12 Month Follow-Up: Direct Measurements Form

SECTION 1. DIRECT MEASUREMENTS

Name of study coordinator completing this form: _____

1. Date of 12 month patient study visit:	___ ___ / ___ ___ / ___ ___ ___ ___ *(MM/DD/YYYY)*
2. Patient height:	intHeightFeet ___ FEET intHeightInches ___ ___ INCHES *OR* intHeightCentimeters ___ ___ ___CENTIMETERS
3. Patient weight:	intWeightPounds ___ ___ ___ POUNDS *OR* intWeightKilos ___ ___ ___ KILOGRAMS
4. Has the patient smoked in the past 24 hours?	❑ YES ➔***Go to Question 4a*** intSmokePast24Months ❑ NO ➔***Skip to Question 5***
4a. If yes, patient's last cigarette was smoked:	intSmokeLastCigarette ❑ LESS THAN OR EQUAL TO 20 MINUTES AGO ➔ ***Delay BP measurement until more than 20 minutes has elapsed since patient last smoked.*** ❑ MORE THAN 20 MINUTES AGO ➔ ***Go to Question 5***
5. Time of day of BP recording	___ ___ : ___ ___ ❑ AM ❑ PM
6. Arm used for BP recording *(Use right arm if possible and if no blood draw was done using the right arm in the last 5-7 days):*	❑ RIGHT ARM intArmUsed ❑ LEFT ARM
7. Midpoint circumference of arm being used:	___ ___ ___ CENTIMETERS intMidpointCircum
8. Size of cuff used (check one):	❑ SMALL ADULT (17-22 CM) ❑ ADULT (22-32 CM) intCuffSize ❑ LARGE ADULT (32-42 CM) ❑ EXTRA LARGE (42-50 CM)
9. Seated pulse *(see average calculated by the Omron machine, or count beats per minute for 30 seconds and multiply by 2):*	intSeatedPulse ___ ___ ___ BPM

	a. Systolic BP (mm Hg)	b. Diastolic BP (mm Hg)
10. First sitting BP measurement	intSeatedSys1 ___ ___ ___	intSeatedDia1 ___ ___ ___
11. Second sitting BP measurement*	intSeatedSys2 ___ ___ ___	intSeatedDia2 ___ ___ ___
12. Third sitting BP measurement*	intSeatedSys3 ___ ___ ___	intSeatedDia3 ___ ___ ___
*Important➔	***If the 2nd AND 3rd systolic OR diastolic BPs (Questions 11 and 12 above) differ by more than 4 mm, then take a fourth reading and enter the values below.***	
13. Fourth sitting BP measurement	intSeatedSys4 ___ ___ ___	intSeatedDia4 ___ ___ ___

Instructions

- *Have the patient stand quietly for 1 minute and measure the following:*

14. Standing pulse (count beats per minute for 30 seconds and multiply by 2)	intStandingPulse ___ ___ ___ BPM

	a. Systolic BP (mm Hg)	b. Diastolic BP (mm Hg)
15. Standing BP measurement	intStandingSys ___ ___ ___	intStandingDia ___ ___ ___

SECTION 2. LAB TEST RESULTS

Instructions

- *Record the values below from the blood tests after they have been obtained.*

Lab Test	Value
16. Total Cholesterol intCholesterolTotal	___ ___ ___ mg/dL
17. High-density lipoproteins (HDL) intCholesterolHDL	___ ___ ___ mg/dL
18. Low-density lipoproteins (LDL) intCholesterolLDL	___ ___ ___ mg/dL
19. Triglycerides intTriglycerides	___ ___ ___ mg/dL
20. Hemoglobin A1c (HA1c) decHemoglobinA1c	___ ___ . ___ %

21. (*Optional*) Enter any comments about this form here: _____

_____

_____

Fax the completed form to the University of Iowa at **319-335-9782** and file it in the patient's study folder.

