Able to think clearly and solve day to day problems.
- 2☐ b. Had a little difficulty when trying to think and solve day to day problems.
- 3☐ c. Had some difficulty when trying to think and solve day to day problems.
- 4☐ d. Had great difficulty when trying to think and solve day to day problems.
- 5☐ e. Unable to think or solve day to day problems.

13. Which one of the following best describes your ability, during the past 4 weeks, to perform basic activities? 2*

- 1☐ a. Eat, bathe, dress and use the toilet normally.
- 2☐ b. Eat, bathe, dress and use the toilet independently with difficulty.
- 3☐ c. Required mechanical equipment to eat, bathe, dress or use the toilet independently.
- 4☐ d. Required the help or another person to eat, bathe, dress or use the toilet.

14. Which one of the following best describes how you have been feeling during the past 4 weeks?

- 1☐ a. Generally happy and free from worry. 2*
- 2☐ b. Occasionally fretful, angry, irritable, anxious or depressed.
- 3☐ c. Often fretful, angry, irritable, anxious or depressed.
- 4☐ d. Extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help.

15. Which one of the following best describes the pain or discomfort you have experienced during the past 4 weeks? 2*

- 1☐ a. Free of pain and discomfort.
- 2☐ b. Occasional pain or discomfort. Discomfort relieved by non-prescription drugs or self-control activity without disruption of normal activities.
- 3☐ c. Frequent pain or discomfort. Discomfort relieved by oral medicines with occasional disruption of normal activities.
- 4☐ d. Frequent pain or discomfort; frequent disruption of normal activities. Discomfort required prescription narcotics for relief.
- 5☐ e. Severe pain or discomfort. Pain not relieved by drugs and constantly disrupted normal activities.

1* – Responses used to calculate HUI3Scor
2* – Responses used to calculate HUI2pf

ACCORD COST SUBSTUDY FORM

Participant ID	MASKID [affix ID label here]	Acrostic	*
Date of Visit	* ___ / ___ / ___ (Month Day Year)	Visit Code	VISIT ___ . ___
Form Completed by	*	Data Entered By	
		Date Entered	

Contact Type

1. Indicate below the setting of this participant contact. **CONTTYPE**
   - 1 ☐ Phone/Fax/Email
   - 2 ☐ In person visit (in clinic)

Date of last cost data ascertainment: ___ / ___ / ___ (Month Day Year)

(Refer to this date when inquiring below about events that have occurred or procedures that were performed since the last time cost data were collected.)

Treatments or Procedures

2. Have you been admitted to the hospital since ***[date of last cost data ascertainment]*** **ADMHOSP**

1 ☐ Yes ➔ **ADMITN**

List the approximate date of the last 5 admissions	Hospital Name	Reason for admission
* ___ / ___ / ___ (Month Day Year)	*	*
Was this admission reported as an Outcome or SAE as well? 1 ☐ Yes 2 ☐ No *		
* ___ / ___ / ___ (Month Day Year)	*	*
Was this admission reported as an Outcome or SAE as well? 1 ☐ Yes 2 ☐ No *		
* ___ / ___ / ___ (Month Day Year)	*	*
Was this admission reported as an Outcome or SAE as well? 1 ☐ Yes 2 ☐ No *		
* ___ / ___ / ___ (Month Day Year)	*	*
Was this admission reported as an Outcome or SAE as well? 1 ☐ Yes 2 ☐ No *		
* ___ / ___ / ___ (Month Day Year)	*	*
Was this admission reported as an Outcome or SAE as well? 1 ☐ Yes 2 ☐ No *		

2 ☐ No

3. How many times did you visit your physician or receive outpatient treatment in the last 30 days? ___ ___ **TREATTIMES** (number of times)

   Insert "0" for no visits

*** Variables not available in Public Use Data Set**

Acrostic

Treatments or Procedures continued

4. Have you had any diagnostic tests as an outpatient since *[date of last cost data ascertainment]*? DAIGTESTS

1☐ Yes → 1☐ Heart Test HEARTTEST (e.g., ECG, echo, or stress test) 1☐ X-ray XRAY 1☐ Angiogram ANGIO (catheterization) 1☐ CT/MRI CTMRI

2☐ No 1☐ Other (specify) DIAGOTHE *

5. Have you participated in one of the following rehabilitation programs since *[date of last cost data ascertainment]*?

(a) Cardiac Rehabilitation: 1☐ Yes 2☐ No	(b) Stroke Rehabilitation: 1☐ Yes 2☐ No
CARDREHAB	STROKREHAB

6. On average since your last visit, how many visits from a home health nurse have you had in a typical week? HMVISITS (number of visits/week) *Insert "0" for no visits*

Insurance Status

7. "Which of the following best describes your current type of insurance coverage?" (mark all that apply)

1☐ Medicare INS_COVER 1☐ Medicaid 1☐ VA 1☐ Tricare/CHAMPVA 1☐ Provincial Health Insurance Plan

1☐ Private/Commercial 1☐ HMO 1☐ Don't Know 1☐ Uninsured

DK_UNINS

8. "Do you have full or partial drug benefits under your insurance or Provincial health plan?"

1☐ Yes 2☐ No 3☐ Don't Know 4☐ Uninsured DRUGBENE

* Variables not available in Public Use Data Set

ACCORD HEALTH RELATED QUALITY OF LIFE FORMS

Participant Name

(To be completed by study staff.)

Participant ID	MASKID [affix ID label here]	Acrostic	*	Data Entered By
Date of Visit	* / / (Month, Day, Year)	Visit Code	VISIT .	Date Entered
Form Reviewed by	*			

* Variables not available in Public Use Data Set

ACCORD TREATMENT SATISFACTION FORM

This section is about your experiences with your current diabetes treatment, over the past 2 WEEKS. For each question, please mark the one box that describes you best.

1. How satisfied are you with your current treatment?

Very satisfied			**TS01**			Very dissatisfied
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐

2. How often have you felt that your blood sugars have been unacceptably high recently?

Most of the time			**TS02**			None of the time
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐

3. How often have you felt that your blood sugars have been unacceptably low recently?

Most of the time			**TS03**			None of the time
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐

4. How convenient have you been finding your treatment to be recently?

Very convenient			**TS04**			Very inconvenient
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐

5. How flexible have you been finding your treatment to be recently?

Very flexible			**TS05**			Very inflexible
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐

6. How satisfied are you with your understanding of your diabetes?

Very satisfied			**TS06**			Very dissatisfied
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐

7. How satisfied would you be to continue with your present form of diabetes treatment?

Very satisfied			**TS07**			Very dissatisfied
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐

8. Would you recommend this form of treatment to someone else?

No, I would definitely not recommend this treatment			**TS08**			Yes, I would definitely recommend this treatment
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐

- See notes section for explanations of created variables

Acrostic						

Over the last 2 WEEKS, how often have you been bothered by any of the following problems?		***Not at all***	***Several days***	***More than half the days***	***Nearly Every day***
9. Little interest or pleasure in doing things	TS09	0 ☐	1 ☐	2 ☐	3 ☐
10. Feeling down, depressed or hopeless	TS10	0 ☐	1 ☐	2 ☐	3 ☐
11. Trouble falling or staying asleep, or sleeping too much	TS11	0 ☐	1 ☐	2 ☐	3 ☐
12. Feeling tired or having little energy	TS12	0 ☐	1 ☐	2 ☐	3 ☐
13. Poor appetite or overeating	TS13	0 ☐	1 ☐	2 ☐	3 ☐
14. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	TS14	0 ☐	1 ☐	2 ☐	3 ☐
15. Trouble concentrating on things, such as reading the newspaper or watching television	TS15	0 ☐	1 ☐	2 ☐	3 ☐
16. Moving or speaking so slowly that other people could have noticed or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	TS16	0 ☐	1 ☐	2 ☐	3 ☐
17. Thoughts that you would be better off dead or of hurting yourself in some way	TS17	0 ☐	1 ☐	2 ☐	3 ☐

- See notes section for explanations of created variables

Acrostic						

ACCORD HEALTH SURVEY FORM

Instructions for Completing the Questionnaire

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by marking the box that best represents your response.

