MANUAL OF PROCEDURES

Intervention Sites

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1. INTRODUCTION

1.1. Protocol Synopsis

Cardiovascular disease (CVD) causes 2,200 deaths in Americans every day, with one death occurring every 39 seconds. Although deaths can be prevented with better risk factor management, many risk factors remain uncontrolled. Patients with CVD have high levels of complexity and tend to have numerous chronic conditions.

The Patient-Centered Medical Home (Medical Home), including self-management, personalized health records and team-based care, has been proposed as a strategy to improve care for patients with multiple chronic conditions. In addition, several Cochrane reviews and meta-analyses have found evidence that adding pharmacists or nurses to the primary care team improves risk factor control and physician adherence to guidelines. More specifically, managed care organizations have found that a centralized cardiovascular risk service managed by pharmacists can reduce mortality.

It is not known if a comprehensive Prevention Health & Cardiovascular Risk Service (PHCVRS) that includes a cancer screening model can be implemented in private office practices that lack clinical pharmacists or specialized nurses. This lack of evidence is a major gap in the literature. This study will be the first to evaluate a behavioral intervention using a PHCVRS model in private practice.

1.1.1. Aims

This study will test the implementation of a novel strategy to improve secondary prevention of cardiovascular disease (CVD). The goals are to determine whether:

1) a web-based prevention health and cardiovascular risk service (PHCVRS) managed by clinical pharmacists will be implemented within diverse primary care offices
2) the PHCVRS intervention diffuses throughout offices that use the PHCVRS
3) the PHCVRS if cost-effective

1.1.2. Design

Fourteen clinics throughout Iowa are or will be participating in the study. Each clinic will enroll 25 subjects who require secondary prevention for CVD. Participating clinics have been randomized either to a PHCVRS intervention group or to a control group. Subjects who are enrolled at clinics in the intervention group will have ongoing contact with a clinical pharmacist at the PHCVRS, who will implement the study's intervention. Your clinic is participating as an intervention clinic, so each enrolled patient will receive the study intervention.

Toward the end of the study, clinics will also abstract medical record data for an additional 25 clinic patients who are not consented into the study. Detailed information about this group of patients will be provided later in the study.

Clinic providers will be asked to complete two surveys at the beginning of the study and during year 4 of the study.

1.1.3. Outcomes

1.1.3.1. Primary Outcome

The primary outcome for the study will be provider adherence to all of the Guideline Advantage criteria that apply to each consented subject (N=25). We will create three numeric scores for each subject, with each score serving as a surrogate measure for quality of care. Each score will be determined on the basis of information collected from the subject's medical record. Scores will be created at the time of subject consent, 12 months following consent and 36 months following consent.

1.1.3.2. Secondary Outcomes

1) We will measure provider adherence to the Guideline Advantage criteria that apply to an additional 25 clinic patients who meet study eligibility criteria but who only have their medical records abstracted for specific information. These patients will not be consented into the study. Scores for these patients will be created based on patient clinic visits that occur approximately when consented subjects are enrolled, 12 months later, and 36 months later.
2) We will compare all of the costs associated with the care for subjects in the PHCVRS and the control groups. We will also calculate incremental costs as a function of differences in guideline adherence, blood pressure (BP), LDL cholesterol, or HbA1C at each of the time periods. A cost-effectiveness (CE) ratio will then be computed to make clear to institutions the cost of the intervention for each outcome improvement resulting from the intervention.

1.2. Inclusion and Exclusion Criteria

1.2.1. Inclusion Criteria

1) English-speaking males or females
2) Age ≥50 years
3) Utilize the physician office at least once in the previous 24 months
4) Have a history of coronary artery disease (CAD), myocardial infarction (MI), stroke, transient ischemic attack (TIA), atrial fibrillation, or systolic heart failure or specified CAD risk equivalents (peripheral vascular disease/claudication, carotid artery disease or diabetes mellitus with co-existing uncontrolled hypertension and/or hyperlipidemia).

1.2.2. Exclusion Criteria

1) Inability to give informed consent
2) Pregnancy
3) Diagnosis of pulmonary hypertension
4) Cancer diagnosis with an estimated life expectancy less than 2 years
5) Residence in a nursing home or diagnosis of dementia
6) No telephone or have a hearing impairment not allowing them to use a phone
7) Refusal to consider attempting to use the internet at home, community center, library, medical office or other source
8) Patient has plans to move from the area or transfer care to a different clinic in the next 12 months
9) Arm blood pressure cuff cannot be used on patient for any reason

A detailed listing of the inclusion/exclusion criteria is provided in **APPENDIX I**.

1.3. Study Organization

The **Clinical Coordinating Center (CCC)** within the College of Pharmacy at the University of Iowa is responsible for the following key aspects of the trial: selection of participating sites; assisting sites in obtaining approval to conduct the study from their local Institutional Review Board (IRB); negotiating with sites the work that is to be completed and the compensation that sites will receive; training of site staff.

Clinical Coordinating Center Team		
Barry L. Carter, Principal Investigator	barry-carter@uiowa.edu	319-335-8456
Brian Gryzlak, Project Coordinator	brian-gryzlak@uiowa.edu	319-353-3857 319-335-8218
Nick Rudzianski, Data Entry, Administrative Support	nicholas-rudzianski@uiowa.edu	319-335-9783
CCC Fax Number		319-335-9782

Prevention Health & Cardiovascular Risk Service (PHCVRS) Pharmacists		
Christopher Parker, Clinical Pharmacist	christopher-parker@uiowa.edu	866-227-9873
Rachel Finkelstein, Clinical Pharmacist	rachel-finkelstein@uiowa.edu	866-227-9873
Tyler Gums, Clinical Pharmacist	tyler-gums@uiowa.edu	866-227-9873

The **Data Management Center (DMC)** within the Department of Family Medicine at the University of Iowa is responsible for the following key aspects of the trial: oversight of data submission, monitoring procedures at research sites, and data analyses.

Data Management Center		
Barcey T. Levy, Co-Principal Investigator & Director, DMC	barcey-levy@uiowa.edu	319-384-7000
Carol Moss, Study Monitor, Scheduling	carol-moss@uiowa.edu	319-356-4486
Yinghui Xu, Data Manager	yinghui-xu@uiowa.edu	319-384-5497

The **Iowa Personal Health & Research Management System (IowaPHRM)** is a web-based tool that simultaneously gives patients an opportunity to increase involvement in managing their health and serves as the study's online database. IowaPHRM will be managed by the following team within the College of Public Health and the Institute for Clinical and Translational Science at the University of Iowa.

IowaPHRM Team		
Brian Gryzlak, Research Specialist	brian-gryzlak@uiowa.edu	319-335-8218 319-353-3857
Michael Mueller, Lead IowaPHRM Administrator	michael-mueller@uiowa.edu	319-384-1547
Ryan Lorentzen, Application Analyst	ryan-lorentzen@uiowa.edu	319-353-8015

1.4. Regulatory and Billing Requirements

Each site will be required to complete the following study-related tasks and to store and transmit to the University of Iowa CCC the relevant documents listed for each task.

1.4.1. IRB Oversight

Each clinic must be overseen by an IRB of record. There are two options for the IRB of record:

1) Local IRB: The clinic may use a local IRB which is already in place to oversee research affiliated with the clinic. Information needed for a local IRB application will be provided by the CCC. The clinic will need to provide the following documents on an ongoing basis:
   - The Institutional Review Board's letters of approval for the study
   - All stamped informed consent documents approved and dated by the local IRB
2) University of Iowa IRB: Clinics that do not have oversight by a local IRB may use the University of Iowa IRB as their IRB of record. The following documentation will need to be submitted:
   - A letter of agreement addressed to the University of Iowa Principal Investigator
   - A HIPAA letter from the clinic's Privacy Officer
   - Documentation of Human Subjects Protection Training
   - The clinic's FWA number or an Individual Investigators Agreement to conduct the project in accordance with the University of Iowa's FWA
   - An IRB Authorization Agreement

The University of Iowa CCC will assist clinics in obtaining required documentation for either a local IRB or the UI IRB. IRB approval should be completed within three months of initiation for a clinic to remain in the study.

Each IRB-related document should be stored both in hard copy form in an organized binder and electronically. See Section "Organizing and Maintaining Study Files" for details.

1.4.2. Subaward Agreement with the University of Iowa

Administrative personnel at each site must also negotiate and sign a Subaward document created by the University of Iowa's Department of Sponsored Programs. The agreement describes the terms and conditions for reimbursing sites for study-related costs. The agreement should be signed by an authorized individual at the clinic and returned to the University of Iowa within one month of receipt. The subaward budget will be negotiated on an annual basis, with an authorized signature required each year on the amended award.

Please note that payments are based upon work that is completed. So a clinic that does not complete expected tasks for a given year would not be able to receive all the funds designated in the budget for that year. Questions regarding the subaward agreement should be directed to Brian Gryzlak at **brian-gryzlak@uiowa.edu**

1.4.3. Invoicing the University of Iowa

The Grant Accounting Department at the University of Iowa requests quarterly invoicing for project expenses. The following procedures will be maintained for submitting invoices:

1) Brian Gryzlak at the CCC will email a quarterly draft invoice to the clinic staff member who is designated as responsible for invoicing. Mr. Gryzlak should be notified immediately of any change in person responsible for invoicing.
2) Each draft quarterly invoice will detail all costs that are reimbursable during that quarter; only tasks completed during the quarter will be included on the invoice.
3) Should a clinic's invoice not agree with any items on the invoice or not included in the invoice, please notify Mr. Gryzlak at brian-gryzlak@uiowa.edu.
4) A completed invoice should be pasted onto your billing stationery and signed by an authorized individual in your clinic.
5) The signed invoice should be mailed to the address noted in the subaward contract. Contact Brian Gryzlak for guidance on this.
6) Payment typically occurs within 30 days of invoice receipt.

2. SITE TRAINING AND MONITORING

2.1. Initial Information and Training Sessions

2.1.1. Provider Information Session and Surveys

University of Iowa study investigators will visit each participating study site early in the study and before subject enrollment begins. Investigators will provide clinic providers with a detailed explanation of the study, preliminary activities and study expectations and relevant national guideline information. Clinics who are randomized to the intervention arm of the study will also receive training from study investigators on team building. The information session will be scheduled at a time preferred by the clinic's providers.

The physician leader at each clinic will read the accompanying letter of consent and, if willing, complete the Medical Home Index, a validated, self-assessment tool for evaluating primary care practice. Physician leaders will complete this tool before training and again in year 4 to determine how each office has improved on adoption of the Medical Home and if there is greater adoption in intervention offices compared to controls. We have also pioneered a validated instrument to measure physician-pharmacist collaboration and we will administer this tool to physicians at baseline and in year 4 to evaluate the level and type of communication between providers and pharmacists.

2.2. Study Coordinator Training

Each clinic will identify 1-2 staff members to serve as the Study Coordinator (SC). This person(s) will 1) identify and consent subjects, 2) instruct subjects in use of IowaPHRM, used to provide subjects with a way of documenting their self-monitoring and self-management activities, 3) conduct study visits at baseline, i.e., at the time of consent, and 12 months later, 4) abstract limited subject medical record data covering the time period that spans two years prior to consent through three years following consent and 5) report any serious events such as hospitalizations or emergency department visits as soon as possible once your office knows of the event. The SC(s) will be trained in use of IowaPHRM and in use of data collection forms either during the visit by University of Iowa study investigators or remotely through a webinar. The SC(s) will also receive regular contacts by CCC staff to reinforce the initial training.

2.3. Teleconference Calls

Iowa investigators will schedule periodic conference calls with the lead physician and study coordinator on an as needed basis during the first year of the intervention, perhaps as often as quarterly, and then at least once a year thereafter. The purpose of these calls will be to solicit input from providers on strategies to optimize communication and to improve the intervention, if necessary. These calls will also be used to ensure fidelity to the intervention. In addition, one investigator will visit each intervention office at least yearly to obtain feedback, maintain strong provider-investigator relationships and retain high fidelity to the intervention.

2.4. Interim Monitoring Visits

All sites will be monitored by study personnel ("monitors") from the Data Management Center. The purpose of the monitoring visit is to ensure that the protocol is being followed, that subjects' rights and safety are being protected, and to confirm data integrity and quality. The first monitoring visit will occur after 3-5 subjects have been enrolled at a center or approximately three months after the first subject is enrolled, depending on the progress a site is making and/or the challenges they are experiencing. All centers will have a visit approximately 12 months after the first patient is enrolled, a close-out visit after all data are submitted and additional visits as needed for problems.

Study monitors will need access to medical records but will have NO contact with patient subjects. Once study sites have enrolled their first subject, the CCC will send an email to the Lead Physician and Study Coordinator requesting such access to the office's medical record system ahead of the first monitoring visit.

2.4.1. Pre-Monitoring Procedures

1) Approximately two weeks ahead of the initial anticipated visit, if possible, and 4-6 weeks ahead of each subsequent monitoring visit, the monitor will email the SC to negotiate and finalize a date for the visit. The SC and PI should be available to meet with the monitor during the visit.

2) The monitor will send a letter to the site approximately one week ahead of the initial baseline visit date and 2 weeks ahead of subsequent monitoring visit dates, explaining objectives of the visit and necessary materials. The monitor will need a reserved space in which to work and access to a photocopy machine and electronic records, if applicable. The following items should be available for review:

    - Screening Logs
    - Patient Clinic/Medical records
    - Paper copy case report forms (CRFs) and any other study-related source documents and records
    - Regulatory Documents
        - IRB approvals (either UI or local IRB)
        - Approved informed consent documents
        - Approved recruitment materials
        - IRB correspondence
        - Blood pressure measurement certifications

2.4.2. On-site Monitoring

1) An initial meeting (approximately 30 minutes) will occur between the SC and the monitor to orient the monitor to clinic/medical records, answer study questions, and review protocol procedures. The SC should be available periodically throughout the visit to answer questions or to make data corrections, if necessary.
2) In addition to review of the items listed above, the monitor will re-certify the SC in BP measurement procedures on an annual basis.
3) At the end of the monitoring visit, the monitor will meet briefly with the SC and PI to discuss findings and a plan of action.

2.4.3. Post-Monitoring

1) The monitor will send the site a formal report containing feedback and a detailed listing of all findings within approximately four weeks of concluding the monitoring visit.
2) The monitor will contact the SC to discuss pending items until all items are resolved. The SC will respond to pending items in a timely manner and inform the monitor of any issues delaying resolution of the item.

2.5. Close-Out Visits

A study monitor from the University of Iowa will visit each site at the end of the study to close out that site's participation in the study.

2.6. Organizing and Maintaining Study Files

Each patient should have a study file containing the signed informed consent document, completed case report forms and other source documentation. Arrange patient files in order of study visits.

Retain the Screening Log/Verification Form (see later section) for all patients initially screened. Keep together in one of two folders: if patient does not meet screening criteria, file in "Eligibility Failure" folder; if patient meets screening criteria, file in "Meets Eligibility" folder. Later, if patient agrees to participate in the study, transfer Screening Log/Verification Form to patient's individual folder. Fax remaining Screening Log/Verification Forms, i.e., screening failures (those who were ineligible or others who met criteria but declined participation), to the CCC in batch form on a quarterly basis.

2.6.1. Completed paper versions of case report forms (CRFs)

Enter all required fields on the CRFs. Do not leave any field blank. **If corrections to paper copies are needed, draw a single line through the incorrect response, write the correct response, and**

initial and date the correction. White-Out or other similar products that obscure the original response may not be used on source documents.

2.6.2. Keep all regulatory documents together in hard copy form in a binder

1) IRB of record documents
    - IRB documents tab: All approval letters, modification/amendment submissions, approved and stamped copies of documents (e.g., recruitment materials and informed consent documents), and any correspondence with the IRB.
    - IRB reports tab: Some IRBs have separate templates for sites to report serious adverse events and protocol deviations. If you have your own IRB and it requires such reporting, please include these reports under this tab.

    Each IRB document should also be stored electronically on a secure computer and emailed to brian-gryzlak@uiowa.edu (for sites with local IRB oversight)

2) ICARE Study tab: Letters and reports related to study monitoring and blood pressure training certifications should be filed here.

3. SCREENING AND ENROLLMENT

A complete list of the study's inclusion/exclusion criteria is provided in **APPENDIX I** (per the *Screening Log and Verification of Inclusion and Exclusion Criteria* form). The list is comprised of a complex formula that requires diligence to accurately implement.

When screening clinic patients for possible enrollment into the study, it is imperative to determine that they fully meet all of the inclusion criteria for the study and that they do not meet any of the exclusion criteria.