For issues or questions about this form, contact:

- Brian Gryzlak (Study Coordinator) 319-353-3857 brian-gryzlak@uiowa.edu
  OR
- Nick Rudzianski (Data Entry Specialist) 319-335-9783 nicholas-rudzianski@uiowa.edu

ParticipantID

12 Month Follow-Up: Medical Record Form

Form Instructions

- *Name of study coordinator completing this form: _____*
- ***IMPORTANT:*** *When completing this form please:*
  - ***Thoroughly search all locations in your medical record*** *where the information to answer the form question could be found. Depending on your specific medical record, these locations could include:*
    - *Notes (office, phone)*
    - *Encounters*
    - *Media tabs*
    - *External documents*
    - *Vaccinations*
  - ***Thoroughly search your medical record for documentation from any provider****, including:*
    - *Physicians and physician assistants*
    - *Nurses and nurse practitioners*
    - *LPNs, CNAs, and health coaches*
    - *Pharmacists*
  - ***Thoroughly search all documents and communications from outside clinics or providers, which may include:***
    - *Consults and imaging*
    - *Vaccinations*
    - *Recommendations*
    - *Other screenings*

intDeceased: 0 = NO; 1 = Yes
No field on the CRF - was written in text on first page if YES

- *Please complete all items on this form on the same date as the patient 12-month visit. If this is not possible, please answer questions on this form **as of** the date of the 12-month visit.*
- *The date of the patient's baseline visit is included in applicable questions below for your reference.*

1. Date this form was completed: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)

SECTION 1. CONDITIONS, SYMPTOMS AND LAB TESTS

Instructions

- *For each question below, check "YES" if the condition has been documented in the patient's medical record since the baseline visit on «Baseline Date», and "NO" if it is not.*
- *Answers to Questions 2-18 below are required.*

Condition Since the baseline visit on «Baseline Date», has the condition been documented in the patient's medical record?		Answer from the Medical Record	
		YES	NO
2. Hypertension?	intHypertension	❒	❒
3. Hyperlipidemia?	intHyperlipidemia	❒	❒
4. Congestive heart failure?	intCHF	❒	❒
5. Coronary artery disease?	intCAD	❒	❒
6. Atrial fibrillation?	intAfib	❒	❒

Instructions

- *For each question below, check "YES" if the condition has been documented in the patient's medical record since the baseline visit on «Baseline_Date», and "NO" if it is not.*
- *Answers to Questions 2-18 below are required.*

Condition Since the baseline visit on «Baseline_Date», has the condition been documented in the patient's medical record?		Answer from the Medical Record YES	NO
7. Heart attack (myocardial infarction)?	intHeartAttack	❒	❒
8. Stroke or TIA?	intStrokeTIA	❒	❒
9. Peripheral artery disease?	intPAD	❒	❒
10. Asthma? *(excluding exercise induced asthma)*	intAsthma	❒	❒
11. COPD?	intCOPD	❒	❒
12. Diabetes?	intDiabetes	❒	❒
13. Chronic kidney disease?	intCKD	❒	❒
14. Seizures/other neurological disorder?	intSeizures	❒	❒
15. Liver disease?	intLiverDisease	❒	❒
16. Depression?	intDepression	❒	❒
17. Anxiety?	intAnxiety	❒	❒
18. Arthritis/DJD/chronic pain?	intArthritisDJDPain	❒	❒

Instructions

- *For each question below, enter the appropriate response from the medical record.*
- *Answers to all main questions (e.g., 19, 20, 21…) are required.*

Condition or Value		Answer from the Medical Record
19. Most recent chart recorded blood pressure	intHypertensionRecentSys / intHypertensionRecentDia	___ ___ ___ / ___ ___ ___ **mmHg**
19a. Date of most recent chart recorded blood pressure	datHypertensionRecentBP_d	___ ___ / ___ ___ / ___ ___ ___ ___ *(MM/DD/YYYY)*
20. Since «Baseline_Date», has an Ejection Fraction (EF) been documented in the chart?	intCHFEjectionFrac	❒ YES ➔ ***Go to 20a*** ❒ NO➔ ***Skip to 21***
20a. Most recent chart recorded EF:	intCHFEjectionFracPercent	____ ____ **%**

Instructions

- *For each question below, enter the appropriate response from the medical record.*
- *Answers to all main questions (e.g., 19, 20, 21…) are required.*