Example

This is for your review. Do not answer this question. The questionnaire begins with the section *Your Health in General* below.

For each question you will be asked to mark a box in each line.

1. How strongly do you agree or disagree with each of the following statements?

	Strongly Agree	***Agree***	***Uncertain***	***Disagree***	***Strongly Disagree***
a. I enjoy listening to music	0☐	1☐	2☐	3☐	4☐
b. I enjoy reading magazines	0☐	1☐	2☐	3☐	4☐

Please begin answering questions now.

YOUR HEALTH IN GENERAL

1. In general, would you say your health is: **HS01**

Excellent	Very Good	Good	Fair	Poor
0☐	1☐	2☐	3☐	4☐

2. Compared to one year ago, how would you rate your health in general now? **HS02**

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
0☐	1☐	2☐	3☐	4☐

- See notes section for explanations of created variables

Acrostic						

3. The following questions are about activities you might do during atypical day. Does your health now limit you in these activities? If so, how much?

		Yes, Limited a lot	Yes, Limited a little	No, not limited at all
a. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	HS03A	0☐	1☐	2☐
b. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	HS03B	0☐	1☐	2☐
c. Lifting or carrying groceries	HS03C	0☐	1☐	2☐
d. Climbing **several** flights of stairs	HS03D	0☐	1☐	2☐
e. Climbing **one** flight of stairs	HS03E	0☐	1☐	2☐
f. Bending, kneeling, or stooping	HS03F	0☐	1☐	2☐
g. Walking **more than a mile**	HS03G	0☐	1☐	2☐
h. Walking **several hundred yards**	HS03H	0☐	1☐	2☐
i. Walking **one hundred yards**	HS03I	0☐	1☐	2☐
j. Bathing or dressing yourself	HS03J	0☐	1☐	2☐

4. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the **amount of time** you spent on work or other activities	HS04A	0☐	1☐	2☐	3☐	4☐
b. **Accomplished less** than you would like	HS04B	0☐	1☐	2☐	3☐	4☐
c. Were limited in the **kind of work** of other activitie	HS04C	0☐	1☐	2☐	3☐	4☐
d. Had **difficulty** performing the work or other activities (for example, it took extra effort)	HS04D	0☐	1☐	2☐	3☐	4☐

5. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the **amount of time** you spent on work or other activities	HS05A	0☐	1☐	2☐	3☐	4☐
b. **Accomplished less** than you would like	HS05B	0☐	1☐	2☐	3☐	4☐
c. Did work or other activities **less carefully** than usi	HS05C	0☐	1☐	2☐	3☐	4☐

- See notes section for explanations of created variables

Acrostic						

6. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? HS06

Not at all	Slightly	Moderately	Quite a bit	Extremely
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

7. How much bodily pain have you had during the past 4 weeks? HS07

None	Very Mild	Mild	Moderate	Severe	Very Severe
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

8. During the **past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)? HS08

Not at all	Slightly	Moderately	Quite a bit	Extremely
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

9. These question are about how you feel and how things have been with you during the **past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past 4 weeks**....

		All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a. did you feel full of life?	HS09A	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
b. have you been very nervous?	HS09B	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
c. have you felt so down in the dumps nothing could cheer you up?	HS09C	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
d. have you felt calm and peaceful?	HS09D	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
e. did you have a lot of energy?	HS09E	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
f. have you felt downhearted and depressed?	HS09F	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
g. did you feel worn out?	HS09G	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
h. have you been happy?	HS09H	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
i. did you feel tired?	HS09I	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

10. During the **past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)? HS10

All of the time	Most of the time	Some of the time	A little of the time	None of the time
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

- See notes section for explanations of created variables

Acrostic						

11. How TRUE or FALSE is each of the following statements for you?		Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other peo	HS11A	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
b. I am as healthy as anybody I know	HS11B	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
c. I expect my health to get worse	HS11C	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
d. My health is excellent	HS11D	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

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- See notes section for explanations of created variables

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ACCORD SIDE EFFECT AND SYMPTOM INDEX

DURING THE PAST MONTH, have you experienced this symptom or feeling?

Please mark either 0☐ No 1☐ Yes

If YES, answer "How distressing was it?" Either → **Not at all** 0☐ **Somewhat** 1☐ **Moderately** 2☐ **Very Much** 3☐ **Extremely** 4☐

Symptom or Feeling?				***How distressing was it? (Check one box)*** Not at all	Somewhat	Moderately	Very Much	Extremely
1. Increase in hunger	SES01	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
2. Cold sweat, clammy skin	SES02	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
3. Being thirsty	SES03	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
4. Gaining weight	SES04	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
5. Skin infections or ulcers	SES05	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
6. Nauseous, queasy, sick to stomach	SES06	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
7. Having to urinate frequently	SES07	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
8. Decrease in appetite	SES08	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
9. High blood sugar reacti	SES09	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
10. Sweating, perspiring	SES10	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
11. Headaches	SES11	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
12. Trembling	SES12	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
13. Drinking a lot of fluids	SES13	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
14. Feeling over weight	SES14	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
15. Low blood sugar reaction	SES15	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
16. Itching, scratching	SES16	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
17. Foot cramps, foot pain	SES17	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
18. Impaired or worsening vision	SES18	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
19. Heart pounding, beating hard	SES19	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
20. Crabby, short-tempered	SES20	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
21. Losing weight	SES21	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐
22. Sweet taste in mouth	SES22	0☐ No	1☐ Yes→ *	0☐	1☐	2☐	3☐	4☐

- See notes section for explanations of created variables
*** Variables not available in Public Use Data Set**

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Symptom or Feeling?		No	Yes	Not at all	Somewhat	Moderately	Very Much	Extremely
				How distressing was it? (Check one box)				
23. Drowsy or sleepy	SES23	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
24. Dizziness when standin	SES24	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
25. Dryness of mouth, eyes, or nose	SES25	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
26. General weakness or fatigue	SES26	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
27. Confusion	SES27	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
28. Heartburn	SES28	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
29. Shortness of breath or breathing hard	SES29	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
30. Inability to sleep, insomnia	SES30	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
31. Lethargy, no energy to do things	SES31	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
32. Diarrhea	SES32	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
33. Nightmares	SES33	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
34. Blurred or double visior	SES34	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
35. Lightheadedness	SES35	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
36. Tired, feeling weary	SES36	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
37. Constipation	SES37	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
38. Fast pulse, rapid heartbeat, palpitations	SES38	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
39. Numbness or tingling or hands or feet	SES39	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
40. Swelling of feet or ankl	SES40	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
41. Muscle cramps	SES41	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
42. Vomiting	SES42	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
43. Skin rash	SES43	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
44. Cold hands or feet	SES44	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
45. Vertigo, sensation of spinning	SES45	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
46. Flushing, sensation of heat	SES46	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
47. Abdominal cramps	SES47	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
48. Numbness of lips or mc	SES48	0 ☐ No	1 ☐ Yes➔ *	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

- See notes section for explanations of created variables
* Variables not available in Public Use Data Set