The basic screening and enrollment process consists of the following and is described in more detail, below:

1) **Running patient lists**: Review medical records to generate lists of potentially eligible patients
2) **Screening log**: Review the patients on the list in detail by completing a Screening Log and Verification of Inclusion and exclusion Criteria form for each patient on the list.
3) **Patient recruitment**. Either:
    a. **Invite via mail**: Send a letter and postcard to the potentially eligible patients, OR
    b. **Invite in person**: If you are reviewing the medical record to identify patients that have a visit at your office in the next week(s) you can approach the patient in person to discuss the study.
4) Schedule the **baseline visit and review exclusion criteria**
5) Confirm eligibility criteria and review consent document with patient at time of baseline visit.
6) Subject signs consent document

3.1. Running Patient Lists

1) Run or request from your Information Technology staff a list of all patients who:
    a. Are age 50 or older, AND
    b. Were seen in the clinic during the past 24 months, AND
    c. Who have diabetes, high cholesterol, or hypertension, ideally using the ICD-9 codes indicated on *the Screening Log and Verification of Inclusion and Exclusion Criteria* form.
2) Then use this list to complete the *Screening Log and Verification of Inclusion and Exclusion Criteria* form for each patient on the list to determine whether they meet inclusion/exclusion criteria (next section).

    NOTE: depending on the capability of your office, you may or may not be able to run more or less specific lists. This is fine.

3.2. Screening Log and Verification of Inclusion and Exclusion Criteria ("Screening Log/Verification Form")

For each patient you screen (that is, each patient for whom you review their medical record for the purposes of determining if they might be eligible for the study) you should complete a Screening Log/Verification form. A template for the screening log is provided in **APPENDIX I**. (An electronic version (Excel file) of the electronic screening log is also available, if preferred.)

Each patient who is screened for the study should be tracked on this log to record their qualification, willingness to participate and consent outcome.

Retain all *Screening Log/Verification* forms for the duration of the study. You will be asked to fax or securely email a *de-identified copy* of these forms, i.e., one with the patient's name MRN, and phone number marked out or otherwise removed, for those subjects who do not end up enrolling in the study to the CCC quarterly, or more frequently if requested from the CCC. You will also be asked to fax a redacted copy of the screening log for all patients who are enrolled in the study after the baseline visit.

Note: Your log may contain a list of many patients, as generated by IT, or you might find it easier to focus on a smaller set of patients who are referred to you by a provider or staff member in your clinic.

3.2.1. Complete the Screening Log/Verification form with the following steps:

1) Run or otherwise generate the patient list(s) as described in the previous section.
2) Access your site's medical record and have blank copies of the *Screening Log/Verification* form in front of you.
3) Using your office's medical record, complete a *Screening Log/Verification* form for each patient on the list:
    a. Enter the patient name and MRN
    b. Complete the Gender, Ethnicity, and Race fields (required)
    c. Section A: Complete Items 1-3. The answers to Items 1 and 2 must be YES and the answer to Item 3 must be 50 or higher to continue to Section B. If you answer a question so that the patient is ineligible, STOP and file the form in the "Eligibility Failure" folder. Fax in batch, removing the patient name, MRN and phone number in the header to the CCC on a quarterly basis.
    d. Section B: Review each patient's medical record. For the diagnoses that apply in Items 4a, 5a, and 6a, determine if the **most recent** corresponding lab values in the patient's medical record (HbA1c, LDL, SBP) are within guidelines noted for Items 4b, 5b, and 6b.

i. If a patient meets one or more risk factor from Section B, continue with Section C; if not, the patient is not eligible. STOP and file the form in the "Eligibility Failure" folder. Fax in batch quarterly, with identifying information removed.

e. Section C: Enter the date that you are completing Sections B and C in Item 19. Review the patient's medical record over the preceding 24 months to determine whether s/he has a history of any of the listed Cardiovascular Conditions in Section C. Documentation in the patient's Problem List is preferred, but explicit mention of a diagnosis in a provider note can be used if the problem list has not been regularly updated. For the diagnosis that applies in Item 16, determine if the **most recent** corresponding weight in the patient's medical record is within guidelines noted.

f. If a patient meets a total of at least 3 criteria from Sections B and C combined, with at least one of these from Section B, the patient is eligible for further screening; if less than 3, or if none from Section B, the patient is not eligible, and form should be filed in "Eligibility Failure" folder, to be batch faxed later.

g. Section D: This information, with the exception of the Pulmonary Hypertension diagnosis, may come from the medical record, direct observation or from the patient – see guidance for each item on the form itself.

i. To the extent possible, review each of the items in Section D using information from each patient's medical record. If any exclusion criteria are identified, the patient is not eligible. File the form in the "Eligibility Failure" folder.

NOTE: Patients' attempts to access the Internet will not be tracked; thus the patient is excluded only if s/he flatly refuses to make such attempts.

h. Section E: This information should come from the patient at the time they are contacted to schedule a baseline study visit.

i. You need to review Sections D and E again prior to the subject signing consent. This is explained in more detail below.

j. If the inclusion criteria described above were met and none of the exclusion criteria are met, the patient may be invited to participate in the study. File *Screening Log/Verification* form in "Meets Eligibility" folder until patient either agrees or declines study participation.

3.3. Recruitment mailing

The IRB will approve and stamp a letter of invitation about the study as well as a postcard. This letter should be mailed to each patient determined to be potentially eligible based on the criteria in the *Screening Log/Verification* form, filed in the "Meets Eligibility" folder.

The mailing should include:

- An invitational letter (with the IRB stamp) that provides a brief description of the study.
- A response postcard containing a postage stamp. You will need to write the Screening Number from the Screening Log/Verification form somewhere on the response postcard in order to track which potential participant returns it. The letter will include a statement that the patient will be called if the postcard is not returned within ten days and an explanation of how the patient can avoid the call by returning the card or calling the staff to decline participation.

If a patient does not return the response card within 10 days of mailing, make up to three phone contacts, on different days and at different times of day, to determine interest.

When you contact a patient via phone, or a patient returns a postcard stating that they are interested in participating, **answer the questions in Section E of the *Screening Log/Verification* form to make sure the patient does not meet any exclusion criteria in that section.**

Below you will find more detailed information on the rationale for the exclusion criteria:

- It is the coordinator's responsibility to make a determination as to whether the patient is unable to provide informed consent to participate in the study. **If you feel that the patient does not understand what the study is about or what participating in the study means for them do not enroll them into the study.**
- Female patients also should be asked if they are currently pregnant. If they are, they will not be consented into the study. We will take patients' verbal responses regarding pregnancy and will not require pregnancy testing since the study itself does not present any hazards for pregnant women.
- Each patient who is brought in for possible consent will be informed that *willingness* to access the IowaPHRM on the internet, whether at home, at a library, in the clinic, or at any other location, is necessary in order to participate in the study. Any patient who does not have internet access at the time of consent will be informed that they must be willing to access the internet in order to proceed with consent into the study. Patients who state that they definitely are unwilling to access the internet should not be consented into the study.
- Patients whose blood pressure cannot be taken with an arm cuff supplied with the Omron HEM 907-XL machine (e.g., morbidly obese patients who would require use of a <u>thigh cuff</u> for blood pressure monitoring) <u>cannot be enrolled</u> in the study as this is not included with the Omron HEM 907-XL.
- Any patients who know definitely that they will move from the area or transfer care to a different clinic within 12 months should not be enrolled in the study. This is because they would not be able to complete the 12 month follow up visit.
- Similarly, patients with a cancer diagnosis with a life expectancy of less than 2 years should not be enrolled in the study.

3.4. Incorrect Patient Enrollment/Protocol Deviation

If you determine that you enrolled a patient who does not qualify for the study, you must notify Carol Moss at carol-moss@uiowa.edu and Brian Gryzlak at brian-gryzlak@uiowa.edu as soon as possible within 2 working days after you become aware of the error.

4. BASELINE VISIT

Only the Study Coordinator(s), trained and certified in use of the Omron BP monitor by ICARE study staff, may obtain informed consent from patients and enroll patients into the study. Other clinic staff may refer patients to the study but may not review the consent document with patients. Staff members are welcome to take patient questions regarding the study and refer them to the Study Coordinator as needed.

The Study Coordinator MUST obtain signed informed consent from the patient (see details in later section) **before undertaking any baseline research procedures (e.g., taking blood pressures).**

4.1. Pre-Baseline Visit Procedures

Prior to the initial visit:

1) Before meeting with the patient for the Baseline visit, make sure that the IRB-approved consent document is the **current version** being used and is still valid. NOTE: Consent documents are re-issued on a yearly basis; once a patient has been consented on one document, it is not necessary to re-consent them on the updated version.
2) Make sure that the date the patient is being enrolled falls within the dates specified on the consent. You should not have a patient sign a consent that has expired. Unsigned consents that have expired or are otherwise not current should be destroyed, with the exception of one copy that needs to be retained for the regulatory binder, where all versions of the consent should be kept.
3) Complete the Screening Log/Verification form through Question 31.
4) Make sure the date entered on Item 27 of the Screening Log/Verification form is less than 6 months from the date you expect the patient to sign the consent form.

4.2. Steps for Obtaining Informed Consent

1) Review screening criteria in Section D of the Screening Log/Verification form. Confirm that each patient:

A. Is able to provide informed consent
B. Confirm that female patients are not currently pregnant. Any woman who reports being pregnant should not be consented. Pregnancy testing will not be required.
C. Does not have a diagnosis of pulmonary hypertension
D. Does not reside in a nursing home or has a diagnosis of dementia
E. Has a telephone and does not have a hearing impairment that does not allow them to use a phone
F. Is willing to access the internet at some location. Any patient who is not willing to consider obtaining access to the internet should not be consented.

2) Provide the patient with a complete informed consent document, encourage the patient to read the entire document, and allow the patient sufficient time to read the document.

3) Explain the following aspects of the study:

A. Purpose of the research study: To examine whether a pharmacist-managed cardiovascular risk service can work with clinic physicians to decrease risk of cardiovascular disease; explain that patients at this clinic will not be able to work with the pharmacist.

B. Duration of study participation: 3 years

C. Number of research visits:

1. Two visits with me (the SC), including the initial visit and a visit roughly 12 months later.

2. Multiple contacts with a clinical pharmacist at the University of Iowa over a 12 month period; anticipate up to 14 phone contacts over the 12 months in the study.

D. Experimental portion of the study: Having a clinical pharmacist at a central location work with patients by phone and in collaboration with the patient's primary care provider

E. The study procedures/requirements:

1. Must be willing to get access to the internet; will not be required to use the internet.

2. Women cannot be pregnant

3. Two study visits with me (the study coordinator)

4. Multiple surveys

5. Measurement of height, weight and blood pressure

6. Blood draw

4) Multiple contacts with a clinical pharmacist via telephone, text or email; the pharmacist will work with your physician to decrease your risk of developing cardiovascular disease.

5) Data collected from your medical record for up to 3 years after you sign consent.

   A. The risks of the study

      1. Drawing blood could cause discomfort or bruising

      2. It is possible that your physician might try harder to improve your health and might prescribe more medications because you are in the study. But such decisions would be made by you and your physician and are not part of the study itself. You could have a medication reaction, though your doctor will approve all changes to your medications

      3. There is a very slight chance that information about your health could accidentally reach someone who is not connected with the study, but we will store your paper documents about the study in a locked file cabinet, and the website for the IowaPHRM is password protected and housed on a secure research server.

   B. The voluntary nature of the study – that the subject may stop the study at any time.

   C. When a subject's participation in the study may be stopped (safety, compliance, sponsor stops the study).

   D. HIPAA section – the clinic investigators must be allowed to have access to the participant's medical information and to create medical information in order for the subject to be in the study.

   E. Contact information in case of a research-related Injury.

6) Ask the patient what questions s/he has and provide answers.

7) If desired, the patient may take the unsigned consent document, wait up to 10 days to make a final decision and re-schedule the baseline visit if s/he decides to participate.

8) If after reading the consent document and having their questions answered a patient agrees to participate in the study, the patient will sign and date the consent document.

9) You should immediately sign and date the consent document.

10) Make two COMPLETE copies of the consent document:

   A. One copy will be placed in the chart or medical record, unless the clinic does not permit this. (If clinic policy explicitly prohibits placing a copy of the signed consent in the patient's medical record AND the local IRB does not require placing a copy in the medical record, then clinic policy should be followed.)

   B. The patient will be given a copy, and

   C. The original will be placed in the patient's individual study file.

Note: The signed consent forms will be reviewed by study monitors from the University of Iowa during interim monitoring visits to ensure compliance with the informed consent process.

4.3. Case Report Forms (APPENDIX IV)

At the baseline visit, collect from subjects:

1) **Enrollment Form**: Demographic and contact information
2) **Diagnosed Conditions-Care Management Form**: Diagnosed conditions
3) **Medication Reconciliation Form**: List of chronic medications and responses to the medication adherence survey questions; requires verification of current medications from the medical record prior to the visit
4) **Health Behavior Inventory Form:** Health behavior questions
5) **BP-Lab-Cancer Screening** Form: Items on recent smoking and most recent cancer screenings.

4.4. Blood Pressure Measurement

Measure each of the following parameters and enter on the **BP-Lab-Cancer Screening** form:

1) 3-4 BP readings using the automated Omron HEM 907-XL *(see Procedures for Monitoring Research Blood Pressure,* Section H*)*
2) Height and weight
3) Pulse

4.5. Laboratory Specimen Collection

Draw blood required for the following tests:

- Lipid profile
- HbA1c

Typically, a total of two 5 ml. vials of blood will be required for these tests. A fasting lipid profile is optimal. If a patient has documented triglyceride levels $\leq$ 100, then non-fasting lipids are acceptable.

If a patient is referred to the study during a clinic visit and can complete baseline activities the same day, non-fasting labs may be drawn.

Should triglyceride results be elevated such that an LDL cannot be obtained, contact the clinical coordinating center (carol-moss@uiowa.edu) to obtain a calculated LDL level.

Results should be recorded on the **BP-Lab-Cancer Screening** form and faxed to the CCC within 48 hours.

4.6. Patient Orientation To The Iowa Personal Health & Research Management (IowaPHRM) System

The Iowa Personal Health and Management System (IowaPHRM) is an online record of patient health data that may be accessed by the subject, the Study Coordinator at the subject's clinic, the

study pharmacist, ICARE research staff in the University of Iowa Department of Family Medicine and the College of Pharmacy, and database managers in the College of Public Health (Gryzlak, Lorentzen, and Mueller).

Patients should be given a written instruction sheet that will describe:

(1) the potential benefits of using IowaPHRM

(2) how to log onto IowaPHRM using a unique User ID and password and how to populate the fields

(3) how they can interact with the study pharmacist through IowaPHRM

This instruction sheet is found in the patient's study folder.

4.7. Faxing Data to The CCC Within Two Days

Once a patient is fully screened, consented and enrolled, and the Baseline visit is completed, the Study Coordinator should fax the five baseline forms and a redacted version of the screening log (remove or cover up patient name, MRN and phone number) to the Clinical Coordinating Center (CCC) **within two working days**.

- **The most important document to fax us is the Enrollment form.**
    - Once this document is uploaded, the PHCVRS pharmacist will be notified that a new patient has been enrolled.
- **Please fax this form to the CCC as soon as possible.**
    - Laboratory results should be faxed to the CCC as soon as they become available. The PHCVRS pharmacist will use these results to guide the intervention.

4.8. Patient Reimbursement

Patients will be compensated through the University of Iowa eVoucher system. A member of the University of Iowa research team will initiate up to two payments based on completion of study visits. It is imperative that visit forms be faxed to the CCC promptly so that patients receive timely reimbursement.

Total possible compensation = $150.00, to be distributed as follows:

$75.00 will be paid for each subject who completes the first (baseline) visit.

Subjects who fail any portion of screening at the first visit will not be compensated.

$75.00 will be paid for each subject who completes the 2nd visit (roughly 12 months later).

Any subject who does not complete the 2nd visit will not receive the 2nd payment.

The total payment amount is designed to compensate patient subjects for their year-long active participation in the study, including two phlebotomy draws.

Payment should arrive in the form of a check from the University of Iowa within four weeks of the completed visit. Should a patient not receive a check, the study coordinator should contact Brian Gryzlak at 319-335-8218 or brian-gryzlak@uiowa.edu.

5. Procedures for measuring Research Blood Pressures

Note: The manufacturer of the Omron HEM 907-XL gives a method for checking accuracy (compared to a calibrated mercury manometer) on page 26 of the Omron Instruction Manual and recommends doing this check if you get suspicious readings or if you drop the device. The manufacturer recommends re-calibration per the manufacturer every 5 years for light use (< 5 times daily), more often for heavy use.

5.1. Preparing the Subject

The subject ideally should refrain from smoking or ingesting caffeine for 20-30 minutes prior to the blood pressure measurement.

Have the subject remove all clothing that covers the location of cuff placement.

The subject should be comfortably seated in a chair, with:

- the back supported
- legs uncrossed and flat on the floor
- the arm supported, ideally at heart level on a desk
- the palm of the hand facing upward

Have the subject sit for **at least 5 minutes**. Instruct the patient to relax as much as possible. Then take patient's pulse while sitting (count beats per minute for 30 seconds and multiply by 2). Record seated pulse on line 1 of the **BP-Lab-Cancer Screening** form.

5.2. Cuff Measurement

The subject's arm circumference should be measured at the baseline visit. This does not need to be repeated at follow-up visits unless the subject exhibits a marked change in weight.