Condition or Value	Answer from the Medical Record
20b. EF date: datCHFEjectionFracPercent_d	___ ___ / ___ ___ / ___ ___ ___ ___ *(MM/DD/YYYY)*
21. Since «Baseline_Date», is there documentation that an MD, DO, nurse practitioner, physician assistant, or pharmacist asked the patient about dyspnea (shortness of breath)?	intCADDyspnea ❒ YES ❒ NO
22. Since «Baseline_Date», is there documentation that an MD, DO, nurse practitioner, physician assistant, or pharmacist asked the patient about chest pain?	intCADChestPain ❒ YES ❒ NO
23. Is there documentation the patient was angina-free (free of chest pain) at the last clinic visit?	intCADAnginaFree ❒ YES ❒ NO
24. Since «Baseline_Date», has the patient experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation?	intCADAMICABG ❒ YES ❒ NO
25. Since «Baseline_Date», has chronic stable angina (CSA) been documented in the patient medical record?	intCADCSA ❒ YES ❒ NO
26. Since «Baseline_Date», has the patient participated in an early outpatient cardiac rehabilitation/secondary prevention program for the qualifying event/diagnosis?	intCADEarlyOutputProgram ❒ YES ❒ NO
27. Since «Baseline_Date», has the patient been referred to such a program?	intCADReferred ❒ YES ❒ NO
28. Since «Baseline_Date», has the patient been assessed for the need of anticoagulation?	intAFIBAnticoag ❒ YES ❒ NO
29. Since «Baseline_Date», if the patient is on warfarin, has an INR been recorded an average of at least every 2 months (6 times) for the last year?	intAFIBWarfarinINR ❒ YES ❒ NO ❒ NOT ON WARFARIN
30. Since «Baseline_Date», has the patient received a dilated eye exam?	intDMEyeExam ❒ YES ❒ NO

Instructions

- *For each question below, enter the appropriate response from the medical record.*
- *Answers to all main questions (e.g., 19, 20, 21…) are required.*

Condition or Value	Answer from the Medical Record
31. Since «Baseline_Date», has the patient received urine protein screening (microalbumin laboratory value)?	❒ YES ➔ ***Go to 31a*** ❒ NO ➔ ***Skip to 32*** intDMUrineScreening
31a. Most recent microalbumin value: intDMMicroalbumin	_____ **mg/g**
32. Since «Baseline_Date», has the patient received an HbA1c test?	❒ YES ➔ ***Go to 32a*** ❒ NO ➔ ***Skip to 33*** intDMA1cTest
32a. Most recent HbA1c value: decDMA1cValue	_____ **.** _____ **%**
33. Since «Baseline_Date», has the patient received an LDL cholesterol test?	❒ YES ➔ ***Go to 33a*** ❒ NO ➔ ***Skip to 34*** intDMLDLTest
33a. Most recent LDL value: intDMLDLValue	_____ **mg/dL**
34. Since «Baseline_Date», has the patient received a foot examination?	❒ YES ❒ NO intDMFootExam
35. Since «Baseline_Date», has the patient received a pneumonia immunization?	❒ YES ❒ NO intDMPneumoniaVacc
36. Has the patient received an influenza immunization during the most recent flu season (September-February)?	❒ YES ❒ NO intInfluenzaVacc
37. In the past 6 months, has a plan on how to achieve or maintain ideal body weight been documented in the patient's medical record? *Can include 'lifestyle modification' plans, including diet and exercise.*	❒ YES ❒ NO intBodyWeightPlans
38. Does the patient currently use tobacco?	❒ YES ❒ NO intUsesTobacco
39. Since «Baseline_Date», is there documentation of tobacco screening in the medical record?	❒ YES ➔ ***Go to 39a*** ❒ NO ➔ ***Skip to 40*** intAssessingTobaccoUse
39a. Date of most recent screening: datMostRecentTobScreening_d	___ ___ / ___ ___ / ___ ___ ___ ___ *(MM/DD/YYYY)*
40. Since «Baseline_Date», is there documentation in the medical record of advising on the risk of tobacco use?	❒ YES ❒ NO intAdviseRiskTobaccoUse