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Symptom or Feeling?				How distressing was it? (Check one box) Not at all	Somewhat	Moderately	Very Much	Extremely
49. Getting up often during the night to urinate	SES49	0☐ No	1☐ Yes➔ *	0☐	1☐	2☐	3☐	4☐
50. Wheezing, lung congestion or difficulty breathing	SES50	0☐ No	1☐ Yes➔ *	0☐	1☐	2☐	3☐	4☐
51. Pains in legs or calves when walking	SES51	0☐ No	1☐ Yes➔ *	0☐	1☐	2☐	3☐	4☐
52. Tightness or pain in chest during exercise or emotional stress	SES52	0☐ No	1☐ Yes➔ *	0☐	1☐	2☐	3☐	4☐
53. Difficulty concentrating	SES53	0☐ No	1☐ Yes➔ *	0☐	1☐	2☐	3☐	4☐
54. Difficulty remembering	SES54	0☐ No	1☐ Yes➔ *	0☐	1☐	2☐	3☐	4☐
55. Cough	SES55	0☐ No	1☐ Yes➔ *	0☐	1☐	2☐	3☐	4☐
56. Hives or swelling of body or facial areas	SES56	0☐ No	1☐ Yes➔ *	0☐	1☐	2☐	3☐	4☐
57. Difficulty thinking	SES57	0☐ No	1☐ Yes➔ *	0☐	1☐	2☐	3☐	4☐
58. Disorientation (suddenly not knowing what's going on)	SES58	0☐ No	1☐ Yes➔ *	0☐	1☐	2☐	3☐	4☐
59. Edema, fluid retention	SES59	0☐ No	1☐ Yes➔ *	0☐	1☐	2☐	3☐	4☐
60. Vision problems	SES60	0☐ No	1☐ Yes➔ *	0☐	1☐	2☐	3☐	4☐

DTSQ[1]

PHQ9[1]

Physical[1]

Mental[1]

brazindex[1]

SES[1]

- See notes section for explanations of created variables
* Variables not available in Public Use Data Set
1 HRQL Scores

ACCORD DIET QUESTIONNAIRE FORM

Patient Name

(To be completed by study staff.)

Participant ID	MASKID [affix ID label here]	Acrostic *	Data Entered By
Date of Visit * Month / Day / Year	Visit Code VISIT .	Form Reviewed by *	Date Entered

* Variables not available in Public Use Data Set

Acrostic						

PLEASE ANSWER THE FOLLOWING QUESTIONS ABOUT THE FOOD YOU ATE DURING THE PAST 3 MONTHS.

In the past 3 months...

1. Did you eat chicken? ATECHKN
   - 1☐ Yes
   - 2☐ No
   - 3☐ Don't Know

(Please answer both questions.)

When you ate chicken,

	Usually	Often	Some-times	Rarely or Never	Don't Know
1a. How often was it fried? Would you say... ATECKFRY	1☐	2☐	3☐	4☐	5☐
1b. How often did you take off the skin? ATECKSKN	1☐	2☐	3☐	4☐	5☐

2. Did you eat red meat such as beef, pork, or lamb? ATERDMT
   - 1☐ Yes
   - 2☐ No
   - 3☐ Don't Know

	Usually	Often	Some-times	Rarely or Never	Don't Know
2a. When you ate red meat, how often did you trim all the visible fat? ATERDFAT	1☐	2☐	3☐	4☐	5☐

3. Did you eat ground meat? ATEGDMT
   - 1☐ Yes
   - 2☐ No
   - 3☐ Don't Know

	Usually	Often	Some-times	Rarely or Never	Don't Know
3a. When you ate ground meat, how often did you choose extra lean ground meat? ATEGMFAT	1☐	2☐	3☐	4☐	5☐

4. Did you eat fish? ATEFISH
   - 1☐ Yes
   - 2☐ No
   - 3☐ Don't Know

	Usually	Often	Some-times	Rarely or Never	Don't Know
4a. When you ate fish, how often was it fried? ATEFHFRY	1☐	2☐	3☐	4☐	5☐

5. Did you have at least one vegetarian dinner or main meal, that is, without meat, fish, eggs or cheese? ATEVEGE
   - 1☐ Yes
   - 2☐ No
   - 3☐ Don't Know

	Usually	Often	Some-times	Rarely or Never	Don't Know
5a. How often did you have a vegetarian dinner? ATEVGDIN	☐	2☐	3☐	4☐	5☐

- See notes section for explanations of created variables

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In the past 3 months...

	Usually	Often	Some-times	Rarely or Never	Don't Know
6. Did you eat spaghetti or noodles? ATEPAST					
1☐ Yes — 6a. When you ate spaghetti or noodles, how often did you eat them plain, or with a red sauce or tomato sauce without meat? ATEPTPLN	1☐	2☐	3☐	4☐	5☐
2☐ No					
3☐ Don't Know					
7. Did you eat cooked vegetables? ATECVEG					
1☐ Yes — *(Please answer both questions.)* 7a. When you ate cooked vegetables, how often did you add butter, margarine, or other fat? ATECVFAT	1☐	2☐	3☐	4☐	5☐
2☐ No — 7b. How often were they fried? ATECVFRY	1☐	2☐	3☐	4☐	5☐
3☐ Don't Know					
8. Did you eat potatoes? ATEPOTA					
1☐ Yes — 8a. When you ate potatoes, how often were they fried, like French fries or hash browns? ATEPTFRY	1☐	2☐	3☐	4☐	5☐
2☐ No — Go to Question 10					
3☐ Don't Know — Go to Question 10					
9. Did you eat boiled or baked potatoes? ATEBPOT					
1☐ Yes — 9a. When you ate boiled or baked potatoes, how often did you eat them without any butter, margarine or sour cream? ATEBPFAT	1☐	2☐	3☐	4☐	5☐
2☐ No					
3☐ Don't Know					

- See notes section for explanations of created variables

Acrostic

In the past 3 months...

	Usually	Often	Sometimes	Rarely or Never	Don't Know

10. Did you eat green salads? ATEGSAL

1☐ Yes
2☐ No
3☐ Don't Know

(Please answer both questions.)

	Usually	Often	Sometimes	Rarely or Never	Don't Know
10a. How often did you use lowfat or nonfat salad dressing? ATEGSFAT	1☐	2☐	3☐	4☐	5☐
10b. When you ate green salads, how often did you use no dressing? ATEGSDRS	1☐	2☐	3☐	4☐	5☐

11. Did you eat bread, rolls, or muffins? ATEROLL

1☐ Yes
2☐ No
3☐ Don't Know

	Usually	Often	Sometimes	Rarely or Never	Don't Know
11a. When you ate bread, rolls or muffins, how often did you eat them without butter or margarine? ATERLFAT	1☐	2☐	3☐	4☐	5☐

12. Did you drink milk or use milk on cereal? ATEMILK

1☐ Yes
2☐ No
3☐ Don't Know

	Usually	Often	Sometimes	Rarely or Never	Don't Know
12a. When you had milk, how often was it 1% or nonfat milk? ATEMKFAT	1☐	2☐	3☐	4☐	5☐

13. Did you eat cheese, including cheese on sandwiches or in cooking? ATECHEZ

1☐ Yes
2☐ No
3☐ Don't Know

	Usually	Often	Sometimes	Rarely or Never	Don't Know
13a. When you ate cheese, how often was it specially-made, low-fat cheese? ATECZFAT	1☐	2☐	3☐	4☐	5☐

14. Did you eat dessert? ATEDSRT

1☐ Yes
2☐ No
3☐ Don't Know

	Usually	Often	Sometimes	Rarely or Never	Don't Know
14a. When you ate dessert, how often did you eat only fruit? ATEDTFAT	1☐	2☐	3☐	4☐	5☐

- See notes section for explanations of created variables

Acrostic						

In the past 3 months...