The ideal cuff should have a bladder length that is 80% of arm circumference and a width that is at least 40% of arm circumference. The **INDEX ↑** that is marked on the edge of the cuff should fall within the range bar on the cuff. Recommended cuff sizes are:

- Arm circumference 17-22 cm: use "small adult" cuff
- Arm circumference 22-32 cm: use "adult" cuff
- Arm circumference 32-42 cm: use "large adult" cuff
- Arm circumference 42-50 cm: use "extra large adult" cuff

Subjects who require use of a thigh cuff cannot continue in the study.

5.3. Cuff Placement

Do not allow a sleeve to form a tourniquet on the arm.

Palpate the brachial artery in the antecubital fossa and place the **ART ↓** that is marked on the midline of the bladder of the cuff so that it is over the arterial pulsation of the patient's bare upper arm.

The lower end of the cuff should be ½ to 1 inch above the inner side of the elbow joint.

The middle of the cuff should be at the level of the right atrium (the mid-point of the sternum).

Pull the cuff snugly around the bare upper arm so that you can insert only one finger between the cuff and the arm.

5.4. Blood Pressure Measurement

Have the **BP-Lab-Cancer Screening** form and the Omron monitor beside you on the desk.

Tell the patient that you will be taking at least 3 blood pressure readings and that **neither the patient nor the study coordinator should talk** during the measurements.

Push the ON/OFF button on the monitor to turn on the power.

Take a single BP reading

- Set the MODE selector to "SINGLE."
- Set the P-Set knob to "AUTO."
- Push the START button.
- Record the displayed blood pressure on line 2 of the **BP-Lab-Cancer Screening** form.
- Also record the displayed pulse reading on line 1 of the **BP-Lab-Cancer Screening** form.

Wait 60 seconds before taking the next blood pressure.

Take a double BP reading

- Set the MODE selector to AVG.
- Push the START button.
- The machine will show you TWO individual BP readings – be ready to record the second one as the machine goes on quickly to display the average – and the average of these two readings, automatically counting down from 60 seconds between readings.
- Record the first of these double readings on line 3 and the second of these double readings on line 4 of the **BP-Lab-Cancer Screening** form.
- If both systolic and diastolic measurements of the double BP readings differ by ≤ 4mm, record the displayed average BP reading on the **BP-Lab-Cancer Screening** form.

If either systolic or diastolic readings of the second and third (double) BPs differ by > 4 mm:

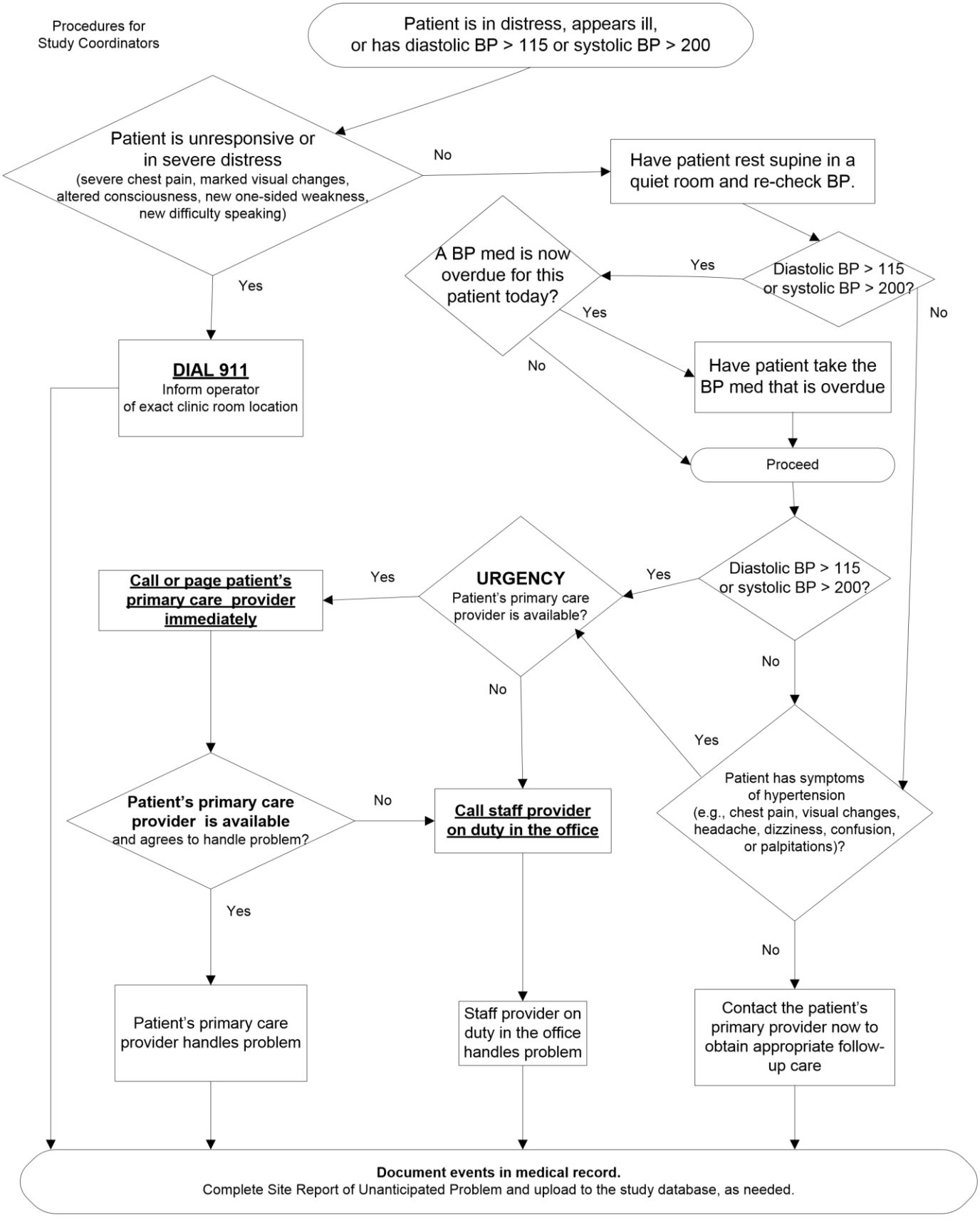
- Set the MODE selector to "SINGLE." Wait 60 seconds.
- Push the START button.
- Record the displayed fourth reading on line 15 of the **BP-Lab-Cancer Screening** form.
- Manually average the **two closest systolic** measurements and the **two closest diastolic** from the 2nd, 3rd and 4th blood pressure readings, and enter those averages onto the **BP-Lab-Cancer Screening** form (lines 6 and 7). If all 3 systolic or diastolic readings are equidistant apart, select the two **HIGHEST** readings to average.

Have the patient **stand for one minute** and then:

- Take another pulse, recording it on line 8 of the **BP-Lab-Cancer Screening** form.
- Take another **single BP reading** according to the instructions, above, and record on line 9 of the **BP-Lab-Cancer Screening** form.

IF YOU GET AN ERROR MESSAGE AT ANY POINT, START THE SEQUENCE OVER.

HANDLING HYPERTENSIVE URGENCY



6. MEDICAL RECORD DATA COLLECTION AT 4 AND 8 MONTHS

At roughly 4 months and 8 months following enrollment, the study coordinator will abstract data from the patient's medical record on specific laboratory testing, hospital and emergency room visits, and new diagnoses (*see* **Four and Eight Month Data Collection** form, **APPENDIX IV**) :

Note that no patient visit is involved for the 4 and 8 month data collection.

1. 4 months following the enrollment visit
    a. Abstraction should occur no later than 5 working days following the 4 month time point
    b. Abstraction should cover the time period from the baseline/enrollment visit through the date that is 4 months following the enrollment date.
    c. The form should be faxed to the CCC no later than 7 working days following the 4 month time point
2. 8 months following the enrollment visit
    d. Abstraction should occur no later than 5 working days following the 8 month time point
    e. Abstraction should cover the time period from the baseline/enrollment visit through the date that is 8 months following the enrollment date.
    f. The form should be faxed to the CCC no later than 7 working days following the 8 month time point

Specific data to be abstracted for the 4 and 8 month time points:

1. Laboratory tests when warranted based on diagnosed conditions
    a) Diabetes: HgA1c
    b) Anticoagulation: INR
    c) Hyperlipidemia: Total Cholesterol, LDL Cholesterol, HDL Cholesterol and Triglycerides
2. Clinic blood pressure
    a. Use the most recent clinical blood pressure that is documented
    b. If more than one BP is documented at a visit, select the lowest reading
3. Dates of ALL hospitalizations and emergency room visits
4. New diagnoses pertinent to cardiovascular functioning

7. 12-MONTH VISIT

The 12-month visit should be scheduled so that it occurs no sooner than 11 months after enrollment and no later than 13 months after enrollment.

At this visit, the SC will:

1) Measure (**BP-Lab-Cancer Screening** form, check "12 month" box):
    a. Height and weight
    b. Pulse
    c. 3-4 BP readings using the automated Omron HEM 907-XL
2) Collect from subjects:
    a. Diagnosed conditions (**Diagnosed Conditions-Care Management** form, check "12 month" box)
    b. List of chronic medications and responses to the medication adherence survey questions (**Medication Reconciliation** form, check "12 month" box)
    c. Ask whether the patient has been hospitalized or visited the emergency room and screen the medical record for unanticipated problems (**Site Report of Unanticipated Problem** form)
3) Draw blood required for a lipid profile and HbA1c, requiring a total of two vials of blood (results recorded on **BP-Lab-Cancer Screening** form)
4) Verify or obtain the following data from the subject's medical record for the time period that spans the 12 month period following the initial baseline visit. This review of the medical record should be completed after the patient visit.
    a. Chronic medications (**Medication Reconciliation** form)
    b. Co-morbid conditions (**Diagnosed Conditions-Care Management** form)
    c. Most recent chart recorded blood pressure (**Diagnosed Conditions-Care Management** form)
    d. Dates and results of labs and screening related to lipid management and diabetes management (LDL and HbA1c) (**BP-Lab-Cancer Screening** and **Diagnosed Conditions-Care Management** forms)
    e. Evidence from the MR, i.e., from notes or Problem List, of unanticipated problems/SAEs (**UNANTICIPATED PROBLEM (UP) EVENT-DRIVEN FORM**)
    f. Evidence from the MR of the following assessments/encounters *when applicable* (**Diagnosed Conditions Care Management** and **BP-Lab-Cancer Screening** forms):
        i. Chest pain
        ii. Shortness of breath
        iii. Plan for achieving or maintaining ideal body weight
        iv. Smoking assessment and nicotine replacement
        v. Alcohol use
        vi. Recent values for HbA1c and LDL cholesterol
        vii. Cardiac rehabilitation after myocardial infarction
        viii. Foot exam

ix. Urine screen for microalbuminuria

x. Immunizations

- -Influenza
- -Pneumonia

xi. Cancer screenings

1. Mammogram
2. Pap
3. Colorectal

8. Medical Record Data Abstraction at 36 months

Each site Study Coordinator will also collect medical record data that covers the time period extending from the 12 month study visit until 36 months following enrollment.

Abstracted data should not extend past the 36 month time point, and it should be submitted by 37 months following enrollment.

The following data will be collected for all subjects:

1) Diagnosed conditions (**Diagnosed Conditions-Care Management** form)
2) Clinic blood pressure (**36 Month Blood Pressure, Laboratory and Medication** form)
3) Laboratory tests (**36 Month Blood Pressure, Laboratory and Medication** form):
    a. HbA1c
    b. Total Cholesterol
    c. HDL Cholesterol
    d. HDL Cholesterol
    e. Triglycerides
4) Prescribed medications related to cardiac and circulatory functioning
5) Any evidence of an unanticipated problem **UNANTICIPATED PROBLEM (UP) EVENT-DRIVEN FORM**

9. UNANTICIPATED PROBLEMS (UPs)

9.1. Key Definitions

Unanticipated Problems (**UPs**) are considered to be any event or problem that is:

- Unexpected

AND

- Possibly, probably, or definitely related to study participation

AND ONE OR BOTH OF THE FOLLOWING:

- Is fatal, life-threatening or serious [(UP + Serious Adverse Event (SAE)]

OR

- Suggests greater risk of harm to study participant(s) than was previously known or recognized (UP), including a breach of confidentiality, a subject complaint that can't be resolved by study investigators, or identification of a new risk (UP) related to the study.

Note: *If there is any question concerning classification of an event as a UP, Local Investigators must contact UI Investigators for a clarification or recommendation.*

9.2. Responsibilities of Involved Parties

The monitoring and reporting of UPs is an important process for ensuring the safety of subjects participating in clinical research.

A decision tree for these problems/events can be found at the end of this section.

9.2.1. Local Investigators

Investigators and research personnel at local sites have primary responsibility for discovery and preliminary evaluation of UPs, and for the submission of UP reports to the University of Iowa (UI) Investigators via fax.

A Local Investigator who is uncertain about the need to report a specific problem/event should contact UI Investigators for a recommendation.

Detailed instructions for reporting UPs are given later in this section.

Reporting of UPs to Institutional Review Boards (IRBs) depends on which IRB is overseeing the study at each site:

1. Local site personnel who are overseen by the UI IRB will have their reportable UPs submitted by UI staff members. Local personnel at these sites do not need to contact the UI IRB.
2. Local site personnel who are overseen by a Local IRB should submit reports of UPs to their IRB per their IRB's policy.

Please note that a study monitor from the team of UI investigators will review the medical records of enrolled patients to ensure that all UPs have been reported.

9.2.2. Local IRBs

Local IRBs who are overseeing a study site have two responsibilities related to UPs:

1. Review of individual UP cases
    a. The Local IRB receives and reviews reports from Local Investigators regarding on-site UPs involving risks to subjects or others.
    b. The Local IRB has the prerogative to halt any activities at their site that have been associated with unanticipated serious harm to participants and/or to mandate that new information be added to the informed consent document at their site.
    c. The Local IRB should provide Local Investigators with a formal decision regarding their review of the problem/event and what actions are determined to be necessary.
    d. Local Investigators should then forward the Local IRB decision to University of Iowa Investigators.
2. Annual review of research at the Local Site
    a. Either the UI IRB or the Local IRB will conduct an annual continuing review of research at the site that includes consideration of UPs/ SAEs, interim findings, and any recent literature that may be relevant to the research.
    b. A Local IRB may rely on a current statement from the study's Data and Safety Monitoring Board (DSMB) or sponsor indicating that it has reviewed study-wide SAEs, interim findings, and any recent literature that may be relevant to the research, in lieu of requiring that this information be submitted directly to the IRB. Institutions and IRBs may require additional information for continuing review, at their discretion.

9.2.3. University of Iowa Investigators and Staff

1. UI Investigators receive submitted reports of UPs from Local Investigators, and forward them to the study's Physician Monitor for review.
2. Members of the research staff will also forward all reportable UPs to the UI IRB per IRB policy.
3. The Physician Monitor will contact UI Investigators if an expedited UP report to the study funder is required. In these cases,
    a. UI Investigators will develop a plan to address the event or problem.

i. Should UI Investigators determine that a site UP resulted from either improper or deficient procedures or unjustified disease management practices at the site, UI Investigators will request that the site develop a Corrective Action Preventive Action (CAPA) plan.

ii. UI Investigators, in collaboration with Local Investigators, will revise the plan as needed to optimally decrease the likelihood that the UP will recur.

iii. UI Investigators and UI Study Monitors will monitor both implementation of the plan and resolution of the identified deficiency through site teleconferences.

b. UI Investigators will submit the expedited UP report to the study funder's Project Officer and send a copy of the report to Local Investigators, to the IRB that is responsible for study oversight at the site and to the study's DSMB.

c. If the event or problem is of a nature that it would affect the entire study, UI Investigators will send the report to all Local Investigators for transmission to their Local IRBs.

4. Should UI Investigators learn of information that is relevant to the ICARE Study or that may impact subjects (e.g. results from another clinical trial), they will communicate an advisory to Local Investigators and Coordinators through an email listserv. The listserv mechanism is in place to relay any critical information immediately, if necessary.

9.3. Detailed Instructions for Submitting Reports of UPs

1. Study Coordinators must search for documented or reported problems at the two time points:
   a. The 12 month study visit (screening question to patient and medical record review)
   b. The 36 month medical record review

   The "UNANTICIPATED PROBLEM (UP) SCREENING FORM" (see **APPENDIX IV**) should be completed on hard copy and faxed to the CCC at both time points.
2. Local Investigators and Study Coordinators must also report problems that they identify outside of the 12 and 36 month time points and that meet the criteria for reporting. All such problems must be faxed to the CCC within 2 days of identifying the problem.
3. Local Investigators/Study Coordinators must fax to the CCC the **UNANTICIPATED PROBLEM (UP) EVENT-DRIVEN FORM** for all identified UPs that meet the criteria for reporting; each report should be faxed within two working days of the time that a research team member becomes aware of the event.