Instructions

- *For each question below, enter the appropriate response from the medical record.*
- *Answers to all main questions (e.g., 19, 20, 21…) are required.*

Condition or Value	Answer from the Medical Record
41. Since «Baseline_Date», is there documentation in the medical record of assessing the patient's willingness to quit tobacco?	❒ YES ❒ NO intAssessWillingnessQuit
42. Is the patient currently using nicotine replacement (patch, gum, lozenge, inhaler), bupropion, or Chantix® (varenicline)?	❒ YES ❒ NO intUsingNicotineReplacementThera
43. Since «Baseline_Date», is there documentation in the medical record that the patient has been asked about his or her alcohol consumption?	❒ YES ❒ NO intAskedAlcohol

SECTION 2. CANCER SCREENING TESTS AND PROCEDURES

Instructions

- *Review the medical record and enter the month and year of each test or procedure below if performed since the baseline visit on «Baseline_Date» and documented in the medical record.*
- *Select "NO" if not performed within the given period, or not documented in the medical record.*

Test or Procedure Since the baseline visit on «Baseline_Date», have the following tests and procedures been documented in the patient's medical record?	Response from the Medical Record Date of Last Screening (MM / YYYY)	OR	Check "No" or "Not applicable" intLastMammogramNotApplicable
44. *(If patient is female)* Mammogram intLastMammogramNotFound	strLastMammogram_M ___ ___ / ___ ___ ___ ___	OR	❒ NO ❒ NOT APPLICABLE
45. *(If patient is female)* Cervical cancer screening or 'Pap test'	strLastCervicalExam_m ___ ___ / ___ ___ ___ ___	OR	❒ NO ❒ NOT APPLICABLE intLastCervicalExamNotFound intLastCervicalNotApplicable
46. Colonoscopy (flexible fiberoptic/optical)	strColoColonoscopyDate_m ___ ___ / ___ ___ ___ ___	OR	❒ NO intColoColonoscopyNotFound
47. 3 Card FOBT (guaiac)	strColo3CardFOBTDate_m ___ ___ / ___ ___ ___ ___	OR	❒ NO intColo3CardFOBTNotFound
48. 3 Card Fecal Immunochemical Test (FIT)	strColo3CardFITDate_m ___ ___ / ___ ___ ___ ___	OR	❒ NO intColo3CardFITNotFound
49. 2 Card Fecal Immunochemical Test (FIT)	strColo2CardFITDate_m ___ ___ / ___ ___ ___ ___	OR	❒ NO strColo1CardFITDate
50. 1 Card Fecal Immunochemical Test (FIT)	strColo1CardFITDate_m ___ ___ / ___ ___ ___ ___	OR	❒ NO intColo1CardFITNotFound
51. Flexible Sigmoidoscopy	strColoFlexSigmoidDate ___ ___ / ___ ___ ___ ___	OR	❒ NO intColoFlexSigmoidNotFound
52. CT colonoscopy/CT colonography	strColoCTDate_m	OR	❒ NO intColoCTNotFound

53. Digital rectal exam in office (guaiac)	___ ___ / ___ ___ ___ ___ strColoDigitalRectalDate_m ___ ___ / ___ ___ ___ ___	intColoDigitalRectalNotFound OR ❒ NO

SECTION 3. MEDICATIONS

Instructions

- *Review the patient's medical record and record the generic med name, strength, and directions for use. Using the list provided, find and include the medication code.*
- *Only include anti-hypertensive agents, anti-diabetic agents, lipid-lowering agents, antiarrhythmics, anti-asthmatics and anti-coagulants/antiplatelet agents.*
- *If you are unsure about whether to include a certain medication, contact the study team for guidance, or simply include the medication on this form and the study team will make a decision as to whether to enter the medication in the study database.*

#	Medication Name	intMedInEMR Med Code	Medical Record Strength	Medical Record Directions for Use
A.	MedicationName	intFKMedCodeId ___ ___ ___ ___	EMRReportedStrength MedDoseUnit decMedicationDose intFKMedicationDoseUnitId	MedFrequency intCKMedicationFrequencyId
B.		___ ___ ___ ___		
C.		___ ___ ___ ___		
D.		___ ___ ___ ___		
E.		___ ___ ___ ___		
F.		___ ___ ___ ___		
G.		___ ___ ___ ___		
H.		___ ___ ___ ___		
I.		___ ___ ___ ___		
J.		___ ___ ___ ___		