	Usually	Often	Some-times	Rarely or Never	Don't Know
15. Did you eat home-baked cookies, cakes or pies? **ATEHMBK**					
1☐ Yes — 15a. When you ate home baked cookies, cakes or pies, how often were they made with less butter, margarine or oil than the recipe called for? **ATEHBFAT**	1☐	2☐	3☐	4☐	5☐
2☐ No					
3☐ Don't Know					
16. Did you eat frozen desserts like ice cream or sherbet? **ATEFZDT**					
1☐ Yes — 16a. When you ate frozen desserts, how often did you choose frozen yogurt, sherbet, or low-fat or nonfat ice cream? **ATEFZFAT**	1☐	2☐	3☐	4☐	5☐
2☐ No					
3☐ Don't Know					
17. Did you eat snacks between meals? **ATESNACK**					
1☐ Yes — 17a. When you ate between meals, how often did you eat raw vegetables or fresh fruit? **ATESKFAT**	1☐	2☐	3☐	4☐	5☐
2☐ No					
3☐ Don't Know					
18. Did you sauté or pan fry any foods? **ATEPNFRY**					
1☐ Yes — 18a. When you sautéed or pan fried foods, how often did you use Pam ® or other non-stick spray instead of oil, margarine, or butter? **ATEPFPAM**	1☐	2☐	3☐	4☐	5☐
2☐ No					
3☐ Don't Know					

- See notes section for explanations of created variables

Acrostic						

	Usually	Often	Some-times	Rarely or Never	Don't Know
19. Did you use mayonnaise or mayonnaise-type spread? **ATEMAYO**					
1☐ Yes — 19a. When you used mayonnaise or mayonnaise-type spread, how often did you use low-fat or nonfat types?	1☐ **ATEMYFAT**	2☐	3☐	4☐	5☐
2☐ No					
3☐ Don't Know					

Substitution[1]

ModifyMeat[1]

AvoidFrying[1]

Replace[1]

AvoidFat[1]

Summary Score[1]

- See notes section for explanations of created variables
1 Diet Scores

ACCORD TRIAL

Modified CHAMPS Activities Questionnaire Form

Participant Name

(To be completed by study staff.)

Participant ID	MASKID [affix ID label here]	Acrostic	*
Date of Visit	* / / (Month Day Year)	Visit Code	VISIT
Form Reviewed by	*		
Data Entered By		Date Entered	

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Stanford Center for Research in Disease Prevention, Stanford University
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*** Variables not available in Public Use Data Set**

Acrostic						

INSTRUCTIONS: PLEASE READ CAREFULLY

Think about the past 4 weeks. The next few pages list various activities you might have done. Certain activities are done more frequently at different times of year, but we only want you to think about the last 4 weeks. Before you begin, please review the following steps and examples:

Step #1: Number of times each week

> For each activity, write in the space provided how many times each week, on average, you did that activity.

> If you did an activity less than once a week or not at all, please write a zero in the space provided.

> If you did not do an activity at least one time per week, skip step 2.

For example, if you did not do the activity at all or did it less than once a week during the past 4 weeks:

Example A **Step #1** **Step #2**

Activities:	**Number of times a week** (If less than 1 time per week or none, write "0")	*(When "Times a week" is "0", skip this part)* Less than 1 hour a week	1-2½ hours a week	3-4½ hours a week	5-6½ hours a week	7-8½ hours a week	9 hours a week
Mow Lawn	Times a week ☐☐ →	1☐	2☐	3☐	4☐	5☐	6☐

Step #2: Total Time, average, each week

> If you did the activity at least once a week, mark one box representing how much total time, on average, you spent doing it each week. For example, if you go to the senior center 30 minutes on Monday, 30 minutes on Wednesday, and 30 minutes on Friday for a total of 1½ hours each week:

Example B **Step #1** **Step #2**

Activities:	**Number of times a week** (If less than 1 time per week or none, write "0")	Less than 1 hour a week	1-2½ hours a week	3-4½ hours a week	5-6½ hours a week	7-8½ hours a week	9 hours a week
Go to the senior center	Times a week ☐☐ →	1☐	2☐	3☐	4☐	5☐	6☐

Acrostic						

Recreation and Hobbies:	Number of times a week (If less than 1 time per week or none, write "0")	Less than 1 hour a week	1-2½ hours a week	3-4½ hours a week	5-6½ hours a week	7-8½ hours a week	9 hours a week
1. Dance, such as square, folk, line, or ballroom (do not count aerobic dance here).	Times a week RH01TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
2. Play golf, riding a cart (count walking time only).	Times a week RH02TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
3. Play golf, carrying or pulling your equipment (count walking time only).	Times a week RH03TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
4. Play singles tennis (do not count doubles).	Times a week RH04TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
5. Play doubles tennis (do not count singles).	Times a week RH05TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
6. Skate (ice, roller, or in-line).	Times a week RH06TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
Work Around the House:							
7. Do heavy work around the house, such as washing windows or cleaning gutters.	Times a week WH01TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
8. Do light work around the house such as sweeping or vacuuming.	Times a week WH02TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
9. Do heavy gardening, such as spading or raking.	Times a week WH03TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐

- See notes section for explanations of created variables
* Variables not available in Public Use Data Set

Acrostic						

Work Around the House:		Number of times a week (If less than 1 time per week or none, write "0")	Less than 1 hour a week	1-2½ hours a week	3-4½ hours a week	5-6½ hours a week	7-8½ hours a week	9 hours a week
10.	Do light gardening, such as watering plants.	Times a week WH04TIME	* 1☐	2☐	3☐	4☐	5☐	6☐
Walking and Jogging, Including Treadmill:								
11▪	Walk leisurely for exercise or pleasure.	Times a week WJ01TIME	* 1☐	2☐	3☐	4☐	5☐	6☐
12▪	Walk to do errands, such as to/from a store or to take children to school (count walk time only).	Times a week WJ02TIME	* 1☐	2☐	3☐	4☐	5☐	6☐
13▪	Walk fast or briskly for exercise (do not count walking leisurely).	Times a week WJ03TIME	* 1☐	2☐	3☐	4☐	5☐	6☐
14▪	Jog or run.	Times a week WJ04TIME	* 1☐	2☐	3☐	4☐	5☐	6☐
Other Types of Exercise:								
15▪	Ride a bicycle or stationary cycle using legs only.	Times a week OE01TIME	* 1☐	2☐	3☐	4☐	5☐	6☐
16▪	Do aerobic machines involving arms and legs, such as rowing or cross-country ski machines.	Times a week OE02TIME	* 1☐	2☐	3☐	4☐	5☐	6☐
17▪	Do stair or step machine.	Times a week OE03TIME	* 1☐	2☐	3☐	4☐	5☐	6☐
18▪	Swim gently.	Times a week OE04TIME	* 1☐	2☐	3☐	4☐	5☐	6☐

▪ See notes section for explanations of created variables
*** Variables not available in Public Use Data Set**

Acrostic

Other Types of Exercise:		Number of times a week (If less than 1 time per week or none, write "0")	Less than 1 hour a week	1-2½ hours a week	3-4½ hours a week	5-6½ hours a week	7-8½ hours a week	9 hours a week
19••	Swim moderately or fast.	Times a week OE05TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
20••	Do water exercises (do not count other swimming).	Times a week OE06TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
21••	Do stretching or flexibility exercises (do not count yoga or Tai-chi).	Times a week OE07TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
22••	Do yoga or Tai-chi.	Times a week OE08TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
23••	Do aerobics or aerobic dancing.	Times a week OE09TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
24••	Do moderate to heavy strength training, such as hand-held weights of more than 5 lbs., weight machines or push-ups.	Times a week OE10TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
25••	Do light strength training, such as hand-held weights of 5 lbs. or less or elastic bands.	Times a week OE11TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
26.	Do general conditioning exercises, such as light calisthenics or chair exercises (do not count strength training).	Times a week OE12TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐
27.	Play basketball, soccer, or racquetball (do not count time on sidelines)	Times a week OE13TIME →	* 1☐	2☐	3☐	4☐	5☐	6☐