   Note: *If there is any question concerning classification of an event as a reportable UP, Local Investigators must contact UI Investigators for a clarification or recommendation.*

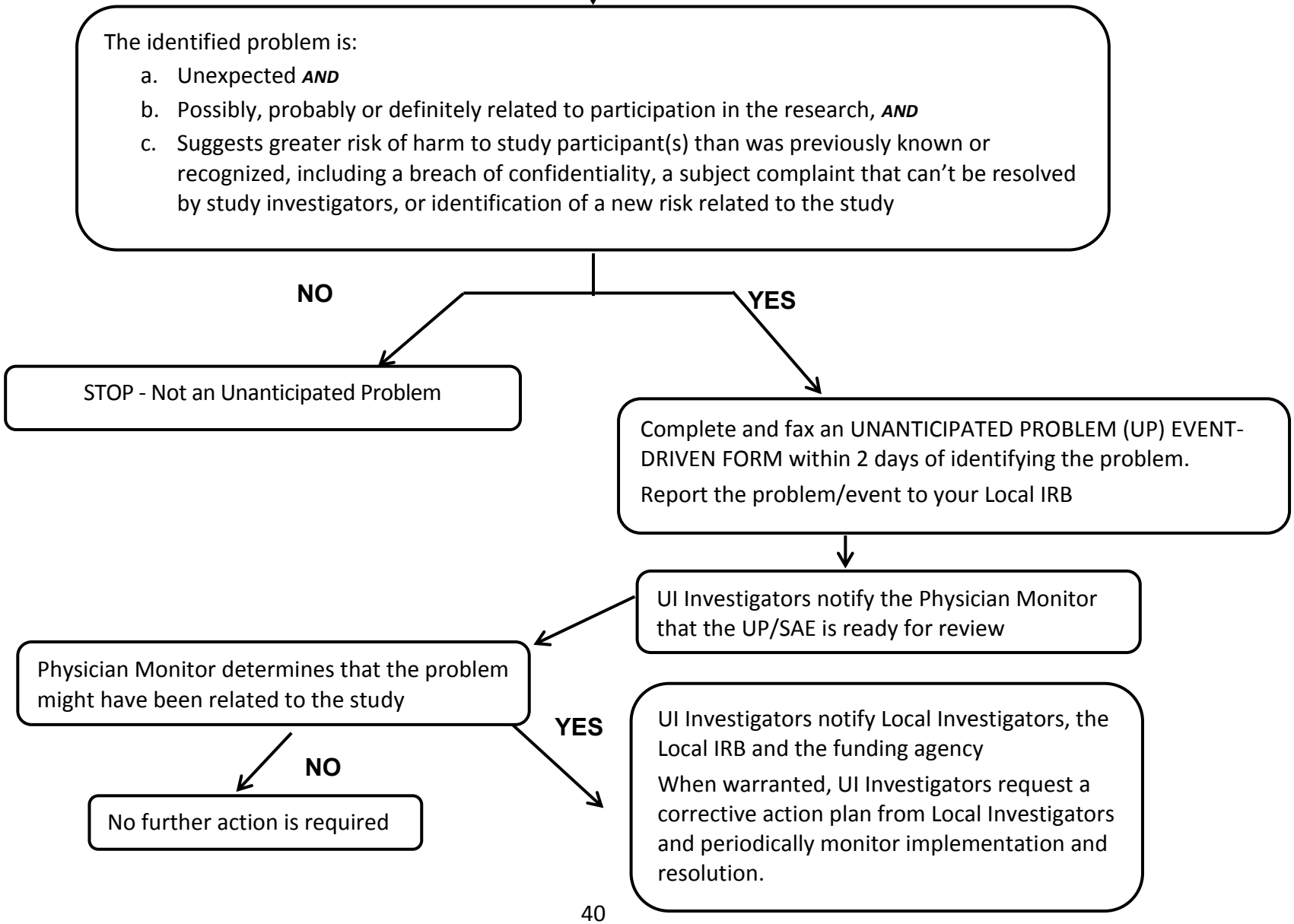
4. Local Investigators must also report UPs to their local IRB per the policy of their IRB.
5. Local IRBs determine what activities are warranted and inform Local Investigators of their decision
6. Local Investigator/Study Coordinator forwards IRB decisions to UI Investigators.

9.3.1. CASE EXAMPLES

Description of Problem	Correct End Classification	Rationale
A 70 year old female patient undergoes a scheduled hip replacement procedure for chronic hip pain.	Do NOT report to the UI team.	Unrelated to participation in the study.
A 58 year old male is admitted to the hospital for evaluation of chest pain. Final determination is that pain was due to a peptic ulcer caused by H. pylori and had no cardiac involvement.	Do NOT report to the UI team.	Unrelated to participation in the study.
A 73 year old female is enrolled with a history of persistent tobacco abuse, persistent hyperlipidemia and two prior heart attacks, the last six months prior to enrollment in the study. Her strength and stamina have been steadily declining for the past two years. The PHCVRS pharmacist recommends an increase in her lipid agent, since her dose is sub-optimal, and her physician agrees. Her lipid values show modest improvements 3 months subsequently but her weakness increases and her activity levels continues to decline. Four months after enrollment, she has a massive heart attack and dies.	REPORTING to the UI team IS STRONGLY ENCOURAGED.	The repeat heart attack is likely due to natural disease progression and not to participation in the study. However, to be cautious, we encourage reporting so that the case can be carefully evaluated.
A 64 year old male patient with a serum creatinine level of 0.9 mg/dL is started on lisinopril 40 mg daily for elevated blood pressures. One month later, he is hospitalized for acute renal failure, which is attributed to the lisinopril.	Do NOT report to the UI team, as long as lisinopril was not contraindicated for the patient.	Acute renal failure is a known side effect of lisinopril, and there was no indication that the patient had any renal insufficiency.
A 66 year old male patient with a serum creatinine level of 1.9 mg/dL is started on lisinopril 40 mg daily for elevated blood pressures. Two weeks later, he develops acute renal failure with a creatinine level of 3.4 mg/dL, which is attributed to the lisinopril.	REPORT to the UI team.	The patient had renal insufficiency, which contraindicates use of lisinopril.

Description of Problem	Correct End Classification	Rationale
A study coordinator takes a patient's personal health information home with her on her laptop computer. The computer is stolen from her car.	REPORT to the UI team.	Potential breach of confidentiality places subjects at greater risk of psychological and social harm.
58 year old patient is started on lisinopril 40 mg daily for elevated pressures. The patient has no contraindications for lisinopril. Two weeks later the patient develops muscle pain and weakness. The patient's physician discontinues the lisinopril and the symptoms resolve.	REPORT to the UI team.	Muscle pain and weakness is not a known side effect of lisinopril. Although it is not clear that the symptoms resulted from the lisinopril, the event should be reported.
Patient had been on Lipitor previously, but it was discontinued 6 months ago (and 1 month prior to enrollment in the study) due to muscle pain and weakness. The PHCVRS pharmacist recommends that the patient start on Crestor for persistent elevations in LDL that do not respond to lifestyle modifications. The patient develops severe muscle pain and weakness and goes to the ER. Creatinine kinase is 320 mcg/L, patient is diagnosed with rhabdomyolysis and admitted for treatment.	REPORT to the UI team.	Rhabdomyolysis is a known side effect of statins, and starting a different statin IS justified by treatment guidelines. However, due the severity of the problem and its direct relationship to the prescription of Crestor, the event should be reported.

8.3.2. Decision Tree for Reporting Unanticipated Problems



10. PROCEDURES FOR PHCVRS CLINICAL PHARMACISTS AND SITE PROVIDERS

10.1. Procedures for the PHCVRS Clinical Pharmacist

10.1.1. SCHEDULED PATIENT VISITS

The clinical pharmacist will follow each patient for approximately 12 months following enrollment in the study. Recommended visit activities and frequencies are outlined below:

10.1.1.1. BASELINE VISIT

The pharmacist will conduct the following activities at the initial visit, requiring 30-45 minutes:

1. Review the patient's medical record and perform a structured interview, including:
    a. A detailed medication history of all prescription, nonprescription, and herbal therapies
    b. An assessment of patient knowledge of medications, purpose of each medication, goals of therapy, medication dosages and timing, and potential medication side effects
    c. Potential contraindications to specific pharmacologic agents (e.g., renal insufficiency for thiazide diuretics, severe obstructive lung disease for beta blockers)
    d. Expectations that there will be future dosage changes and monitoring and that the pharmacist will discuss issues that might become future barriers to lowering cardiovascular risk (e.g., side effects, non-adherence, patient self-efficacy)
    e. Expectations that, since cardiovascular risk is higher at the initial visit (by definition), medications and/or dosages must be intensified unless there is a strong justification not to intensify them.
2. Provide patients with lifestyle educational materials (e.g. "Finding Your Way to a Healthier You" brochure and NHLBI's "The Dash Diet" and "Heart Healthy Recipes Cookbook").
3. Utilize motivational interviewing techniques to assess Stages of Change for key issues such as exercise, diet, weight, tobacco use, immunizations and cancer screenings.
4. Supply a wallet card listing all medications and doses, contact phone numbers for the pharmacist and disease state goals for patients with memory problems or unintentional non-adherence.
5. Create a care plan with treatment recommendations for the physician. The care plan will make specific recommendations to improve medication management to achieve lower cardiovascular risk.
6. Document all visits, recommendations made to the physician and recommendations accepted by the physician in the medical record or the pharmacy record, depending on the policies and procedures in the office.
7. Present the care plan via written, verbal, or electronic communication to the physician.

8. Implement the care plan after obtaining physician agreement or physician modifications.

10.1.1.2. FOLLOW-UP VISITS

The PHCVRS model *recommends* structured follow-up visits with the patient at the following time points after the baseline visit. However, the pharmacist may tailor patient visit schedules to meet the individual patient's needs.

- 2 weeks
- 4 weeks
- 6 weeks
- 8 weeks
- Monthly thereafter

Each follow-up visit is estimated to take 30-45 minutes and will include assessment and documentation of:

1. Current medications
2. Side effects and adverse events
3. Patient medication compliance
4. Modification of the care plan as needed, with changes also documented in the patient's medical record
5. Communication with the patient's physician as needed

11. Patient Termination

Patients will be terminated:

1) When all study time points have been completed through the 36 month medical record data abstraction
2) When a patient is not able to complete all study time points (early termination). Early termination may occur for several reasons:
    - i) Patient's eligibility status changes
        - (a) Although pregnancy is not anticipated in study patients, any patient who becomes pregnant must immediately be terminated
        - (2) Please note that patients who develop a baseline exclusion criterion subsequent to enrollment such as a stroke or advanced cancer will be permitted to stay in the study and should NOT be terminated early
    - ii) Patient chooses to withdraw
    - iii) Patient is lost to follow-up
    - iv) Patient transfers care to another clinic that is not participating in the study
    - v) The research team chooses to terminate the subject
        - (1) Possible scenarios include failure to pay for medical (non-study) services, failure to keep scheduled appointments with providers, and chronic non-adherence to the prescribed medical regimen.
    - vi) Patient withdraws or is terminated due to an adverse event
    - vii) Patient dies

Complete the patient termination form and fax to the CCC for any of the above events.

12. PROCEDURES FOR SITE PROVIDERS

12.1. Provider Surveys

The following surveys will be distributed to providers. These surveys will be distributed at the site training session and should be completed **prior to the beginning of patient enrollment**.

Lead Physician only:

- "Medical Home Index – Adult"

All Providers:

- "Managing Cardiovascular Disease States"
- "Physician Collaboration Survey"

Survey packets will include a letter detailing the elements of consent. No separate consent form will be required; return of the survey will constitute consent. Providers who choose to participate should return the survey to the Study Coordinator sealed in the envelope provided.

Providers will be invited to take the same survey at the end of the study.

Providers will not be compensated for completing the study surveys.

12.2. Referring Patients to the Study

All clinic providers are encouraged to refer patients who might qualify for the study to the clinic's Study Coordinator. The Study Coordinator will review records for each patient a provider refers to make sure that the patient indeed meets the study's complex eligibility criteria.

12.3. Provider Interaction with the PHCVRS Pharmacist

The PHCVRS pharmacist will develop an action plan that addresses gaps in preventive health screening or guideline-concordant therapy. The pharmacist will communicate recommended changes to the treatment to the patient's primary care provider via fax or other communication method preferred by the individual physician. Communication will occur on the study's Pharmacist-Physician Communication form (see APPENDIX IV). This form is initiated by the study pharmacists, and providers are asked to either agree with the proposed changes to the treatment regimen or modify the pharmacist's proposal and then return the form to the study pharmacist by fax as soon as possible. Pharmacist communication to the provider will occur every 3 months or more frequently if urgent issues are identified.

APPENDIX I: SCREENING LOG AND VERIFICATION OF INCLUSION AND EXCLUSION CRITERIA FORM

Patient Name:	MRN:	Phone number:

Do not send information in the row above to the University of Iowa. *Please copy this form and redact or cut out this info before sending.*

SCREENING LOG AND VERIFICATION OF INCLUSION AND EXCLUSION CRITERIA

INSTRUCTIONS

* = *Required for all screened patients*

- Please record screening data below for any patient whose chart you have accessed for the ICARE study.
- Patients that you identify as potentially eligible for the study should be sent a recruitment letter and postcard.
- If you have questions on this form contact Brian at 319-335-8218 or brian-gryzlak@uiowa.edu

Screening Number: *(Write on postcard)*

Screening Number (Write number on postcard):

*Gender	❒Male ❒Female	*Race (Check all that apply): ❒ White ❒ Black/African-American. ❒ Asian ❒ American Indian/Alaska Native ❒ Native Hawaiian/Other Pacific Islander
*Ethnicity	❒Hispanic ❒Not Hispanic	
Date letter and postcard mailed: __ __/__ __/__ __ __ __	❒n/a	
Date postcard returned: __ __/__ __/__ __ __ __	❒n/a	

*Outcome:
- ❒ Patient enrolled in study
- ❒ Patient ineligible for study
- ❒ Patient declined via postcard
- ❒ Patient declined via phone
- ❒ Patient declined in person
- ❒ Unable to reach via mail
- ❒ Unable to reach via phone
- ❒ Other outcome:

Phone contact dates and notes (up to 3 attempts):

Section A: Demographic Criteria

1.	Has the patient been seen in your clinic or practice at least once in the past 24 months?	❒ YES ➔ **Continue to #2** ❒ NO ➔ **STOP – not eligible**
2.	Is the patient an English-speaking male or female?	❒ YES ➔ **Continue to #3** ❒ NO ➔ **STOP - not eligible**
3.	Age of patient in years:	AGE:_____ **IF >= 50, go to #4a. If less than 50, STOP – not eligible.**

Section B: Risk Factors

		Meets Criteria ?
4a. Has a diagnosis of diabetes? *(ICD9 Code 250)*	❒ YES ➔ **Continue to #4b** ❒ NO ➔ **Skip to #5a**	
4b. Enter most recent Hg A1c from chart **IF** ≥ 7.5%:	Hg A1c:_____% Date: __ __ / __ __ / __ __ __ __	If 4a is YES **AND** 4b is >= 7.5%, check box at right. ❒
5a. Has a diagnosis of high cholesterol? *(ICD9 Code 272)*	❒ YES ➔ **Continue to #5b** ❒ NO ➔ **Skip to #6a**	
5b. Enter most recent LDL from chart **IF**: ▪ >110mg/dl for patients with PAD, CAD, Stroke, TIA, or Diabetes **OR** ▪ >140mg/dl	LDL: _____mg/dl Date: __ __ / __ __ / __ __ __ __	If 5a is YES **AND** (5b is >110mg/dl for patients with PAD, CAD, Stroke, TIA, or Diabetes **OR** 5b >140mg/dl), check box at right. ❒
6a. Has a diagnosis of hypertension? *(ICD9 Codes 401, 402, 403, 404, 405)*	❒ YES ➔ **Continue to #6b** ❒ NO ➔ **Skip to #7**	
6b. Enter most recent blood pressure from chart **IF**: ▪ ≥150 mm Hg SBP or ≥ 90 mm Hg DBP for patients with uncomplicated hypertension **OR** ▪ ≥140 mm Hg SBP for patients with diabetes or chronic kidney disease	_____(SBP) Date: _____(DBP) __ __ / __ __ / __ __ __ __	If 6a is YES **AND** (6b ≥150 mm Hg SBP or > 90 mm Hg DBP for patients with uncomplicated hypertension **OR** 6b ≥ 140 mm Hg SBP for patients with diabetes or chronic kidney disease), check box at right. ❒
7. **Section B Total:** In box at the right, add the number of checked boxes above for **Questions 4, 5 and 6.** ➔ **If 1 or more, CONTINUE to Section C. If 0, STOP - not eligible.**		☐

IF PATIENT WAS ENROLLED in the study (signed consent), file a copy of this form in the patient's study folder. ***v.9/19/14*** ***Site:*** ***Screening Number***

IF PATIENT WAS NOT ELIGIBLE or NOT ENROLLED IN THE STUDY, send a copy of this form via fax, mail or email to the University of Iowa.