Instructions

- *Review the patient's medical record and record the generic med name, strength, and directions for use. Using the list provided, find and include the medication code.*
- *Only include anti-hypertensive agents, anti-diabetic agents, lipid-lowering agents, antiarrhythmics, anti-asthmatics and anti-coagulants/antiplatelet agents.*
- *If you are unsure about whether to include a certain medication, contact the study team for guidance, or simply include the medication on this form and the study team will make a decision as to whether to enter the medication in the study database.*

#	Medication Name	Med Code	Medical Record Strength	Medical Record Directions for Use
K.		__ __ __ __		
L.		__ __ __ __		
M.		__ __ __ __		
N.		__ __ __ __		
O.		__ __ __ __		
P.		__ __ __ __		

Please record any additional medications (more than 16) on the '*Additional Medications from Medical Record'* form.

- *Then fax that form along with the other 12-month forms when data collection is complete.*
- *Contact Brian Gryzlak at **brian-gryzlak@uiowa.edu** or 319-353-3857 with any questions*.

SECTION 5. UNANTICIPATED PROBLEM (UP) SCREENING

Definition

*An **Unanticipated Problem (UP)** is any event or problem that is:*

A. *Unexpected, **AND***
B. *Possibly, probably, or definitely related to study participation, **AND***
C. *Suggests greater risk of harm to study participant(s) than was previously known or recognized, including a breach of confidentiality, a subject complaint that can't be resolved by study investigators, or identification of a new risk related to the study*

Instructions

- *The purpose of this section is to help ensure that all UPs have been identified and reported for each study subject during the first 12 months of the subject's participation in the study.*
- *After meeting with the subject for the 12-month study visit, please review the subject's medical record for the previous 12 months and answer the questions that follow.*
- *The following questions guide you through each of the three criteria above for an Unanticipated Problem (UP). Please follow the prompts in the questions that follow.*

55. After meeting with the subject and reviewing the subject's medical record, have you identified one or more incidents, experiences, or outcomes that are **unexpected in terms of nature, severity or frequency** that occurred between the time the subject signed the informed consent document («Consent_Date») and the 12-month study visit date?

intUPUnexpected

❒ NO ➔ ***Skip to Question 56***

❒ YES ➔ ***Continue to Question 55a below***

55a. If YES, please describe the unexpected nature of each occurence:_____

_____

_____

_____

56. After meeting with the subject and reviewing the subject's medical record, have you identified one or more incidents, experiences, or outcomes that are **related or possibly related to this subject's participation in the research study** between the time the subject signed the informed consent document («Consent_Date») and the 12-month study visit date?

❒ NO ➔ ***Skip to Question 57***

intUPPossiblyRelated

❒ YES➔ ***Continue to Question 56a below***

56a. If YES, please describe how each occurence was related to the subject's participation in the research study:_____

_____

_____

57. After meeting with the subject and reviewing the subject's medical record, have you identified one or more incidents, experiences, or outcomes which suggest that the **research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized** between the time the subject signed the informed consent document («Consent_Date») and the 12-month study visit date?

❒ NO ➔ ***Skip to the box below ("!!! READ BEFORE CONTINUING !!!")***

❒ YES➔ ***Continue to Question 57a below*** intUPRiskharm

57a. If YES, please describe how each occurence placed the subject or others at increased risk of harm: _____

_____

_____

!!! READ BEFORE CONTINUING !!!

⇨ If you answered "**YES**" **to Questions 55, 56, AND 57 above, an Unanticipated Problem was identified. Please continue with Question 58 on the next page.**

⇨ If you answered "**NO" to Question 55, 56, OR 57:**

- Your responses indicate that no Unanticipated Problem involving this subject occurred between the baseline visit and the 12-month study visit.
- Skip to Question 59.

58. Have **ALL** of the Unanticipated Problems that you identified above in Questions 55-57 been previously reported to the University of Iowa? That is, have you completed and faxed "UNANTICIPATED PROBLEM (UP) EVENT-DRIVEN" forms for each of these?