ExerCalExp[1]
ModExCalExp[1]

HoursAll[1]
HoursMod[1]
AnyMod[1]

- See notes section for explanations of created variables
* Variables not available in Public Use Data Set
1 Physical Activity Scores

ACCORD INTERVAL HISTORY/FOLLOW-UP FORM

Participant ID	MASKID [affix ID label here]	Acrostic	*	Data Entered By
Date of Visit	* / / (Month Day Year)	Visit Code	VISIT .	Form Completed by *	Date Entered

Contact Type

1. Indicate below the setting of this participant contact. CONTACT
   1 ☐ Phone/Fax/Email
   2 ☐ In person visit (in clinic)

2. What is this participant's current study treatment status? (see instructions on reverse for definitions of terms)

Glycemia Trial 1	***BP Trial*** 1	***Lipid Trial*** 1
1 ☐ Active Participant	1 ☐ Active Participant	1 ☐ Active Participant
2 ☐ Inactive Participant	2 ☐ Inactive Participant	2 ☐ Inactive Participant
	3 ☐ N/A	3 ☐ N/A

Date of last events ascertainment: / / (Month Day Year)

(Refer to this date when inquiring below about events that have occurred or procedures that were performed since the last time event data were collected.)

3. Have you experienced any of the following problems since ***[date of last events ascertainment]***?
   (a) Out of the ordinary severe muscle aches/pains EXPSMUAP
   1 ☐ Yes → Obtain CPK
   2 ☐ No
   (b) Dialysis (end-stage renal disease) *
   1 ☐ Yes → 1 ☐ Hemodialysis * 1 ☐ Peritoneal Dialysis *
   2 ☐ No

4. Have you been seen in an emergency room since ***[date of last events ascertainment]***? EMERVIST
   1 ☐ Yes → How many visits did you make to the emergency room? EMERVCNT umber of visits)
   Were any of these visits due to heart failure or fluid in your lungs? 1 ☐ Yes 2 ☐ No 3 ☐ Unknown LUNGS
   [For each ER visit, document in source notes whe... ...nd why visit was made.]
   2 ☐ No

* Variables not available in Public Use Data Set
1 Available in Analysis Data Set: ActivityStatus

Acrostic						

5. Have you been admitted to the hospital since ***[date of last events ascertainment]****?* HOSPVSIT

1☐ Yes → How many times were you admitted to the hospital? ADMITN ___ (number of times)

2☐ No

Were you hospitalized for, or did any of the following occur during hospitalization(s)?

- * 1☐ PTCI/PTCA/Atherectomy (with or without stenting)
- * ☐ CABG Surgery
- * 1☐ Carotid Endarterectomy
- * 1☐ Aneurysm Repair
- * 1☐ Lower Limb Amputation
- * 1☐ ESRD/Kidney Transplant (Peritoneal or hemodialysis)
- * 1☐ Peripheral Artery Revascularization
- * I☐ CHF
- * 1☐ Carotid Angioplasty (with or without stenting)
- * 1☐ MI (Heart Attack)
- * ☐ Unstable Angina
- * 1☐ Stroke
- * 1☐ Motor vehicle accident in which you were the driver
- * ☐ Other accident or injury (specify) → * ________
- * 1☐ Other (specify) → * ________

Note: For each admission, document in source notes when, where and why participant was admitted. Complete the appropriate EVENT OUTCOME FORM, if applicable. If this participant is part of the Cost Sub-study, then you should obtain a copy of the hospital discharge summary and send it to the Coordinating Center.

6. Since ***[date of last events ascertainment]*** have you had any of the following events and/or procedures without being admitted to a hospital?

Event	Response	Date of Event	Instruction
(a) MI (Heart Attack) *	1☐ Yes → 2☐ No	Date of Event: * __ __ / __ __ / __ __ (Month Day Year)	***Complete an MI REPORT FORM for each event.***
(b) Stroke *	1☐ Yes → 2☐ No	Date of Event: * __ __ / __ __ / __ __ (Month Day Year)	***Complete a STROKE REPORT FORM for each event.***
(c) Coronary Angioplasty (PTCA) (with or without stent) *	1☐ Yes → 2☐ No	Date of Event: * __ __ / __ __ / __ __ (Month Day Year)	***Complete a MISCELLANEOUS CARDIOVASCULAR OUTCOME REPORT FORM for each event.***
(d) Carotid artery angtioplasty (with or without stent) *	1☐ Yes → 2☐ No	Date of Event: * __ __ / __ __ / __ __ (Month Day Year)	***Complete a MISCELLANEOUS CARDIOVASCULAR OUTCOME REPORT FORM for each event.***
(e) Peripheral artery angioplasty (with or without stent) *	1☐ Yes → 2☐ No	Date of Event: * __ __ / __ __ / __ __ (Month Day Year)	***Complete a MISCELLANEOUS CARDIOVASCULAR OUTCOME REPORT FORM for each event.***

7. Has a physician diagnosed you as having heart failure or pulmonary edema since ***[date of last events ascertainment]****?* HARTFAIL

1☐ Yes → Based on review of medications, has this participant been prescribed new meds for treatment of diagnosed heart failure (such as diuretics, ACE inhibitors, beta blockers, or digitalis) since ***[date of last events ascertainment]****?* NEWMEDS Yes 2☐ No

2☐ No

* Variables not available in Public Use Data Set

Acrostic						

PHYSICAL EXAM

8. **Participant Weight:** WT_KG[2] Measurement recorded in: 1 ☐ pounds 2 ☐ kilograms

Sitting Blood Pressures and Heart Rate

COMPLETE BLOOD PRESSURE INFORMATION ONLY FOR LIPID TRIAL PARTICIPANTS OR FOR INACTIVE BP TRIAL PARTICIPANTS ON THIS FORM. For active BP trial participants, mark "N/A" here and complete blood pressure information on BLOOD PRESSURE MANAGEMENT FORM.

9. **Systolic BP** (Average of 3) *	10. **Diastolic BP** (Average of 3) *	11. **Heart Rate** (Average of 3) *
3 mmHg 1 ☐N/A	3 mmHg 1 ☐N/A	3 bpm 1 ☐N/A

Heart Failure Risk

12. Have you experienced any of the following problems since ***[date of last events ascertainment]***?

(a) Swelling of your feet, ankles, or legs? SWELLING	1 ☐ Yes → 2 ☐ No 3 ☐ Unknown	1 ☐ New or worsened 2 ☐ Unchanged or improved SWEDELTA
(b) Shortness of breath while lying, sitting or with minimal exertion? SHORTNES	1 ☐ Yes → 2 ☐ No 3 ☐ Unknown	1 ☐ New or worsened 2 ☐ Unchanged or improved SHODELTA
(c) The need to pass urine three or more times per night? URINE3X	1 ☐ Yes→ 2 ☐ No 3 ☐ Unknown	1 ☐ New or worsened 2 ☐ Unchanged or improved URIDELTA