Section C: Cardiovascular Conditions *(ICD9 Codes)*	**Check if meets inclusion criterion**
8. History of coronary artery disease (CAD) *(ICD9 Code 414)*	❑
9. History of previous MI (heart attack) *(ICD9 Codes 410, 411, 412)*	❑
10. History of stroke *(ICD9 Codes 430, 431, 432, 433, and 434)*	❑
11. History of TIA *(ICD9 Code 435)*	❑
12. History of atrial fibrillation (A. Fib) *(ICD9 Codes 427.31, 427.3)*	❑
13. History of peripheral vascular disease/claudication (PAD) *(ICD9 Codes 440.2, 440.3, and 440.4)*	❑
14. History of carotid artery disease *(ICD9 Code 433.1)*	❑
15. Current smoker *(ICD9 Code 305.1)*	❑
16. Diagnosis of obesity (BMI≥30) *(ICD9 Code 278.0)* Enter most recent BMI >= 30 from chart: _____ Date: ___ ___ / ___ ___ / ___ ___ ___ ___	❑
17. Section C Total: In box at the right, add the number of checked boxes for **Questions 8-16➔**	☐
18. Add the answers for #7 & #17. **If 3 or more, CONTINUE to # 19. If less than 3, STOP – not eligible ➔**	☐
Section D: Exclusion Criteria *(from Medical Record, Direct Observation, OR Self-Report)*	**Check if meets exclusion criterion**
19. Inability to give informed consent - *direct observation OK*	❑
20. Pregnant *(ICD9 Codes V22, V23, V24)*	❑
21. Diagnosis of pulmonary hypertension (*ICD9 Code 416; Note: secondary pulmonary hypertension is OK)*	❑
22. Cancer diagnosis with a life expectancy estimated less than 2 years	❑
23. Residence in a nursing home or diagnosis of dementia –*Self-report OK for N.H. residence*	❑
24. No telephone or have a hearing impairment not allowing them to use a phone – *Direct observation and self-report OK*	❑
25. Omron blood pressure cuff cannot be used on patient's arm for any reason – *direct observation OK* (e.g., patient is morbidly obese and requires use of a thigh cuff)	❑
26. Section D total: In box at the right, add the number of checked boxes for **Questions 19-25➔** **If 0, CONTINUE to Question 27. If 1 or more, STOP– not eligible**	☐
27. Subject is potentially eligible based on your chart review and can be sent a recruitment letter and postcard or otherwise considered for enrollment. At the right, enter the date that the chart review for Sections B, C, and D was completed. Then continue to Question 28 in Section E. Date: __ __ / __ __ / __ __ __ __	
Section E: Exclusion Criteria from Patient Self-Report *(Ask during your contact to schedule the baseline visit)*	**Check if meets exclusion criterion**
28. Refusal to consider attempting to use the internet to access the PHRM	❑
29. Patient has plans to move from the area or transfer care to a different clinic in the next 12 months	❑
30. Section E total: In box at the right, add the number of checked boxes for Questions 28-29➔ **If 0, CONTINUE to Question 31. If 1 or more, STOP– not eligible**	☐
31. Before the subject signs consent, verify that all are correct: ❒ ANSWER TO QUESTION 18 IS 3 OR MORE. ❒ DATE IN QUESTION 27 IS LESS THAN 6 MONTHS FROM THE DATE THAT THE PATIENT WOULD SIGN THE CONSENT DOCUMENT (#32 BELOW). *If the date in Question 27 is MORE THAN 6 months from the date the consent would be signed, rescreen the patient for eligibility with a new screening log using current medical record data.* ❒ PATIENT HAS NONE OF THE EXCLUSION CRITERIA BASED ON MEDICAL RECORD, DIRECT OBSERVATION, OR PATIENT REPORT	
32. Subject may sign consent. Enter date subject signed:	Date: ___ ___ / ___ ___ / ___ ___ ___ ___

IF PATIENT WAS ENROLLED in the study (signed consent), file a copy of this form in the patient's study folder. ***v.9/19/14*** ***Site:*** ***Screening Number***
IF PATIENT WAS NOT ELIGIBLE or NOT ENROLLED IN THE STUDY, send a copy of this form via fax, mail or email to the University of Iowa and file in "Eligibility Failure" folder.

APPENDIX II: QUICK GUIDE TO ICARE STUDY ELIGIBILITY CRITERIA

ICARE Study Quick Guide to Inclusion and Exclusion Criteria

Section A: Demographic Criteria

1. Patient was seen in your clinic or practice at least once in the past 24 months
2. English-speaking male or female
3. Age is 50 or older at medical record screening

Section B: Risk Factors

4. Has ONE OR MORE of the following:
   - ❒ Diagnosis of diabetes *(ICD9 Code 250)* AND most recent:
     - Hg A1C ≥ 7.5%
   - ❒ Diagnosis of high cholesterol *(ICD9 Code 272)* AND most recent:
     - LDL >110mg/dl for patients with PAD, CAD, Stroke, TIA, or Diabetes OR
     - LDL >140mg/dl
   - ❒ Diagnosis of hypertension *(ICD9 Codes 401, 402, 403, 404, 405)* AND most recent blood pressure:
     - ≥ 150 mm Hg SBP or ≥ 90 mm Hg DBP for patients with uncomplicated hypertension OR
     - ≥ 140 mm Hg SBP for patients with diabetes or chronic kidney disease.

Section C: Cardiovascular Conditions

5. Total number of risk factors in Section B (above) plus number of conditions Section C (below) is THREE OR MORE:
   - ❒ History of coronary artery disease (CAD) *(ICD9 Code 414)*
   - ❒ History of previous MI (heart attack) *(ICD9 Codes 410, 411, 412)*
   - ❒ History of stroke *(ICD9 Codes 430, 431, 432, 433, and 434)*
   - ❒ History of TIA *(ICD9 Code 435)*
   - ❒ History of atrial fibrillation (A. Fib) *(ICD9 Codes 427.31, 427.3)*
   - ❒ History of peripheral vascular disease/claudication (PAD) *(ICD9 Codes 440.2, 440.3, and 440.4)*
   - ❒ History of carotid artery disease *(ICD9 Code 433.1)*
   - ❒ Current smoker *(ICD9 Code 305.1)*
   - ❒ Diagnosis of obesity (BMI>30) *(ICD9 Code 278.0)*

   ❒ Medical Record screening date: Patient is enrolled WITHIN 6 MONTHS of the date that Sections B, C and C were completed.

Sections D and E: Exclusion Criteria Prior to Consent

6. Has NONE of the following:
   - ❒ Inability to give informed consent
   - ❒ Pregnant
   - ❒ Diagnosis of pulmonary hypertension (Note: secondary pulmonary hypertension is OK)
   - ❒ Cancer diagnosis with a life expectancy estimated less than 2 years
   - ❒ Residence in a nursing home or diagnosis of dementia
   - ❒ No telephone or a hearing impairment not allowing them to use a phone
   - ❒ Refusal to consider attempting to use the internet at home, community center, library, medical office or other source to access the PHRM
   - ❒ Patient has plans to move from the area or transfer care to a different clinic in the next 12 months
   - ❒ Omron blood pressure cuff cannot be used on patient's arm for any reason

APPENDIX III: BASELINE VISIT CHECKLIST

ICARE Study Subject Enrollment and Baseline Visit Checklist

(Complete for eligible patients only – check each activity below when completed)

Before Visit

- ❒ Gender, race, and ethnicity questions of the *Screening Log and Verification of Inclusion and Exclusion Criteria ("Screening Log / Verification")* form completed
- ❒ Sections A, B, C, D and E of the *Screening Log / Verification* form completed

During Visit

- ❒ Sections D and E of *Screening Log / Verification* are reviewed with patient to confirm that patient has none of the exclusion criteria, and *Screening Log / Verification* form is completed
- ❒ Current, stamped Informed Consent Document reviewed with patient and questions answered
- ❒ Patient signed Informed Consent Document
- ❒ Copies made of <u>all pages</u> of signed informed consent document
  - ❒ Original signed and dated Informed Consent Document (all pages) filed in patient's folder
  - ❒ Copy of signed and dated Informed Consent Document given to patient
  - ❒ Copy of signed and dated Informed Consent Document filed in the patient's medical record *(If applicable per your site's policies)*
- ❒ Labs (HbA1c; lipids, preferably fasting) drawn
- ❒ Blood pressure measured using Omron machine (3 or 4 measurements as needed)
- ❒ Patient instructed on PHRM
- ❒ Patient given PHRM login sheet

All 5 baseline forms administered and completed:

- ❒ *Enrollment*
- ❒ *Diagnosed Conditions and Care Management (patient-reported questions)*
- ❒ *Medication Reconciliation (patient-reported questions)*
- ❒ *Blood Pressure, Laboratory And Cancer Screening Form*
- ❒ *Health Behavior Inventory*

During Visit or Directly After Visit

- ❒ Remaining questions on *Diagnosed Conditions and Care Management* and *Medication Reconciliation* forms that require the medical record to answer are completed.
- ❒ All 5 baseline forms faxed to the Clinical Coordinating Center (CCC) within 48 hours of the visit.
- ❒ *Screening Log / Verification* form faxed to the CCC
- ❒ *Screening Log / Verification* form filed in patient's study folder.
- ❒ All 5 baseline forms are filed in the patient's study folder.

APPENDIX IV: CASE REPORT FORMS

Enrollment Form

Baseline Only

Patient's Name: _____ *(last)* _____ *(first)*

Date Consented: _ _ / _ _ / _ _ _ _ (mm/dd/yyyy)

Date Administered: _ _ / _ _ / _ _ _ _ (mm/dd/yyyy)

Primary Provider: _____

Primary Provider Phone: _____ - _____ - _____

Primary Provider Fax: _____ - _____ - _____

Section I: Contact Information

Address:

_____ *(street)*

_____ *(city, state)*

_____ *(zip code)*

Phone Numbers:

- Home: _____ - _____ - _____
- Cell: _____ - _____ - _____
  - Text Messaging: **Yes** **No**
- Work: _____ - _____ - _____

Email: _____

Preferred Contact *(circle all that apply)*: **Home** **Cell** **Work** **Email**

Section I: Contact Information *(continued)*

Alternative Contact:

- Name: _____
- Relationship: _____
- Phone: _____ - _____ - _____

Section II: Demographics

INSTRUCTIONS (to be read to the subject):

"The first questions ask for some basic information about you."
(Study Coordinator is to check the box corresponding to the subject's answers.)

Birthdate: "What is your date of birth?" _ _ / _ _ / _ _ _ _ (mm/dd/yyyy)

Gender: ☐ M ☐ F

I. Patient Race "Please tell me which of the following racial groups best represent you." (check all that apply)

☐ Black or African American
☐ American Indian or Alaska native
☐ Native Hawaiian or Other Pacific Islander
☐ Asian
☐ White or Caucasian
☐ Unknown/Not Reported

II. Patient Ethnicity "Please tell me which of the following ethnic groups best represent you."

☐ Hispanic/Latino
☐ Non-Hispanic/Non-Latino
☐ Unknown/Not Reported

III. Education "Please tell me the highest grade you completed or the highest degree you have received." (Check only one):

☐$_1$ 1- 5
☐$_2$ 6- 8
☐$_3$ 9- 12
☐$_4$ 2-year technical or associate degree
☐$_5$ 4-year BA or BS degree
☐$_6$ Masters degree
☐$_7$ Doctoral degree

Study ID: _ _-_

Section II: Demographics *(continued)*

IV. Insurance Status "Please tell me what kind of insurance is the primary payer for your healthcare." (Please check only one, the primary insurer.)

☐$_1$ Private insurance (Employer/Group)
☐$_2$ Private insurance (Self-insured)
☐$_3$ Medicare
☐$_4$ Medicaid
☐$_5$ None/Self-pay
☐$_6$ Free care

V. Insurance Coverage for Prescriptions "Do you have insurance coverage for prescriptions?"

☐$_1$ Yes
☐$_0$ No

VI. Annual Household Income "Can you please tell me which category best represents your total annual household income?"

☐$_1$ <$10,000
☐$_2$ $10, 000-$24, 999
☐$_3$ $25,000- $39,999
☐$_4$ $40,000-$54,999
☐$_5$ $55,000-$79,999
☐$_6$ $80,000-$99,999
☐$_7$ $100,000 or greater
☐$_8$ Refused to answer

VII. Marital Status "Can you please tell me which category best represents your current marital status?"

☐$_1$ Never married
☐$_2$ Married
☐$_3$ Divorced or separated
☐$_4$ Widowed

VIII. Smoking Status "Have you ever smoked? If so, are you currently smoking or are you an ex-smoker?"

☐$_0$ Never smoked

☐$_1$ Current smoker

"If you are currently smoking, please tell me the total number of years you have smoked and the approximate number of cigarettes that you smoke each day."

Number of years smoked: __ __

Number of cigarettes smoked per day: __ __

Study ID: _ _-_

Section II: Demographics *(continued)*

☐$_2$ Ex-smoker "If you are an ex-smoker, how many years ago did you quit? Also, how many years did you smoke and approximately how many cigarettes did you smoke each day?"

Years since quit:

☐$_1$ < 5 years

☐$_2$ 5-14 years

☐$_3$ ≥ 15 years

Number of years smoked: __ __

Number of cigarettes smoked per day: __ __

Study ID: «StudyIDs»

Diagnosed Conditions and Care Management
Baseline Visit

Section A. Patient-Reported Conditions and Care Management

1. Date administered: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)

Ask the subject whether they have each of the following conditions.

"Please tell me if you have ever had any of the following medical conditions. Have you ever had ...." *Answers to all questions are required.*	Patient Response	
	YES	NO
2. Hypertension or high blood pressure?	❒	❒
3. Hyperlipidemia or high cholesterol?	❒	❒
4. Congestive heart failure?	❒	❒
5. Coronary artery disease?	❒	❒
6. Atrial fibrillation or A.Fib?	❒	❒
7. Heart attack?	❒	❒
8. Stroke or TIA?	❒	❒
9. Peripheral artery disease?	❒	❒
10. Asthma? (excluding: exercise induced asthma)	❒	❒
11. COPD?	❒	❒
12. Diabetes?	❒	❒
13. Chronic kidney disease?	❒	❒
14. Seizures or other neurological disorder?	❒	❒
15. Liver disease?	❒	❒
16. Depression?	❒	❒
17. Anxiety?	❒	❒
18. Arthritis, Degenerative joint disease, or chronic pain?	❒	❒

Study ID: «StudyIDs»

Ask the patient the following questions:	YES	NO
19. "Are you free of chest pain?"	❒	❒
20. "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 in the past 12 months? **OR** do you have chronic stable angina?"	❒	❒
21. "Have you participated in a cardiac rehabilitation program?"	❒	❒
22. "Have you ever been referred to such a program?	❒	❒
23. "Have you received a dilated eye exam in the past 12 months?	❒	❒
24. "Have you received a foot examination in the past 12 months?"	❒	❒
25. "Have you received a pneumonia immunization?"	❒	❒
26. "Do you use tobacco?"	❒	❒
27. "Are you currently using nicotine replacement (patch, gum, lozenge, inhaler), buproprion, or Chantix® (varenicline)?"	❒	❒
28. "Have you received an influenza immunization during the most recent flu season (September-February)?"	❒	❒

Study coordinator should answer these questions. Review the <u>patient-reported</u> medications from the Medication Reconciliation form you completed and answer the following questions:	YES	NO
29. "Is the patient prescribed at least two anti-anginal medications (Drug Codes: 200s, 400s, 900s, or Ranolazine)?"	❒	❒
30. Is the patient currently on anticoagulation (Drug Codes: 5001, 5003, 5004, 5201, 5202, 5301, 5401)?	❒	❒

Study ID: «StudyIDs»

Section B. Medical Record-Reported Conditions and Care Management

For each question below, check "YES" if the condition is documented in the patient's medical record and "NO / NOT PRESENT" if it is not. *Answers to all main questions (e.g., 1, 2, 3, …) are required.*	Answer from the Medical Record	
	YES	NO / NOT PRESENT
1. HYPERTENSION?	❒	❒
2. HYPERLIPIDEMIA?	❒	❒
3. CONGESTIVE HEART FAILURE?	❒	❒
4. CORONARY ARTERY DISEASE?	❒	❒
5. ATRIAL FIBRILLATION?	❒	❒
6. HEART ATTACK (myocardial infarction)?	❒	❒
7. STROKE OR TIA?	❒	❒
8. PERIPHERAL ARTERY DISEASE?	❒	❒
9. ASTHMA? *(Excluding exercise induced asthma)*	❒	❒
10. DIABETES?	❒	❒
11. CHRONIC KIDNEY DISEASE?	❒	❒
12. SEIZURES/OTHER NEUROLOGICAL DISORDER?	❒	❒
13. LIVER DISEASE?	❒	❒
14. DEPRESSION?	❒	❒
15. ANXIETY?	❒	❒
16. ARTHRITIS/DJD/CHRONIC PAIN?	❒	❒

Study ID: «StudyIDs»