YES intUPAllReported	NO
❑	❑
🡻	🡻
You indicated that ALL occurrences of Unanticipated Problems involving this subject have been reported to the University of Iowa.	You indicated that one or more Unanticipated Problems involving this subject **have not been reported** to the University of Iowa. ○ **It is important that you submit all Unantipcated Problems as soon as possible**. ○ **Please submit an "UNANTICIPATED PROBLEM (UP) EVENT-DRIVEN" form for each event you identified in Questions 55-57 above.** If you have any questions about Unanticipated Problems or the process of reporting them to the University of Iowa, please contact Brian Gryzlak at 319-353-3857 or email brian-gryzlak@uiowa.edu

59. (*Optional*) Enter any comments about this form here: _____

_____

_____

_____

Fax the completed form to the University of Iowa at **319-335-9782** and file it in the patient's study folder.

For issues or questions about this form, contact:

Brian Gryzlak	(Study Coordinator)	319-353-3857 brian-gryzlak@uiowa.edu
OR		
Nick Rudzianski	(Data Entry Specialist)	319-335-9783 nicholas-rudzianski@uiowa.edu

ParticipantID

12 Month Follow-Up: Patient Report Form

Instructions

- *Enter name of study coordinator completing this form: _____*
- *Ask the following questions of the patient during the 12 month follow up visit and record patient responses.*

1. Date of 12 month follow-up patient visit: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)

2. Contact Information (to confirm that the compensation check is sent to the correct address):

2a. Patient first and last name:_____

2b. Address1:_____

2c. Address2:_____

2d. City:_____

2e. State:_____

2f. Zip:_____

Instructions

- *Tell the patient: "About 12 months ago you were asked about health conditions that you had. Now, we're interested in health conditions that have been newly diagnosed since «Baseline_Date». For the following conditions, please say YES if a doctor or other health professional has told you that you have the condition since «Baseline_Date» or "NO" if you don't have the condition or if it was diagnosed before «Baseline_Date»."*
- *Answers to all questions are required.*

Condition	Patient Response			
	YES Patient reports that this is a NEW condition		NO Patient does not have this condition or had it prior to «Baseline_Date»	
3. Hypertension or high blood pressure?	❒	intHypertension	❒	
4. Hyperlipidemia or high cholesterol?	❒	intHyperlipidemia	❒	
5. Congestive heart failure?	❒	intCHF	❒	
6. Coronary artery disease?	❒	intCAD	❒	
7. Atrial fibrillation or A.Fib?	❒	intAFib	❒	
8. Heart attack?	❒	intHeartAttack	❒	
9. Stroke or TIA?	❒	intStrokeTIA	❒	

Instructions

- *Tell the patient: "About 12 months ago you were asked about health conditions that you had. Now, we're interested in health conditions that have been newly diagnosed since «Baseline_Date». For the following conditions, please say YES if a doctor or other health professional has told you that you have the condition since «Baseline_Date» or "NO" if you don't have the condition or if it was diagnosed before «Baseline_Date»."*
- *Answers to all questions are required.*

Condition	Patient Response	
	YES Patient reports that this is a NEW condition	**NO** Patient does not have this condition or had it prior to «Baseline_Date»
10. Peripheral artery disease?	❒ intPAD	❒
11. Asthma? (do not include exercise-induced asthma)	❒ intAsthma	❒
12. COPD?	❒ intCOPD	❒
13. Diabetes?	❒ intDiabetes	❒
14. Chronic kidney disease?	❒ intCKD	❒
15. Seizures or other neurological disorder?	❒ intSeizures	❒
16. Liver disease?	❒ intLiverDisease	❒
17. Depression?	❒ intDepression	❒
18. Anxiety?	❒ intAnxiety	❒
19. Arthritis, degenerative joint disease, or chronic pain?	❒ intArthritisDJDPain	❒