Edema Exam

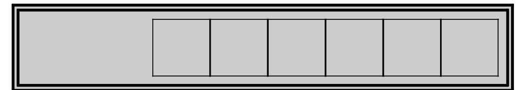
13. **Right Foot**	14. **Left Foot**
Grade Pre-tibial edema based on today's vist. (mark one only)	Grade Pre-tibial edema based on today's vist. (mark one only)
1 ☐ 1+ 2 ☐ 2+ C_RFPTED	1 ☐ 1+ 2 ☐ 2+ C_LFPTED
3 ☐ 3+ 4 ☐ 4+	3 ☐ 3+ 4 ☐ 4+
5 ☐ None 6 ☐ N/A	5 ☐ None 6 ☐ N/A

Chest Exam

15. **Complete only if any of the responses to 12 (a), (b), or (c) is 'Yes' or if edema was found on today's exam (grade of 1+ or greater).** CHEST_EXAM[4]

Auscultation of lungs:	1 ☐No rales	2 ☐Basilar rales only	3 ☐ Rales greater than basilar
Third heart sound present?	1 ☐Yes	2 ☐No	

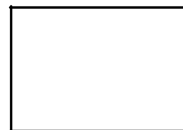
* Variables not available in Public Use Data Set
2 All units converted to metric system (kg or cm)
3 Available in Analysis Data Set: BloodPressure
4 Changed to combine two questions into yes/no response

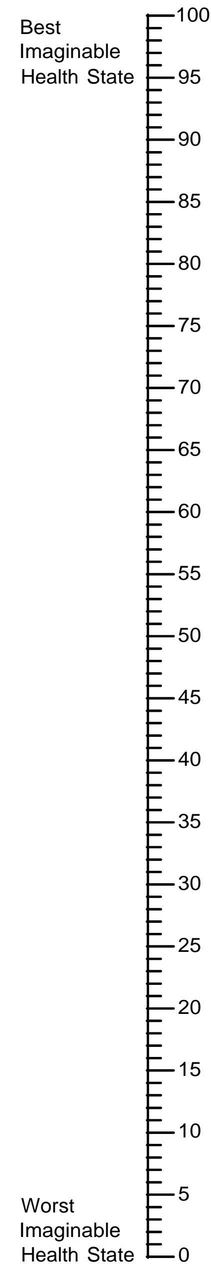


TO BE COMPLETED BY THE PARTICIPANT

Feeling Thermometer: To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

We would like for you to indicate on this scale, in your opinion, how good or bad your own health is **TODAY.** Please do this by drawing a line from the the center of the box below to whichever point on the scale indicates how good or bad your current health state is.





Score ___ FEELTHER

ACCORD ANNUAL FOLLOW-UP AND PHYSICAL EXAM FORM

Participant ID	MASKID [affix ID label here]	Acrostic	*	Data Entered By
Date of Visit	* / / (Month Day Year)	Visit Code	VISIT .	Form Completed by *	Date Entered

Remember to update the PARTICIPANT CONTACT INFORMATION FORM at this visit.

Contact Type

1. Indicate below the setting of this participant contact. CTTYPE

   1 ☐ Phone/Fax/Email   2 ☐ In person visit (in clinic)

2. What is this participant's current study treatment status? (see instructions on reverse for definitions of terms)

Glycemia Trial 1	***BP Trial*** 1	***Lipid Trial*** 1
1 ☐ Active Participant	1 ☐ Active Participant	1 ☐ Active Participant
2 ☐ Inactive Participant	2 ☐ Inactive Participant	2 ☐ Inactive Participant
	3 ☐ N/A	3 ☐ N/A

Follow-up Events Ascertainment

Date of last events ascertainment: ___ / ___ / ___ (Month Day Year)

(Refer to this date when inquiring below about events that have occurred or procedures that were performed since the last time event data were collected.)

3. Have you experienced any of the following problems since ***[date of last events ascertainment]***?

   (a) Out of the ordinary severe muscle aches/pains ACHES
   1 ☐ Yes → Obtain CPK
   2 ☐ No

   (b) Dialysis (end-stage renal disease) *
   1 ☐ Yes → 1 ☐ Hemodialysis * ; 1 ☐ Peritoneal Dialysis *
   2 ☐ No

4. Have you been seen in an emergency room since ***[date of last events ascertainment]***? ERROOM

   1 ☐ Yes → How many visits did you make to the emergency room? EMERVCNT (number of visits)

   Were any of these visits due to heart failure or fluid in your lungs? 1 ☐ Yes 2 ☐ No 3 ☐ U ERDUETO

   [For each ER visit, document in source notes when, where, and why visit was made.]

   2 ☐ No

* Variables not available in Public Use Data Set
1 Variables available in Analysis Data Set: Activity Status

Acrostic

5. Have you been admitted to the hospital since ***[date of last events ascertainment]***? HOSPITAL

1 ☐ Yes → How many times were you admitted to the hospital? ADMITTED (number of times)

2 ☐ No

Were you hospitalized for, or did any of the following occur during hospitalization(s)?

1 ☐ PTCI/PTCA/Atherectomy (with or without stenting) *
1 ☐ CABG Surgery *
1 ☐ Carotid Endarterectomy *
1 ☐ Aneurysm Repair *
1 ☐ Lower Limb Amputation *
1 ☐ ESRD/Kidney Transplant (Peritoneal or hemodialysis) *
1 ☐ Peripheral Artery Revascularization *
1 ☐ CHF *
1 ☐ Carotid Angioplasty (with or without stenting) *
1 ☐ MI (Heart Attack) *
1 ☐ Unstable Angina *
1 ☐ Stroke *
1 ☐ Motor vehicle accident in which you were the driver *
1 ☐ Other accident or injury (specify) → *
1 ☐ Other (specify) → * *

*

Note: For each admission, document in source notes when, where and why participant was admitted. Complete the appropriate EVENT OUTCOME FORM, if applicable. If this participant is part of the Cost Sub-study, then you should obtain a copy of the hospital discharge summary and send it to the Coordinating Center.

6. Since ***[date of last events ascertainment]*** have you had any of the following events or procedures without being admitted to a hospital?

Event	Response	Date of Event	Instruction
(a) MI (Heart Attack) *	1 ☐ Yes → 2 ☐ No	Date of Event: * __ __ / __ __ / __ __ (Month / Day / Year)	***Complete the MI REPORT FORM for each event.***
(b) Stroke *	1 ☐ Yes → 2 ☐ No	Date of Event: * __ __ / __ __ / __ __ (Month / Day / Year)	***Complete the STROKE REPORT FORM for each event.***
(c) Coronary Angioplasty (PTCA) (with or without stent) *	1 ☐ Yes → 2 ☐ No	Date of Event: * __ __ / __ __ / __ __ (Month / Day / Year)	***Complete a MISCELLANEOUS CARDIOVASCULAR OUTCOME REPORT FORM for each event.***
(d) Carotid artery angioplasty (with or without stent) *	1 ☐ Yes → 2 ☐ No	Date of Event: * __ __ / __ __ / __ __ (Month / Day / Year)	***Complete a MISCELLANEOUS CARDIOVASCULAR OUTCOME REPORT FORM for each event.***
(e) Peripheral artery angioplasty (with or without stent) *	1 ☐ Yes → 2 ☐ No	Date of Event: * __ __ / __ __ / __ __ (Month / Day / Year)	***Complete a MISCELLANEOUS CARDIOVASCULAR OUTCOME REPORT FORM for each event.***

7. Has a physician diagnosed you as having heart failure or pulmonary edema since ***[date of last events ascertainment]***? HARTFAIL

1 ☐ Yes → Based on review of medications, has this participant been prescribed new meds for treatment of diagnosed heart failure (such as diuretics, ACE inhibitors, beta blockers, or digitalis) since ***[date of last events ascertainment]***? 1 ☐ Yes 2 ☐ No NEWMEDS

2 ☐ No

Health Habits

[Ask the following question verbatim]

8. "Have you smoked cigarettes in the last 30 days?" 1 ☐ Yes 2 ☐ No SMOKED

* Variables not available in Public Use Data Set

Acrostic						

All data on this page available in Analysis Data Set: ConcomitantMeds

Concomitant Medications

9. Indicate all ***NON-STUDY PRESCRIBED*** medications that the participant is currently taking ***on a regular basis*** by marking the appropriate boxes.