For each question below, answer the question using the medical record or check "YES" if the answer is documented in the patient's medical record and "NO / NOT PRESENT" if it is not. *Answers to all main questions (e.g., 1, 2, 3, …) are required.*	**Answer from the Medical Record**
17. Most recent chart recorded blood pressure	___ ___ ___ / ___ ___ ___ **mmHg**
18. Date of most recent chart recorded blood pressure	___ ___ / ___ ___ / ___ ___ ___ ___ *(MM/DD/YYYY)*
19. Is there a documented Ejection Fraction (EF) in the chart?	❒ YES ➔ ***Go to 19a*** ❒ NO / NOT PRESENT ➔ ***Skip to 20***
19a. Most recent chart recorded EF:	____ ____ **%**
19b. EF date:	___ ___ / ___ ___ / ___ ___ ___ ___ *(MM/DD/YYYY)*
20. Is there documentation the provider asked the patient about dyspnea (shortness of breath)?	❒ YES ❒ NO / NOT PRESENT
21. Is there documentation the provider asked the patient about chest pain?	❒ YES ❒ NO / NOT PRESENT
22. Is the patient angina-free (free of chest pain)?	❒ YES ❒ NO / NOT PRESENT
23. Is the patient prescribed at least two anti-anginal medications (Drug Codes: 200s, 400s, 900s, or Ranolazine)?	❒ YES ❒ NO / NOT PRESENT
24. 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 in the past 12 months? **OR** does the patient have chronic stable angina (CSA)?	❒ YES ❒ NO / NOT PRESENT
25. Has the patient participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis?	❒ YES ❒ NO / NOT PRESENT
26. Has the patient been referred to such a program?	❒ YES ❒ NO / NOT PRESENT

Study ID: «StudyIDs»

For each question below, answer the question using the medical record or check "YES" if the answer is documented in the patient's medical record and "NO / NOT PRESENT" if it is not. *Answers to all main questions (e.g., 1, 2, 3, …) are required.*	Answer from the Medical Record
27. Is the patient currently on anticoagulation (Drug Codes: 5001, 5003, 5004, 5201, 5202, 5301, 5401) **OR** has the patient been assessed for the need of anticoagulation?	❒ YES ❒ NO / NOT PRESENT
28. 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?	❒ YES ❒ NO / NOT PRESENT ❒ NOT ON WARFARIN
29. Has the patient received a dilated eye exam in the past 12 months?	❒ YES ❒ NO / NOT PRESENT
30. Has the patient received urine protein screening (microalbumin laboratory value) in the past 12 months?	❒ YES ➔ ***Go to 30a*** ❒ NO / NOT PRESENT ➔ ***Skip to 31***
30a. Microalbumin value:	_____ **mg/g**
31. Have they received an HbA1c test in the past 12 months?	❒ YES ➔ ***Go to 31a*** ❒ NO / NOT PRESENT ➔ ***Skip to 32***
31a. HbA1c value:	_____ . _____ **%**
32. Have they received an LDL cholesterol test in the past 12 months?	❒ YES ➔ ***Go to 32a*** ❒ NO / NOT PRESENT ➔ ***Go to 33***
32a. LDL value:	_____ **mg/dL**
33. Have they received a foot examination in the past 12 months?	❒ YES ❒ NO / NOT PRESENT
34. Has the patient received a pneumonia immunization?	❒ YES ❒ NO / NOT PRESENT
35. Is a plan on how to achieve or maintain ideal body weight within the past 6 months documented in the patient's MR? (Can include 'lifestyle modification' plans, including diet and exercise)	❒ YES ❒ NO / NOT PRESENT
36. Does the patient use tobacco?	❒ YES ❒ NO / NOT PRESENT

Study ID: «StudyIDs»

For each question below, answer the question using the medical record or check "YES" if the answer is documented in the patient's medical record and "NO / NOT PRESENT" if it is not. *Answers to all main questions (e.g., 1, 2, 3, …) are required.*	Answer from the Medical Record
37. Is there documentation in the MR of assessing tobacco use?	❒ YES ❒ NO / NOT PRESENT
38. Is there documentation in the MR of advising on the risk of tobacco use?	❒ YES ❒ NO / NOT PRESENT
39. Is there documentation in the MR of assessing the willingness to quit?	❒ YES ❒ NO / NOT PRESENT
40. Is the patient currently using nicotine replacement (patch, gum, lozenge, inhaler), buproprion, or Chantix® (varenicline)?	❒ YES ❒ NO / NOT PRESENT
41. Is there documentation of tobacco screening in the MR?	❒ YES ➔ ***Go to 41a*** ❒ NO / NOT PRESENT ➔ ***Skip to 42***
41a. Date of most recent screening	___ ___ / ___ ___ / ___ ___ ___ ___ *(MM/DD/YYYY)*
42. Is there documentation in the Medical Record that the patient has been asked how much alcohol they drink at least once in the previous 24 months?	❒ YES ❒ NO / NOT PRESENT
43. Has the patient received an influenza immunization during the most recent flu season (September-February)?	❒ YES ❒ NO / NOT PRESENT
44. Has the patient received a pneumonia immunization?	❒ YES ❒ NO / NOT PRESENT

Study ID: _ _-_ _

ICARE
Improved Cardiovascular Risk Reduction to Enhance Rural Primary Care

Medication Reconciliation

Study Visit: ○ Baseline ○ 12 months **Date Administered: _ _ / _ _ / _ _ _ _** (mm/dd/yyyy)

List all drug allergies: _____ or check ☐ No allergies

1. List medications that are either a) documented in the **patient's medical record** prior to patient visit AND/OR b) reported by the patient during the study visit. ONLY include **antihypertensive agents**, **hyperglycemic agents**, **cholesterol agents**, **asthma agents** and **anticoagulants/antiplatelet agents**

   INSTRUCTIONS (to be read to the subject): "Please tell me what medications you are taking for **high blood pressure, high cholesterol, high blood sugars, asthma or thinning your blood**." Ask about missed doses in the past week and how well it works.

	Medication Name & Code	In the EMR	EMR Strength	EMR Directions for Use	Reported by Patient	Patient Reported Strength	Patient Reported Directions for Use	# Doses Missed in Past Week	How well does it work?
1.	_____ **Code:** _ _ _ _ _	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**
2.	_____ **Code:** _ _ _ _ _	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**
3.	_____ **Code:** _ _ _ _ _	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**
4.	_____ **Code:** _ _ _ _ _	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**
5.	_____ **Code:** _ _ _ _ _	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**
6.	_____ **Code:** _ _ _ _ _	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**

Study ID: _ _-_ _

	Medication Name & Code	In the EMR	EMR Strength	EMR Directions for Use	Reported by Patient	Patient Reported Strength	Patient Reported Directions for Use	# Doses Missed in Past Week	How well does it work?
7.	_____ **Code:** __ __ __ __	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**
8.	_____ **Code:** __ __ __ __	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**
9.	_____ **Code:** __ __ __ __	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**
10.	_____ **Code:** __ __ __ __	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**
11.	_____ **Code:** __ __ __ __	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**
12.	_____ **Code:** __ __ __ __	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**
13.	_____ **Code:** __ __ __ __	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**
14.	_____ **Code:** __ __ __ __	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**
15.	_____ **Code:** __ __ __ __	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**
16.	_____ **Code:** __ __ __ __	☐ Yes ☐ No			☐ Yes ☐ No				**Well Okay Not Well**

Study ID: _ _-_ _

2. INSTRUCTIONS (to be read to the subject): "Do any of these medications **bother you** in any way?" **YES _____** **NO _____**

i) If YES, please fill out the following for each bothersome medication, asking the subject "**how much** does it bother you?"

Medication Name	A Lot	Some	A Little	In what way does it bother you?
	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	

3. INSTRUCTIONS (to be read to the subject): "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."

Problems	Very Hard	Somewhat Hard	Not Hard at all	Which Medication? ("All" or specify)
Open or close the medicine bottle	☐	☐	☐	
Read the print on the bottle	☐	☐	☐	
Remember to take all of the pills	☐	☐	☐	
Get your refills on time	☐	☐	☐	
Take so many pills at the same time	☐	☐	☐	

*Adapted from: Svarstad BL, Chewning BA, Sleath BL, Claesson C. The Brief Medication Questionnaire: a tool for screening patient adherence and barriers to adherence. *Patient Educ Couns.* Jun 1999;37(2):113-124

Study ID: _ _-_ _

HEALTH BEHAVIOR INVENTORY

(baseline only)

Date Administered: _ _ / _ _ / _ _ _ _ (mm/dd/yyyy)

	Strongly Disagree	**Moderately Disagree**	**Agree Somewhat**	**Moderately Agree**	**Strongly Agree**	**Refused to Answer**
If I get sick, it is my own behavior which determines how soon I get well again.	Strongly Disagree	Moderately Disagree	Agree Somewhat	Moderately Agree	Strongly Agree	Refused to Answer
I am in control of my health.	Strongly Disagree	Moderately Disagree	Agree Somewhat	Moderately Agree	Strongly Agree	Refused to Answer
When I get sick I am to blame.	Strongly Disagree	Moderately Disagree	Agree Somewhat	Moderately Agree	Strongly Agree	Refused to Answer
The main thing which affects my health is what I myself do.	Strongly Disagree	Moderately Disagree	Agree Somewhat	Moderately Agree	Strongly Agree	Refused to Answer
If I take care of myself, I can avoid illness.	Strongly Disagree	Moderately Disagree	Agree Somewhat	Moderately Agree	Strongly Agree	Refused to Answer
If I take the right actions, I can stay healthy.	Strongly Disagree	Moderately Disagree	Agree Somewhat	Moderately Agree	Strongly Agree	Refused to Answer

Adopted from: Wallston, K. A., Wallston, B. S. & DeVellis, R. (1978). Development of the multidimensional health locus of control (MHLC) scales. Health Education Monographs, 6, 160-17

ICARE
Improved Cardiovascular Risk Reduction to Enhance Rural Primary Care

Blood Pressure, Laboratory and Cancer Screening Form

Study ID: _ _ _ _ _ _	**Date Administered:** *(mm/dd/yyyy)* __ __ / __ __ / __ __ __ __
Height: __ feet __ __ inches *or* __ __ __ cm	**Weight:** (lbs or kg) __ __ __ lbs *or* __ __ __ kg
Visit *(check one)*: ☐ **Baseline** ☐ **12 months**	

Has the patient smoked in the past 24 months? ☐ Yes ☐ No

If yes, patient's last cigarette was smoked: ☐ > 20 minutes ago ☐ ≤ 20 minutes ago

Delay BP measurement until > 20 minutes has elapsed since patient last smoked.

Time of day of BP recording …… __ __ : __ __ ☐ am ☐ pm

Midpoint circumference of arm being used (right is preferred)……. __ __ cm

Size of cuff used (check one): ☐$_1$ Adult (22-32 cm) ☐$_2$ Small adult (17-22 cm)
☐$_3$ Large adult (32-42 cm) ☐$_4$ Extra Large (42-50 cm)

1. **Seated pulse** (count beats per minute for 30 seconds and multiply by 2)	__ __ __ BPM

	a. Systolic BP (mm Hg)	b. Diastolic BP (mm Hg)
2. **First sitting BP measurement**	___ ___ ___	___ ___ ___
3. **Second sitting BP measurement**	___ ___ ___	___ ___ ___
4. **Third sitting BP measurement**	___ ___ ___	___ ___ ___
5. **Fourth sitting BP measurement** (take ONLY if 2nd & 3rd BPs differ by > 4 mm)	___ ___ ___	___ ___ ___

6. **Average Systolic Pressure** (add the **2 closest** measurements from **3a, 4a** and 5**a** and divide by 2)	___ ___ ___
7. **Average Diastolic Pressure** (add the **2 closest** measurements from **3b, 4b** and 5**b** and divide by 2)	___ ___ ___

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

8. **Standing pulse** (count beats per minute for 30 seconds and multiply by 2)	__ __ __ BPM

	a. Systolic BP (mm Hg)	b. Diastolic BP (mm Hg)
9. **Standing BP measurement**	___ ___ ___	___ ___ ___

Study ID: _ _ - _ _

Draw blood and record cholesterol and HA1c values as soon as results are obtained:

10. **Total Cholesterol**	___ ___ ___ mg/dl
11. **High-density lipoproteins (HDL)**	___ ___ ___ mg/dl
12. **Low-density lipoproteins (LDL)**	___ ___ ___ mg/dl
13. **Triglycerides**	___ ___ ___ mg/dl

14. **Hemoglobin A1c (HA1c)**	___ ___ . ___ %

The following should be obtained from both the Medical Record and patient:

Screening or Test	Response from Medical Record		Response from Patient	
	Date of Screening *MM/YYYY*	Not Found	Date of Screening *MM/YYYY*	Not Found
15. Most recent mammogram – Women age 40-69	__ __ / __ __ __ __	❑	__ __ / __ __ __ __	❑
16. Most recent cervical cancer screening (Pap test) – Women age 21-63	__ __ / __ __ __ __	❑	__ __ / __ __ __ __	❑
17. Most recent colorectal cancer screening – Age 50-75				
a. Colonoscopy (flexible fiberoptic/optical)	__ __ / __ __ __ __	❑	__ __ / __ __ __ __	❑
b. 3 Card FOBT (guaiac)	__ __ / __ __ __ __	❑	__ __ / __ __ __ __	❑
c. 3 Card Fecal Immunochemical Test (FIT)	__ __ / __ __ __ __	❑	__ __ / __ __ __ __	❑
d. 2 Card Fecal Immunochemical Test (FIT)	__ __ / __ __ __ __	❑	__ __ / __ __ __ __	❑
e. Flexible Sigmoidoscopy	__ __ / __ __ __ __	❑	__ __ / __ __ __ __	❑
f. CT colonoscopy/CT colonography	__ __ / __ __ __ __	❑	__ __ / __ __ __ __	❑
18. Digital rectal exam in office (guaiac)	__ __ / __ __ __ __	❑	__ __ / __ __ __ __	❑

Study ID: __ __ - __ __

Four and Eight Month Data Collection

(Intervention Sites Only)

Time Since Enrollment *(check one)*: ☐ **4 months** ☐ **8 months**

For <u>every</u> "Diagnosis" row listed below, complete only ***ONE*** of the following options:

- If the diagnosis is confirmed for the patient, either:
  a. Provide the date the test was performed and the value obtained ***IF*** it was completed since the review of laboratory tests at baseline enrollment or 4 months **OR**
  b. Check N/F if no new tests have been performed since baseline
- If the patient does NOT have the diagnosis, check No

Diagnosis	Has Diagnosis	Test	Test Date	Value	Not Found
Diabetes	☐ Yes ☐ No	HgA1c	__ __ / __ __ / __ __	__ __ . __ %	☐ N/F
Hypertension	☐ Yes ☐ No	Blood Pressure	__ __ / __ __ / __ __	_____ / _____ mmHg	☐ N/F
Atrial Fibrillation	☐ Yes ☐ No	INR (if on Warfarin)	__ __ / __ __ / __ __	__ . __	☐ N/F
Hyperlipidemia	☐ Yes ☐ No	Total Cholesterol	__ __ / __ __ / __ __	__ __ __ mg/dl	☐ N/F
		LDL	__ __ / __ __ / __ __	__ __ __ mg/dl	☐ N/F
		HDL	__ __ / __ __ / __ __	__ __ __ mg/dl	☐ N/F
		Triglycerides	__ __ / __ __ / __ __	__ __ __ mg/dl	☐ N/F

I-CARE
Improved Cardiovascular Risk Reduction to Enhance Rural Primary Care

Clinic Visit Tracking Form

Study ID: __ __- __ __

Study Time Point: ○ 12 month ○ 36 month

Baseline Study Visit: _ _ / _ _ / _ _ _ _ (mm/dd/yyyy)

Data Collection Date: _ _ / _ _ / _ _ _ _ (mm/dd/yyyy)

<u>Instructions</u>:

Review the patient's medical record. Complete a row for every patient visit to the clinic at which the patient saw a physician, nurse practitioner, physician's assistant, pharmacist or health coach.

- At the 12 month visit collect <u>ONLY</u> visits including baseline, 12 month and all visits in between.
- At month 36 collect <u>ONLY</u> visits occurring AFTER the 12 month visit and through 36 months.