Instructions

- *Ask the patient the following questions and record their responses below.*

Question	YES	NO
20. "Are you currently free of chest pain?" intCADAnginaFree	❒	❒
21. "Since «Baseline Date», have you ever experienced an acute myocardial infarction (heart attack), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation?" intCADAMICABG	❒	❒
22. "Since «Baseline Date», have you been told you have chronic stable angina?" intCADCSA	❒	❒
23. "Since «Baseline Date», have you participated in a cardiac rehabilitation program?" intCADEarlyOutputProgram	❒	❒
24. "Since «Baseline Date», have you ever been referred to such a program?" intCADReferred	❒	❒
25. "Since «Baseline Date», have you received a dilated eye exam?" intDMEyeExam	❒	❒
26. "Since «Baseline Date», have you received a foot examination?" intDMFootExam	❒	❒
27. "Since «Baseline Date», have you received a pneumonia immunization?" intPneumoniaVacc	❒	❒
28. "Do you currently use tobacco?" intUsesTobacco	❒	❒
29. "Are you currently using nicotine replacement (patch, gum, lozenge, inhaler), bupropion, or Chantix® (varenicline)?" intUsingNicotineReplacemenThera	❒	❒
30. "Have you received an influenza immunization during the most recent flu season (September-February)?" intReceivedInfluenzaImmunization	❒	❒
31. "Are you allergic to any medications?" intMedicationAllergies	❒	❒

31a. [IF YES] "What medications are you allergic to?" _____

_____

_____

Instructions

- *Ask the patient the following questions and record their responses below.*

Question	Response
32. "Have you ever smoked? If so, are you currently smoking or are you an ex-smoker?"	❒ NEVER SMOKED ➔ ***Skip to 33*** intSmoker ❒ CURRENT SMOKER ➔ ***Go to 32a*** ❒ EX-SMOKER ➔ ***Skip to 33***
32a. "Please tell me the approximate number of cigarettes that you smoke each day."	intNumberSmokedPerDay Number smoked per day _____
33. "Since «Baseline_Date», have you had a colon cancer screening test?" intColonScreening	❒ YES ➔ ***Answer Questions 33a – 33h*** ❒ NO ➔ ***Skip to Question 34***

Test or Procedure	Patient Response *(Enter Month and Year OR check No OR check Not Applicable)*		
	Month & Year of Last Screening (MM / YYYY)	**No**	**Not applicable**
(Continued from Question 33.) "Which of the following colon cancer screening tests or procedures have you had since «Baseline_Date»?"			
33a. Colonoscopy?" (flexible fiberoptic or optical)	strColoColonoscopyDate_m ___ ___ / ___ ___ ___ ___	intColoColonMonthNR_pat ❒ intColoColonoscopyNotFound	
33b. "3 Card FOBT?" (guaiac)	strColo3CardFOBTDate_m ___ ___ / ___ ___ ___ ___	intColo3CardFOBTNotFound ❒	
33c. "3 Card Fecal Immunochemical Test?" (FIT)	strColo3CardFITDate_m ___ ___ / ___ ___ ___ ___	intColo3CardFITNotFound ❒	
33d. "2 Card Fecal Immunochemical Test?" (FIT)	strColo2CardFITDate_m ___ ___ / ___ ___ ___ ___	intColo2CardFITNotFound ❒	
33e. "1 Card Fecal Immunochemical Test?" (FIT)	strColo1CardFITDate_m ___ ___ / ___ ___ ___ ___	intColo1CardFITNotFound ❒	
33f. "Flexible Sigmoidoscopy?"	strColoFlexSigmoidDate_m ___ ___ / ___ ___ ___ ___	intColoFlexSigmoidNotFound ❒	
33g. "CT colonoscopy or CT colonography?"	strColoCTDate_m ___ ___ / ___ ___ ___ ___	intColoCTNotFound ❒	
33h. "Digital rectal exam in office?" (guaiac)	strLastCervicalExam_m ___ ___ / ___ ___ ___ ___	intColoDigitalRectalNotFound ❒	
34. *(If patient is female)* "Since «Baseline_Date», have you had a mammogram?"	strLastMammogram_m ___ ___ / ___ ___ ___ ___	intLastMammogramNotFound ❒	intLastMammogramNotApplicable ❒
35. *(If patient is female)* "Since «Baseline_Date», have you had a cervical cancer screening or 'Pap test'?"	strLastCervicalExam_m ___ ___ / ___ ___ ___ ___	intLastCervicalExamNotFound intLastCervicalExamNotApplicable ❒	❒