If participant is not taking any **NON-STUDY PRESCRIBED** medications on a regular basis, check here: 1

Antihypertensive Agents *(Complete for participants in the Lipid Trial and for inactive participants in the BP Trial)*

1 ☐ Loop diuretics
1 ☐ Thiazide diuretics
1 ☐ K-sparing diuretic agents
1 ☐ Potassium supplements
1 ☐ Angiotensin type 2 antagonists (ARB)
1 ☐ ACE inhibitors
1 ☐ Any dihydropyridine calcium-channel blocker (CCB)
1 ☐ Any non-dihydropyridine calcium-channel blocker (CCB)
1 ☐ Peripheral alpha-blockers
1 ☐ Central alpha-adrenergic agonists
1 ☐ Beta-blockers
1 ☐ Vasodilators
1 ☐ Reserpine
1 ☐ Other antihypertensive agents

Cardiovascular Drugs

1 ☐ Digitalis preparations
1 ☐ Anti-arrhythmics
1 ☐ Nitrates
1 ☐ Other cardiovascular drugs

NON-STUDY Diabetes Treatments

1 ☐ Sulfonylureas
1 ☐ Biguanides
1 ☐ Meglitinides
1 ☐ Alpha-glucosidase inhibitors
1 ☐ Glargine, NPH, UL or L Insulins
1 ☐ Thiazolidinediones
1 ☐ Regular Insulins
1 ☐ Lispro or Aspart Insulins
1 ☐ Other diabetes treatments

Lipid-lowering Drugs *(Complete for participants in the BP Trial and for inactive participant in the Lipid Trial)*

1 ☐ Bile-acid sequestrants
1 ☐ HMG CoA reductace inhibitors (statins)
1 ☐ Fibrates
1 ☐ Other lipid-lowering drugs
1 ☐ Cholesterol absorption inhibitors
1 ☐ Niacin and nicotinic acid

Miscellaneous Prescribed Therapies

1 ☐ Oral anticoagulants (warfarin, coumadin, anisindione)
1 ☐ Non-steroidal anti-inflammatory agents (excluding aspirin)
1 ☐ Inhibitors of platelet aggregation (except aspirin)
1 ☐ Cox-2 inhibitors
1 ☐ Heparins
1 ☐ Aspirin
1 ☐ Progestins
1 ☐ Estrogens (excluding vaginal creams)
1 ☐ Thyroid agents
1 ☐ Oral asthma drugs (except steroids)
1 ☐ Inhaled steroids for asthma
1 ☐ Oral steroids
1 ☐ Any antidepressant
1 ☐ Any antipsychotic
1 ☐ Weight loss drugs
1 ☐ Erectile dysfunction drugs
1 ☐ Drugs for Osteoporosis
1 ☐ Diuretic for fluid retention
1 ☐ Any other (prescribed) medication not listed above

Miscellaneous Non-prescribed Therapies

1 ☐ Vitamins and/or nutritional supplements
1 ☐ Over-the-counter medications
1 ☐ Herbal/alternative medication therapies

Acrostic

Falls

10. ***In the last 12 months*** have you fallen and landed on the floor or ground, OR fallen and hit an object like a table or stair? FALL

1☐ Yes → How many times have you fallen in the last 12 months? → NFALL ☐☐ (number of times)

2☐ No

Fractures

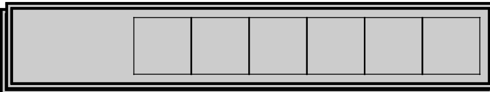
11. Has a doctor or other health care provider told you that you have broken or fractured any bones ***since your last annual ACCORD visit***? FRAC

1☐ Yes → Did you break or fracture anything other than your spine (vertebrae)? FRACNONV

1☐ Yes → Fill out the Fracture Preliminary Event Notification Form if your site is participating in the ACCORD-Bone study

2☐ No

2☐ No



PHYSICAL EXAM

12. **Participant Weight:**	WT_KG[2] .	Measurement recorded in:	1 ☐ pounds 2 ☐ kilograms
13. **Participant Height:**	HT_CM[2] .	Measurement recorded in:	1 ☐ inches 2 ☐ centimeters
14. **Waist Circumference:**	WAIST_CM[2]	Measurement recorded in:	1 ☐ inches 2 ☐ centimeters

Sitting Blood Pressures and Heart Rate

COMPLETE BLOOD PRESSURE INFORMATION ONLY FOR LIPID TRIAL PARTICIPANTS OR FOR INACTIVE BP TRIAL PARTICIPANTS ON THIS FORM. For active BP trial participants, mark "N/A" here and complete blood pressure information on BLOOD PRESSURE MANAGEMENT FORM.

15. **Systolic BP** (Average of 3)	16. **Diastolic BP** (Average of 3)	17. **Heart Rate** (Average of 3)
3 mmHg 1 ☐ N/A	3 mmHg 1 ☐ N/A	3 bpm 1 ☐ N/A

Corrected Visual Acuity

Follow up assessment of visual acuity should be performed at the F24.0, F48.0, F72.0, and F96.0 or EXIT visits ONLY.

18. **Right Eye**	19. **Left Eye**
(a) Blindness * 1 ☐ Yes 2 ☐ No	(a) Blindness * 1 ☐ Yes 2 ☐ No
If Yes, Go to Left Eye (Q19)	***If Yes, Go to Eye Disease During Past Year (Q20)***
(b) Visual Acuity Score RE_VAS (0 – 100)	(b) Visual Acuity Score LE_VAS (0 – 100)
(c) Snellen Fraction 20 / *	(c) Snellen Fraction 20 / *

If visual acuity (Snellen fraction) is worse than 20/40, then refer participant to his/her ophthalmologist (remember to send OPHTHALMOLOGIST EXAM FORM with participant).

Eye Disease During Past Year

20. Has the participant had eye surgery, including laser photocoagulation, during the past year? EYESURG
1 ☐ Yes → Please indicate type below.
2 ☐ No

Right Eye	**Left Eye**
1 ☐ Cataract removal RE_CAT_YAG	1 ☐ Cataract removal LE_CAT
1 ☐ Retinal laser photocoagulation for diabetic retinopathy LE_CAT_YAG	1 ☐ Retinal laser photocoagulation for diabetic retinopathy LE_RET
1 ☐ Yag laser for cataract capsule RE_RET_VIT	1 ☐ Yag laser for cataract capsule LE_YAG
1 ☐ Vitrectomy for diabetic retinopathy LE_RET_VIT	1 ☐ Vitrectomy for diabetic retinopathy LE_VIT
1 ☐ Other * RE_OTH	1 ☐ Other * LE_OTH

21. Has the participant experienced any of the following vision problems during the past year?

(a) Retinopathy RETPATHY 1 ☐ Yes → Indicate Eye → 1 ☐ Left LRTPATHY 1 ☐ Right RRTPATHY
☐ No

(b) Vision Loss VISLOSS 1 ☐ Yes → Indicate Eye → 1 ☐ Left LE_VLOSS 1 ☐ Right RE_VLOSS
2 ☐ No