Date of Clinic Visit	Chronic Conditions Addressed at This Visit (check all that apply)	Was this an annual physical?
_ _ / _ _ / _ _ _ _ Provider Type(s)*: ___ ___ ___	☐ Diabetes ☐ Coronary Artery Disease ☐ Cholesterol ☐ Peripheral Vascular Disease ☐ Hypertension ☐ Carotid Artery Disease ☐ COPD ☐ None of the above ☐ Atrial fibrillation	☐ Yes ☐ No
_ _ / _ _ / _ _ _ _ Provider Type(s)*: ___ ___ ___	☐ Diabetes ☐ Coronary Artery Disease ☐ Cholesterol ☐ Peripheral Vascular Disease ☐ Hypertension ☐ Carotid Artery Disease ☐ COPD ☐ None of the above ☐ Atrial fibrillation	☐ Yes ☐ No
_ _ / _ _ / _ _ _ _ Provider Type(s)*: ___ ___ ___	☐ Diabetes ☐ Coronary Artery Disease ☐ Cholesterol ☐ Peripheral Vascular Disease ☐ Hypertension ☐ Carotid Artery Disease ☐ COPD ☐ None of the above ☐ Atrial fibrillation	☐ Yes ☐ No
_ _ / _ _ / _ _ _ _ Provider Type(s)*: ___ ___ ___	☐ Diabetes ☐ Coronary Artery Disease ☐ Cholesterol ☐ Peripheral Vascular Disease ☐ Hypertension ☐ Carotid Artery Disease ☐ COPD ☐ None of the above ☐ Atrial fibrillation	☐ Yes ☐ No

* 1=MD, DO, PA, ARNP; 2= clinic pharmacist; 3=health coach *(fill in all that apply)*

Study ID: __ __- __ __

Date of Clinic Visit	Chronic Conditions Addressed at This Visit (check all that apply)		Was this an annual physical?
_ _ / _ _ / _ _ _ _ Provider Type(s)*: ___ ___ ___	☐ Diabetes ☐ Cholesterol ☐ Hypertension ☐ COPD ☐ Atrial fibrillation	☐ Coronary Artery Disease ☐ Peripheral Vascular Disease ☐ Carotid Artery Disease ☐ None of the above	☐ Yes ☐ No
_ _ / _ _ / _ _ _ _ Provider Type(s)*: ___ ___ ___	☐ Diabetes ☐ Cholesterol ☐ Hypertension ☐ COPD ☐ Atrial fibrillation	☐ Coronary Artery Disease ☐ Peripheral Vascular Disease ☐ Carotid Artery Disease ☐ None of the above	☐ Yes ☐ No
_ _ / _ _ / _ _ _ _ Provider Type(s)*: ___ ___ ___	☐ Diabetes ☐ Cholesterol ☐ Hypertension ☐ COPD ☐ Atrial fibrillation	☐ Coronary Artery Disease ☐ Peripheral Vascular Disease ☐ Carotid Artery Disease ☐ None of the above	☐ Yes ☐ No
_ _ / _ _ / _ _ _ _ Provider Type(s)*: ___ ___ ___	☐ Diabetes ☐ Cholesterol ☐ Hypertension ☐ COPD ☐ Atrial fibrillation	☐ Coronary Artery Disease ☐ Peripheral Vascular Disease ☐ Carotid Artery Disease ☐ None of the above	☐ Yes ☐ No
_ _ / _ _ / _ _ _ _ Provider Type(s)*: ___ ___ ___	☐ Diabetes ☐ Cholesterol ☐ Hypertension ☐ COPD ☐ Atrial fibrillation	☐ Coronary Artery Disease ☐ Peripheral Vascular Disease ☐ Carotid Artery Disease ☐ None of the above	☐ Yes ☐ No
_ _ / _ _ / _ _ _ _ Provider Type(s)*: ___ ___ ___	☐ Diabetes ☐ Cholesterol ☐ Hypertension ☐ COPD ☐ Atrial fibrillation	☐ Coronary Artery Disease ☐ Peripheral Vascular Disease ☐ Carotid Artery Disease ☐ None of the above	☐ Yes ☐ No

* 1=MD, DO, PA, ARNP; 2= clinic pharmacist; 3=health coach *(fill in all that apply)*

ICARE
Improved Cardiovascular Risk Reduction to Enhance Rural Primary Care

36 Month Blood Pressure, Laboratory and Medication Form

This form should be completed and faxed no later than 37 months following enrollment

Study ID: _ _ _ _ _	**Today's Date:** *(mm/dd/yyyy)* _ _ / _ _ / _ _ _ _
Enrollment date:	_ _ / _ _ / _ _ _ _
Date 24 months after enrollment:	_ _ / _ _ / _ _ _ _
Date 36 months after enrollment:	_ _ / _ _ / _ _ _ _

A. Record values documented in the patient's medical record no earlier than 24 months after enrollment and no later than 36 months following enrollment:

- If multiple values are found, select the value that is closest to 36 months following enrollment
- If there are no values found between 24-36 months after enrollment, mark "no entry in time frame"

	Date (mm/dd/yyy)	a. Systolic BP (mm Hg)	b. Diastolic BP (mm Hg)	No Entry in Time Frame
10. **Blood Pressure**	_ _ / _ _ / _ _ _ _	_ _ _	_ _ _	☐
11. **Total Cholesterol**	_ _ / _ _ / _ _ _ _	_ _ _ mg/dl		☐
12. **High-density lipoproteins (HDL)**	_ _ / _ _ / _ _ _ _	_ _ _ mg/dl		☐
13. **Low-density lipoproteins (LDL)**	_ _ / _ _ / _ _ _ _	_ _ _ mg/dl		☐
14. **Triglycerides**	_ _ / _ _ / _ _ _ _	_ _ _ mg/dl		☐
15. **Hemoglobin A1c (HbA1c)**	_ _ / _ _ / _ _ _ _	_ _ _ . _ _ _ %		☐

Study ID: _ _-_ _

B. Record medications documented in the patient's medical record no earlier than 24 months after enrollment and no later than 36 months following enrollment:

- **If multiple lists are found, select the list that is closest to 36 months following enrollment.**
- ONLY include **antihypertensive agents**, **hyperglycemic agents**, **cholesterol agents**, **asthma agents** and **anticoagulants/antiplatelet agents**

Medication Name & Code	Strength	Directions for Use
1. _____ **Code:** __ __ __ __		
2. _____ **Code:** __ __ __ __		
3. _____ **Code:** __ __ __ __		
4. _____ **Code:** __ __ __ __		
5. _____ **Code:** __ __ __ __		
6. _____ **Code:** __ __ __ __		
7. _____ **Code:** __ __ __ __		
8. _____ **Code:** __ __ __ __		

Medication Name & Code	Strength	Directions for Use
9. _____ **Code:** __ __ __ __		
10. _____ **Code:** __ __ __ __		
11. _____ **Code:** __ __ __ __		
12. _____ **Code:** __ __ __ __		
13. _____ **Code:** __ __ __ __		
14. _____ **Code:** __ __ __ __		
15. _____ **Code:** __ __ __ __		
16. _____ **Code:** __ __ __ __		

UNANTICIPATED PROBLEM (UP) SCREENING FORM
12-MONTH STUDY VISIT

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 form 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 and fax the completed form to Nick Rudzianski at the University of Iowa at 319-335-9782, and your local IRB if applicable.*

**PLEASE NOTE: If you are approved to conduct this study by a local Institutional Review Board (IRB) instead of the University of Iowa IRB, all site communication related to UPs reported to your local should also be forwarded to the University of Iowa research team.*

START HERE

1. 12-month study visit date: ____ ____/ ____ ____ / ____ ____ ____ ____ (MM/DD/YYYY)

2. 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 enrolled in the study (signed consent) and the 12-month study visit date?
   - ❒ NO ➔ ***Skip to Question 4***
   - ❒ YES ➔ ***Continue to Question 3 below***

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

4. After meeting with the subject and reviewing the subject's medical record, have you identified one or more **incidents, experiences, or outcomes that are <u>related or possibly related to this subject's participation in the research study</u>** between the time the subject enrolled in the study (signed consent) and the 12-month study visit date?
   - ❒ NO ➔ ***Skip to Question 6***
   - ❒ YES➔ ***Continue to Question 5 below***

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

6. After meeting with the subject and reviewing the subject's medical record, have you identified one or more **incidents, experiences, or outcomes that are <u>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</u>** between the time the subject enrolled in the study (signed consent) through the 12-month study visit date?
   - ❒ NO ➔ ***Skip to the box below ("!!! READ BEFORE CONTINUING !!!")***
   - ❒ YES➔ ***Continue to Question 7 below***

7. 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 2, 4, AND 6, a UP was identified – please continue with Question 8 on the next page.**

⇨ If you answered "**NO" to Question 2, 4 OR 6:**

- STOP here. Your responses indicate that no Unanticipated Problem involving this subject occurred between the baseline visit and the 12-month study visit.
- Do not complete the remaining section.
- Fax this form to Nick Rudzianski at 319-335-9782.
- Date faxed: __ __/ __ __ / __ __ __ __ (MM/DD/YYYY)
- File this hard copy form in the subject's study folder.

8. Have **ALL** of the Unanticipated Problems that you identified above in Questions 2-7 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	NO
❑	❑
⬇	⬇
You indicated that ALL occurrences of Unanticipated Problems involving this subject have been reported to the University of Iowa. Please take the following actions: • Fax this form to Nick Rudzianski at 319-335-9782. • Date faxed: ___ ___/ ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY) • File this hard copy form in the subject's study folder.	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 take the following actions: • Submit an "UNANTICIPATED PROBLEM (UP) EVENT-DRIVEN" form for each event you identified in Questions 2-7 above. • Fax this form to Nick Rudzianski at 319-335-9782. If you have any questions about Unanticipated Problems or the process of reporting them to the University of Iowa, please contact Brian Gryzlak at 319-335-8218 or email brian-gryzlak@uiowa.edu

UNANTICIPATED PROBLEM (UP) EVENT-DRIVEN FORM

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 form is to document and report Unanticipated Problems that have been identified.

The following questions guide you through each of the three criteria above for an Unanticipated Problem (UP). Unless prompted otherwise below, please complete and fax this form Nick Rudzianski at the University of Iowa at 319-335-9782, and your local IRB if applicable.*

**PLEASE NOTE: If you are approved to conduct this study by a local Institutional Review Board (IRB) instead of the University of Iowa IRB, all site communication related to UPs reported to your local should also be forwarded to the University of Iowa research team.*

START HERE

1. How many subjects did the Unanticipated Problem (UP) you are reporting affect or impact?

- ❒ The UP affected **more than one subject** ➔ ***Skip to Question 3***
- ❒ The UP affected **only one subject** ➔ ***Continue to Question 2 below***

2. Enter the study ID for the affected subject: ____ ____ - ____ ____

3. Have you identified an **incident, experience, or outcome that is unexpected in terms of nature, severity or frequency for this subject(s)?**

- ❒ NO ➔ ***Skip to Question 5***
- ❒ YES ➔ ***Continue to Question 4 below***

4. If YES, please describe how the event was unexpected: _____

_____

_____

5. Have you identified an **incident, experience, or outcome that is <u>related or possibly related to this subject's participation in the research study</u>?**
   - ❒ NO ➔ ***Skip to Question 7***
   - ❒ YES➔ ***Continue to Question 6 below***

6. If YES, please describe how the event was related to the subject's participation in the study: _____

_____

_____

7. Have you identified an **incident, experience, or outcome that <u>suggests 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</u>?**
   - ❒ NO ➔ ***Skip to the box below ("!!! READ BEFORE CONTINUING !!!")***
   - ❒ YES➔ ***Continue to Question 8 below***

8. If YES, please describe how the event places subjects or others at greater risk of harm:

_____

_____

!!! READ BEFORE CONTINUING !!!

⇨ If you answered "**YES" to Questions 3, 5, AND 7**, an Unanticipated Problem (UP) was identified – please continue with Question 9 below. <u>After you complete this form, please fax it to Nick Rudzianski at 319-335-9782 and file this hard copy form in the appropriate study folder.</u>

⇨ If you answered **"NO" to Question 3, 5 OR 7:**

- STOP HERE. Your responses indicate that the event you are trying to report is not an Unanticipated Problem.
- Do not complete the remaining sections.
- File this hard copy form in the appropriate study folder.

⇨ If you think that the event you are reporting should still be considered an Unanticipated Problem, please contact the ICARE study coordinator, Brian Gryzlak at 319-335-8218 or brian-gryzlak@uiowa.edu

9. Briefly describe the UP, including any harm or potential harm that occurred to subject(s), whether and how the incident was resolved. (If you have supplementary information related to this UP that you think needs to be reviewed by the study team please fax it to Nick Rudzianski at the University of Iowa at 319-335-9782.)

_____

_____

10. On what date did this UP occur?
__ __/__ __/__ __ __ __ (MM/DD/YYYY)

11. On what date was this UP identified by your clinic?
__ __/__ __/__ __ __ __ (MM/DD/YYYY)

For each of the questions below, please indicate whether you feel the outcome described is attributed to the UP you are reporting. Answers to Questions 11-19 are required.

12. Did any subject **die** as a result of the UP?

- ❒ NO ➔ ***Skip to Question 13***
- ❒ YES ➔ ***Continue to Question 12 below***

13. Death date: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

14. Did any subject experience a **life-threatening condition** as a result of the UP?

- ❒ YES
- ❒ NO

15. Was any subject **hospitalized** as a result of the UP?

- ❒ YES
- ❒ NO

16. Did any subject experience **disability** as a result of the UP?

- ❒ YES
- ❒ NO

17. Did the UP result in **congenital abnormality**?

- ❒ YES
- ❒ NO

18. Did the UP **require intervention in order to prevent permanent impairment or damage** to any subject?

- ❒ YES
- ❒ NO

NOTE: A "yes" answer to Question 17 should only be used for an event that does not result in death, a life-threatening condition, hospitalization, disability or congenital deformity, but that did jeopardize the subject(s) and that required a specific medical intervention to prevent one or more of outcomes in Questions 12-17 from occurring.

19. Did the UP **result in an important medical event** as determined by a physician or designee at your clinic?

❒ YES
❒ NO

NOTE: A "yes" answer to Question 19 should only be used when a site judges the event to represent significant hazard or harm to a research subject(s).

20. Was the UP an **exacerbation of a pre-existing condition** (that is, it existed prior to the subject's enrollment in the study)?

❒ YES
❒ NO

21. Describe any details about the UP that might help us evaluate its relationship to the study.

_____

_____

_____

22. Describe other relevant history, including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction).

_____

_____

_____

23. Describe relevant scans/tests/laboratory data related to the UP, including dates.

_____

_____

_____

24. Describe any action that you have taken as a result of the problem, whether to moderate the impact on the subject(s) or to decease the likelihood that the problem will recur:

_____

_____

_____

Please fax this form to Nick Rudzianski at 319-335-9782 after it is completed and file this hard copy in the appropriate study folder.

ICARE
Improved Cardiovascular Risk Reduction to Enhance Rural Primary Care

Study Termination

(Complete after the 36 month BP-Labs-Medication Form is faxed OR when the patient is terminated early)

1. Did the subject complete all study time points:
   - ☐ Yes
     a. Date of 12 month visit: _ _/_ _/_ _ _ _
     b. Date of 36 month data submission: _ _/_ _/_ _ _ _
   - ☐ No
     b. Date of early termination: _ _/_ _/_ _ _ _
2. If the subject terminated the study early, please indicate the reason:
   - ☐ Subject eligibility status changed
     a. Reason: _____
   - ☐ Subject chose to withdraw
     a. Reason: _____
   - ☐ Subject lost to follow-up (unable to contact)
   - ☐ Subject is no longer a patient at this clinic
   - ☐ Research team chose to discontinue subject
     a. Reason: _____
   - ☐ Subject withdrew/terminated due to an adverse event
     a. Reason: _____
   - ☐ Subject death (enter death date for question 1.b)
   - ☐ Other
     a. Specify: _____
3. Comments:

_____

_____

APPENDIX V: SCHEDULE FOR COMPLETING CASE REPORT FORMS

Schedule for Completing Case Report Forms

All case report forms (CRFs) are provided in **APPENDIX IV**.

All case report forms should be completed on paper. Paper forms are considered to be source documents and should be securely stored in the subject's research file in a locked file cabinet in a locked office.

Study Coordinators should then fax the paper CRF to the CCC.

FORMS SCHEDULE

Scheduled visits should be completed during the 60-day period surrounding the due date, that is, 30 days before the designated time point – 30 days after the designated time point.

Time Points (Study Visit)	Pre-Enrollment	Baseline	4 months	8 months	12 months	36 months	Event Driven
Screening Log and Verification of Inclusion and Exclusion Criteria	X	X					
Enrollment		X					
Diagnosed Conditions and Care Management		X			X	X	
Medication Reconciliation		X			X		
Health Behavior Inventory		X					
Blood Pressure, Laboratory and Cancer Screening		X			X		
4, 8 month data collection			X	X			
Clinic Visit Tracking					X	X	
Unanticipated Problem - 12 Month Screening					X		
Unanticipated Problem - 36 Month Screening						X	
36 Month Blood Pressure, Laboratory & Medications						X	
Site Report of Unanticipated Problem							X
Study Termination							X

ICARE
Improved Cardiovascular Risk Reduction to Enhance Rural Primary Care

Communication Form

Primary Provider:
Fax:
Patient Name:
Birthdate:
Pharmacist:
Date:
Return Fax:

Communication Type:
☐ Initial ☐ Follow-Up ☐ New Problem ☐ Preventive ☒ Other

Thank you for your time,

ICARE CVRS Pharmacist

☐ I agree with the above recommendations.
☐ Proposed modified plan:

Primary Provider Signature: _____ Date: _____

This form will serve as a prescription if recommendations are accepted by the physician.
Information on this fax is confidential. If you have received this fax in error please destroy and call 866-227-9873.