Instructions ParticipantID

- *Read to the subject:* "Please tell me what medications you are currently taking for high blood pressure, high cholesterol, high blood sugars, asthma, controlling your heart rate, or thinning your blood."
- *Then ask about missed doses in the past week, how well each med works, and how much each med bothers them.*
- *Record the generic med name, strength, directions for use and doses missed in the past week based on what the PATIENT reports. Using the list provided, find and include the medication code.*
- *If you are unsure about whether to include a certain medication, contact the study team for guidance, or simply include the medication on this form and the study team will make a decision as to whether to enter the medication in the study database.*

#	intReportedByPatient **Medication Name**	**Med Code**	**Patient Reported Strength**	**Patient Reported Directions for Use**	**# Doses Missed in Past Week**	intHowWellWorks **"How well does it work?"**	intHowMuchDoesItBother **"How much does this medication bother you?"**	**"In what way does it bother you?"**
A.	MedicationName intFKMedCodeId	__ __ __ __	PatientReportedStrength	MedFrequency	strDosesMissedPastWeek	❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	
B.		__ __ __ __				❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	
C.		__ __ __ __				❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	
D.		__ __ __ __				❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	
E.		__ __ __ __				❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	
F.		__ __ __ __				❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	

Instructions

- *Read to the subject:* "Please tell me what medications you are currently taking for high blood pressure, high cholesterol, high blood sugars, asthma, controlling your heart rate, or thinning your blood."
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#	Medication Name	Med Code	Patient Reported Strength	Patient Reported Directions for Use	# Doses Missed in Past Week	"How well does it work?"	"How much does this medication bother you?"	"In what way does it bother you?"
G.		__ __ __ __				❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	
H.		__ __ __ __				❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	
I.		__ __ __ __				❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	
J.		__ __ __ __				❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	
K.		__ __ __ __				❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	
L.		__ __ __ __				❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	

Instructions

- *Read to the subject:* "Please tell me what medications you are currently taking for high blood pressure, high cholesterol, high blood sugars, asthma, controlling your heart rate, or thinning your blood."
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#	Medication Name	Med Code	Patient Reported Strength	Patient Reported Directions for Use	# Doses Missed in Past Week	"How well does it work?"	"How much does this medication bother you?"	"In what way does it bother you?"
M.		__ __ __ __				❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	
N.		__ __ __ __				❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	
O.		__ __ __ __				❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	
P.		__ __ __ __				❒ WELL ❒ OKAY ❒ NOT WELL	❒ A LOT ❒ SOME ❒ A LITTLE ❒ NOT AT ALL	

Instructions

- *Read to the patient: "*I have a list of problems that people sometimes have with their medications. Please tell me **how hard** it is for you to do each of the following.*"*

Problem	VERY HARD	SOMEWHAT HARD	NOT HARD AT ALL	Which Medication? *(Write "All" if true for all medications, or specify which medications)*
36. "Open or close the medicine bottle"	❑ intOpenCloseBottle	❑	❑	intOpenCloseBottleAllMeds
37. "Read the print on the bottle"	❑ intReadPrint	❑	❑	intReadPrintAllMeds
38. "Remember to take all of the pills"	❑ intRememberTakePills	❑	❑	intRememberTakePillsAllMeds
39. "Get your refills on time"	❑ intGetRefillsOnTime	❑	❑	intGetRefillsOnTimeAllMeds
40. "Take so many pills at the same time"	❑ intTakeSoManyPills	❑	❑	intTakeSoManyPillsAllMeds

41. (*Optional*) Enter any comments about this form here: _____

_____

_____

_____

Fax the completed form to the University of Iowa at **319-335-9782** and file it in the patient's study folder.

For issues or questions about this form, contact:

- Brian Gryzlak (Study Coordinator) 319-353-3857 brian-gryzlak@uiowa.edu
  OR
- Nick Rudzianski (Data Entry Specialist) 319-335-9783 nicholas-rudzianski@uiowa.edu