* Variables not available for Public Use Data Set
2 All units converted to metric system (kg or cm)
3 Variables available in Analysis Data Set: BloodPressure

Acrostic						

Heart Failure Risk

22. Have you experienced any of the following problems since ***[date of last events ascertainment]***?

(a) Swelling of your feet, ankles, or legs? SWELLING
- 1 ☐ Yes →
- 2 ☐ No
- 3 ☐ Unknown

  - 1 ☐ New or worsened
  - 2 ☐ Unchanged or improved

  SWELSTAT

(b) Shortness of breath while lying, sitting or with minimal exertion? SHORTNES
- 1 ☐ Yes →
- 2 ☐ No
- 3 ☐ Unknown

  - 1 ☐ New or worsened
  - 2 ☐ Unchanged or improved

  SHORSTAT

(c) The need to pass urine three or more times per night? URINE
- 1 ☐ Yes →
- 2 ☐ No
- 3 ☐ Unknown

  - 1 ☐ New or worsened
  - 2 ☐ Unchanged or improved

  URINSTAT

Edema Exam

23. **Right Foot**	24. **Left Foot**
Grade Pre-tibial edema based on today's visit. (mark one only)	Grade Pre-tibial edema based on today's visit. (mark one only)
1 ☐ 1+ 2 ☐ 2+ C_RFPTED	1 ☐ 1+ 2 ☐ 2+ C_LFPTED
3 ☐ 3+ 4 ☐ 4+	3 ☐ 3+ 4 ☐ 4+
5 ☐ None 6 ☐ N/A	5 ☐ None 6 ☐ N/A

Chest Exam

25. **Complete only if any of the responses to 22 (a), (b), or (c) is 'Yes' or if edema was found on today's exam (grade of 1+ or greater).** CHEST_EXAM[4]

Auscultation of lungs:	1 ☐ No rales	2 ☐ Basilar rales only	3 ☐ Rales greater than basilar
Third heart sound present?	1 ☐ Yes	2 ☐ No	

4 Changed to combine two questions into yes/no response

Acrostic						

Foot Exam

26. Right Foot

Amputation/Foot Inspection: Document amputation history and assess foot characteristics as outlined below.

Has participant ever had amputation of a lower extremity on the right side? **FAMPHIS**[5]

1 ☐ Yes (complete box for amputation description)   2 ☐ No (skip to part (a) below)

Amputation Description (mark one only) *

1 ☐ Toe   2 ☐ Ray (metatarsal)
3 ☐ Forefoot   4 ☐ Foot
5 ☐ Below knee   6 ☐ Above knee

Stop here, *do not* complete (a) – (e) below.

(a) Appearance: **FAPPEAR**[5]

0 ☐ Normal

1 ☐ Abnormal *(complete table below, mark all that apply)*

1 ☐ Deformities **FDEFORM**[5]   1 ☐ Infection **FINFECT**[5]
1 ☐ Dry skin, callus **FDRYSKI**[5]   1 ☐ Fissure **FFISSUR**[5]
1 ☐ Other (specify below) **FOTHER**[5]

[*]

(b) Ulceration **FULCER**[5]

0 ☐ Absent   1 ☐ Present

(c) Ankle Reflexes **FANKLE**[5]

0 ☐ Present   0.5 ☐ Present/Reinforcement
1 ☐ Absent

(d) Vibration (perception at great toe) **FVIBRAT**[5]

0 ☐ Present (≤10 sec)   0.5 ☐ Reduced (>10 sec)
1 ☐ Absent

(e) 10 gm Filament (number of applications detected) **FFILAM**[5]

0 ☐ Present (≥ 8)   0.5 ☐ Reduced (1-7)   1 ☐ Absent

27. Left Foot

Amputation/Foot Inspection: Document amputation history and assess foot characteristics as outlined below.

Has participant ever had amputation of a lower extremity on the left side?

1 ☐ Yes (complete box for amputation description)   2 ☐ No (skip to part (a) below)

Amputation Description (mark one only)

1 ☐ Toe   2 ☐ Ray (metatarsal)
3 ☐ Forefoot   4 ☐ Foot
5 ☐ Below knee   6 ☐ Above knee

Stop here, *do not* complete (a) – (e) below.

(a) Appearance

0 ☐ Normal

1 ☐ Abnormal *(complete table below, mark all that apply)*

1 ☐ Deformities   1 ☐ Infection
1 ☐ Dry skin, callus   1 ☐ Fissure
1 ☐ Other (specify below)

(b) Ulceration

0 ☐ Absent   1 ☐ Present

(c) Ankle Reflexes

0 ☐ Present   0.5 ☐ Present/Reinforcement
1 ☐ Absent

(d) Vibration (perception at great toe)

0 ☐ Present (≤10 sec)   0.5 ☐ Reduced (>10 sec)
1 ☐ Absent

(e) 10 gm Filament (number of applications detected)

0 ☐ Present (≥ 8)   0.5 ☐ Reduced (1-7)   1 ☐ Absent

MNSISCOR[6]

Hypoglycemia Education

28. Was information on hypoglycemic symptoms and ways to avoid hypoglycemia reviewed with the participant at this visit?   1 ☐ Yes   2 ☐ No   *

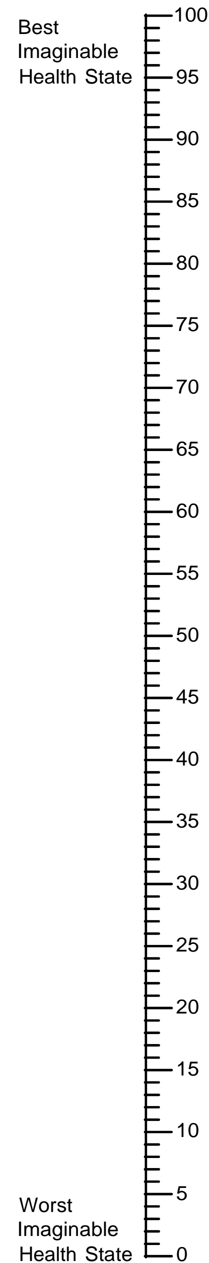
[*] Variables not available for Public Use Data Set
5 All right and left foot exam variables combined
6 Created value to score foot exam

Acrostic						

TO BE COMPLETED BY THE PARTICIPANT

Feeling Thermometer: To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

We would like for you to indicate on this scale, in your opinion, how good or bad your own health is **TODAY**. Please do this by drawing a line from the the center of the box below to whichever point on the scale indicates how good or bad your current health state is.



Score FEELING

ACCORD *STANDING* BLOOD PRESSURE ASSESSMENT FORM

Participant ID	MASKID [affix ID label here]	Acrostic	*
Date of Visit	* / / (Month Day Year)	Visit Code	VISIT
		Form Completed by	*

Data Entered By

Date Entered

Standing Blood Pressures and Heart Rate

This form should be completed only if the participant is active in Bp trial and sitting BP measurements were obtained with the automated Omron device.

1. Has it been at least 90 minutes since the participant's last meal? NINETYMIN
   - 1 ☐ Yes
   - 2 ☐ No

	2. Systolic BP	3. Diastolic BP	4. Heart Rate
First Measure	SYS01 mmHg	DIA01 mmHg	HRATE01 bpm
Second Measure	SYS02 mmHg	DIA02 mmHg	HRATE02 bpm
Third Measure	SYS03 mmHg	DIA03 mmHg	HRATE03 bpm

5. Did participant experience dizziness or lightheaded feelings upon standing for this assessment? DIZZINESS
   - 1 ☐ Yes
   - 2 ☐ No

* Variables not available in Public Use Data Set