APPENDIX VI: STUDY DRUG CODES

Code	Generic Name	Brand Names	Strengths Available
2101	acarbose	Precose	25 mg, 50 mg, 100 mg
201	acebutolol	Sectral	200 mg, 400 mg
1101	aliskiren	Tekturna	150 mg, 300 mg
1102	aliskiren-hydrochlorothiazide	Tekturna HCT	150/12.5 mg, 150/25 mg, 300/12.5 mg, 300/25 mg
1103	aliskiren-valsartan	Valturna	150/160 mg, 300/320 mg
101	amiloride	Midamor	5 mg
102	amiloride/hydrochlorothiazide*	Moduretic	5/50 mg
401	amlodipine	Norvasc	2.5 mg, 5 mg, 10 mg
410	amlodipine/benazepril*	Lotrel	2.5/10 mg, 5/10 mg, 5/20 mg, 5/40 mg, 10/20 mg, 10/40 mg
422	amlodipine/olmesartan	AZOR	5/20 mg, 5/40 mg, 10/20 mg, 10/40 mg
420	amlodipine/valsartan*	Exforge	5/160 mg, 10/160 mg, 5/320 mg, 10/320 mg
421	amlodipine / valsartan / hydrochlorothiazide	Exforge HCT	5/160/12.5 mg, 10/160/12.5 mg, 5/160/25 mg, 10/160/25 mg, 10/320/25 mg
5202	apixaban	Eliquis	2.5mg, 5mg
6201	arformoterol tartrate	Brovana	15 mcg
2001	aspart	Novolog	100U/ml
2002	aspart protamine	Novolog Mix	70/30 – 100U/ml
5401	aspirin	Ecotrin, Bufferin, Aspergum	81mg, 227mg, 325mg, 500mg, 650mg
202	atenolol	Tenormin	25 mg, 50 mg, 100 mg
213	atenolol-chlorthalidone	Tenoretic	50/25 mg, 100/25 mg
4001	atorvastatin	Lipitor	10mg, 20mg, 40mg, 80mg
4301	atorvastatin/amlodipine*	Caduet	2.5/10mg, 2.5/20mg, 2.5/40mg, 5/10mg, 5/20mg, 5/40mg, 5/80mg, 10/10mg, 10/20mg, 10/40mg, 10/80mg
615	azilsartan medoxomil	Edarbi	40 mg, 80 mg
6101	beclomethasone	Beclovent, QVAR	42 mcg, 40 mcg, 80 mcg
301	benazepril	Lotensin	5 mg, 10 mg, 20 mg, 40 mg
311	benazepril-hydrochlorothiazide*	Lotensin HCT	5/6.25 mg, 10/12.5 mg, 20/12.5 mg, 20/25 mg
203	betaxolol	Kerlone	10 mg, 20 mg
204	bisoprolol	Zebeta	5 mg, 10 mg
214	bisoprolol-hydrochlorothiazide*	Ziac	2.5/6.25 mg, 5/6.25 mg, 10/6.25 mg
6102	budesonide	Pulmicort Flexhaler	90 mcg, 180 mcg

Code	Generic Name	Brand Names	Strengths Available
6504	budesonide/ formoterol*	Symbicort	80 mcg-4.5 mcg, 160 mcg-4.5 mcg
103	bumetanide	Bumex	0.5 mg, 1 mg, 2 mg
3401	canagliflozin	Invokana	100mg, 300mg
601	candesartan	Atacand	4 mg, 8 mg, 16 mg, 32 mg
608	candesartan-hydrochlorothiazide	Atacand HCT	16/12.5 mg, 32/12.5 mg, 32/25 mg
302	captopril	Capoten	12.5 mg, 25 mg, 50 mg, 100 mg
312	captopril-hydrochlorothiazide*	Capozide	25/15 mg, 25/25 mg, 50/15 mg, 50/25 mg
220	carvedilol	Coreg	3.125 mg, 6.25 mg, 12.5 mg, 25 mg
222	carvedilol extended release	Coreg CR	10 mg, 20 mg, 40 mg, 80 mg
104	chlorothiazide	Diuril	250 mg, 500 mg
3101	chlorpropamide	Diabinese	100mg, 250mg
105	chlorthalidone	Hygroton and others	25 mg, 50 mg, 100 mg
4802	cholesteramine light	Questran Light, Prevalite	4 gr
4801	cholestyramine	Questran	4 gr
6103	ciclesonide	Alvesco	80 mcg, 160 mcg
701	clonidine	Catapres	0.1 mg, 0.2 mg, 0.3 mg
702	clonidine topical patch	Catapres TTS	0.1 mg, 0.2 mg, 0.3 mg
707	clonidine-chlorthalidone	Clorpres	0.1/15 mg, 0.2/15 mg, 0.3/15 mg
5101	clopidogrel	Plavix	75mg, 300mg
4804	colesevelam	WelChol	625mg tab, 3.75g powder
4803	colestipol	Colestid	1 gr tab, 5 gr granules
5301	dabigatran	Pradaxa	75mg, 150mg
5003	daltaperin	Fragmin	2500U, 5000U, 7500U, 10,000U, 12,500U, 15,000U, 18,000U, 25,000U
3402	dapagliflozin	Farxiga	5mg, 10mg
2003	detemir	Levemir	100U/ml
402	diltiazem	Cardizem, Dilacor, Tiazac	30 mg, 60 mg, 90 mg, 120 mg, 180 mg, 240 mg, 300 mg, 360 mg, 420 mg
501	doxazosin	Cardura	1 mg, 2 mg, 4 mg, 8 mg
303	enalapril	Vasotec	2.5 mg, 5 mg, 10 mg, 20 mg
411	enalapril/felodipine *	Lexxel	5/2.5 mg, 5/5 mg

Code	Generic Name	Brand Names	Strengths Available
313	enalapril-hydrochlorothiazide*	Vaseretic	5/12.5 mg, 10/25 mg
5002	enoxaparin	Lovenox	30mg, 40mg, 60mg, 80mg, 100mg, 120mg, 150mg, 300mg
1001	eplerenone	Inspra	25 mg, 50 mg
602	eprosartan	Teveten	400 mg, 600 mg
609	eprosartan-hydrochlorothiazide	Teveten-HCT	600/12.5 mg, 600/25 mg
115	ethacrynic acid	Edecrin	25g
3001	exanatide	Byetta	5mcg, 10mcg
4601	exetimibe	Zetia	10mg
403	felodipine	Plendil	2.5 mg, 5 mg, 10 mg
4902	fenofibrate	Lipofen, Lofibra, Tricor, Triglide	40mg, 48mg, 50mg, 54mg, 120mg, 145mg, 160mg
4903	fenofibrate - micronized	Lofibra, Antara	43mg, 67mg, 130mg, 134mg, 200mg
6104	flunisolide	Aerobid	.25 mg
6105	fluticasone propionate	Flovent Diskus, Flovent, Flovent HFA	50 mcg, 100 mcg, 250 mcg, 44 mcg, 110 mcg, 220 mcg
6501	fluticasone/ salmeterol*	Advair Diskus, Advair HFA	100mcg-50 mcg, 250 mcg-50 mcg, 500 mcg-50 mcg, 45 mcg-21 mcg, 115 mcg-21 mcg, 230 mcg-21 mcg
6502	fluticasone/ vilanterol*	BREO ELLIPTA	100 mcg-25 mcg
4003	fluvastatin, fluvastatin XL	Lescol, Lescol XL	20mg, 40mg, 80mg
6202	formoterol fumarate	Foradil Aerolizer Inhaler	12 mcg
304	fosinopril	Monopril	10 mg, 20 mg, 40 mg
314	fosinopril-hydrochlorothiazide*	Monopril-HCT	10/12.5 mg, 20/12.5 mg
106	furosemide	Lasix	20 mg, 40 mg, 80 mg
4901	gemfibrozil	Lopid	600mg
2004	glargine	Lantus	100U/ml
3102	glimeperide	Amaryl	1mg, 2mg, 4mg
3301	glimepiride/pioglitazone*	Duetact	2/30mg, 4/30mg
3302	glimepiride/rosiglitazone*	Avandaryl	1/4mg, 2/4mg, 4/4mg,2/8mg, 4/8mg
3103	glipizide	Glucotrol	5mg, 10mg
3104	glipizide XR	Glucotrol XR	2.5mg, 5mg, 10mg
3201	glipizide/metformin*	Metaglip	2.5/250mg, 2.5/500mg, 5/500mg
2005	glulisine	Apidra	100U/ml
3105	glyburide	Diabeta, Micronase	1.25mg, 2.5mg, 5mg

Code	Generic Name	Brand Names	Strengths Available
3106	glyburide – micronized	Glynase	1.5mg, 3mg, 6mg
3202	glyburide/metformin*	Glucovance	1.25/250mg, 2.5/500mg, 5/500mg
703	guanabenz	Wytensin	4 mg, 8 mg
704	guanfacine	Tenex	1 mg, 2 mg
901	hydralazine	Apresoline	10 mg, 25 mg, 50 mg, 100 mg
905	hydralazine-hydrochlorothiazide	Apresazide and Hydra-Zide	25/25 mg, 50/50 mg, 100/50 mg
107	hydrochlorothiazide	Hydrodiuril & others	12.5 mg, 25 mg, 50 mg
6203	indacaterol maleate	Arcapta Neohaler	75 mcg
109	indapamide	Lozol	1.25 mg, 2.5 mg
603	irbesartan	Avapro	75 mg, 150 mg, 300 mg
610	irbesartan-hydrochlorothiazide	Avalide	150/12.5 mg, 300/12.5 mg, 300/25 mg
2008	isophane	Humulin N, Novolin N	100U/ml
902	isosorbide dinitrate	Isordil	2.5 mg, 5 mg, 10 mg, 20 mg, 30 mg, 40 mg
906	isosorbide dinitrate-hydralazine	BiDil	20/37.5 mg
903	isosorbide mononitrate	Imdur	10 mg, 20 mg, 30 mg, 60 mg, 120 mg
404	isradipine	DynaCirc	2.5 mg, 5 mg, 10 mg
221	labetalol	Normodyne, Trandate	100 mg, 200 mg, 300 mg
2404	linagliptin	Tradjenta	5mg
2503	linagliptin-metformin*	Jentadueto	2.5/500mg, 2.5/850mg, 2.5/1000mg
3002	liraglutide	Victoza	18mg/3ml
305	lisinopril	Zestril, Prinivil	2.5 mg, 5 mg, 10 mg, 20 mg, 30 mg, 40 mg
315	lisinopril-hydrochlorothiazide*	Prinzide, Zestoretic	10/12.5 mg, 20/12.5 mg, 20/25 mg
2006	lispro	Humalog	100U/ml
2007	lispro protamine	Humalog Mix	50/50, 75/25
604	losartan	Cozaar	25 mg, 50 mg, 100 mg
611	losartan-hydrochlorothiazide	Hyzaar	50/12.5 mg, 100/12.5 mg, 100/25 mg
4004	lovastatin, lovastatin XR	Mevacor, Altoprev	10mg, 20mg, 40mg, 60mg
4101	lovastatin/niacin*	Advicor	500/20mg, 750/20mg, 1000/20mg, 1000/40mg
2301	metformin	Glucophage, Fortamet, Appformin, Glumetza	500mg, 750mg, 850mg, 1000mg
2701	metformin/repaglinide*	Prandimet	1/500mg, 2/500mg

Code	Generic Name	Brand Names	Strengths Available
705	methyldopa	Aldomet	250 mg, 500 mg
706	methyldopa-hydrochlorothiazide	Aldoril	250/15 mg, 250/25 mg
110	metolazone	Mykrox, Zaroxolyn	2.5 mg, 5 mg, 10 mg
206	metoprolol succinate (extended release)	Toprol XL	25 mg, 50 mg, 100 mg, 200 mg
205	metoprolol tartrate	Lopressor	25 mg, 50 mg, 100 mg
215	metoprolol-hydrochlorothiazide*	Lopressor HCT	50/25 mg, 100/25 mg, 100/50 mg
2102	miglitol	Glyset	25mg, 50mg, 100mg
904	minoxidil	Loniten	2.5 mg, 10 mg
306	moexipril	Univasc	7.5 mg, 15 mg
316	moexipril-hydrochlorothiazide*	Uniretic	7.5/12.5 mg, 15/12.5 mg, 15/25 mg
6106	mometasone	Asmanex Twisthaler/ Twist	220 mcg, 110 mcg
6503	mometasone/ formoterol*	Dulera	100 mcg-5 mcg, 200 mcg-5 mcg
6301	montelukast	Singulair	4 mg, 5 mg, 10 mg
207	nadolol	Corgard	20 mg, 40 mg, 80 mg, 120 mg, 160 mg
216	nadolol-bendroflumethiazide*	Corzide	40/5 mg, 80/5 mg
2601	nateglinide	Starlix	60mg, 120mg
219	nebivolol	Bystolic	2.5 mg, 5 mg, 10 mg, 20 mg
4501	niacin**	Niaspan	500mg, 750mg, 1000mg
405	nicardipine	Cardene	20 mg, 30 mg, 45 mg, 60 mg
406	nifedipine	Adalat, Procardia	10 mg, 20 mg, 30 mg, 60 mg, 90 mg
407	nisoldipine	Sular	8.5 mg, 10 mg, 17 mg, 20 mg, 25.5 mg, 30 mg, 34 mg, 40 mg
605	olmesartan	Benicar	5 mg, 20 mg, 40 mg
612	olmesartan medoxomil-hydrochlorothiazide	Benicar HCT	20/12.5 mg, 40/12.5 mg, 40/25 mg
4701	omega – 3 fatty acids**	Lovaza	1 gr
208	penbutolol	Levatol	20 mg
307	perindopril	Aceon	2 mg, 4 mg, 8 mg
209	pindolol	Visken	5 mg, 10 mg
2801	pioglitazone	Actos	15mg, 30mg, 45mg
2901	pioglitazone/metformin*	ActoPlus	15/500mg, 15/850mg, 15/1000mg, 30/1000mg
4007	pitavastatin	Livalo	1mg, 2mg, 4mg
111	polythiazide	Renese	1 mg, 2 mg, 5 mg

Code	Generic Name	Brand Names	Strengths Available
2201	pramlintide	Symlin	60 and 120
5103	prasugrel	Effient	5mg, 10mg
4005	pravastatin	Pravachol	10mg, 20mg, 40mg, 80mg
502	prazosin	Minipress	1 mg, 2 mg, 5 mg
504	prazosin/polythiazide*	Minizide	1/0.5 mg, 2/0.5 mg, 5/0.5 mg
210	propranolol	Inderal	10 mg, 20 mg, 40 mg, 60 mg, 80 mg
217	propranolol la-hydrochlorothiazide*	Inderide LA	40/25 mg, 80/25 mg
211	propranolol long-acting	Inderal LA	60 mg, 80 mg, 120 mg, 160 mg
308	quinapril	Accupril	5 mg, 10 mg, 20 mg, 40 mg
317	quinapril-hydrochlorothiazide*	Accuretic	10/12.5 mg, 20/12.5 mg, 20/25 mg
309	ramipril	Altace	1.25 mg, 2.5 mg, 5 mg, 10 mg
2009	regular	Humulin R, Novolin R	100U/ml, 500U/ml
2010	regular:isophane	NPH	Novolin 70/30, Humuilin 50/50, Humulin 70/30
2602	repaglinide	Prandin	0.5mg, 1mg, 2mg
801	reserpine	Serpalan, Serpasil	0.1 mg, 0.25 mg
805	reserpine/hydralazine/hydrochlorothiazide*	Ser Ap Es	0.1/25/15 mg
803	reserpine-chlorothiazide	Diupres	0.125/250 mg, 0.125/500 mg
802	reserpine-chlorthalidone	Demi-Regroton	0.125/25, 0.25/50
804	reserpine-hydrochlorothiazide	Hydropres	0.125/25 mg, 0.125/50 mg
5201	rivaroxaban	Xarelto	10mg, 15mg, 20mg
2802	rosiglitazone	Avandia	2mg, 4mg, 8mg
2902	rosiglitazone/metformin*	Avandamet	2/500mg, 2/1000mg, 4/500mg, 4/1000mg
4002	rosuvastatin	Crestor	5mg, 10mg, 20mg, 40mg
6204	salmeterol xinafoate	Serevent Diskus	50 mcg
2403	saxagliptin	Onglyza	2.5mg, 5mg
2504	sexagliptin/metformin XR*	Kombiglyze	2.5/1000mg, 5/500mg, 5/1000mg
4006	simvastatin	Zocor	10mg, 20mg, 40mg, 80mg
4201	simvastatin/exetimibe*	Vytorin	10/10mg, 10/20mg, 10/40mg, 10/80mg
4102	simvastatin/niacin*	Simcor	500/20mg, 500/40mg, 750/20mg, 1000/20mg, 1000/40mg
4401	simvastatin/sitagliptan*	Juvisync	10/100mg, 20/100mg, 40/100mg
2401	sitagliptin	Januvia	25mg, 50mg, 100mg

Code	Generic Name	Brand Names	Strengths Available
2502	sitagliptin/metformin XR*	Janumet XR	50/500mg, 50/1000mg, 100/1000mg
2501	sitagliptin/metformin*	Janumet	50/500mg, 50/1000mg, 100/1000mg
2402	sitagliptin/simvastatin (off-market)*	Juvasync	100-10mg, 100-20mg, 100-40mg
1002	spironolactone	Aldactone	25 mg, 50 mg, 100 mg
112	spironolactone/hydrochlorthiazide*	Aldactazide	25/25 mg, 50/50 mg
606	telmisartan	Micardis	20 mg, 40 mg, 80 mg
613	telmisartan-hydrochlorothiazide	Micardis-HCT	40/12.5 mg, 80/12.5 mg, 80/25 mg
503	terazosin	Hytrin	1 mg, 2 mg, 5 mg, 10 mg
6401	theophylline (12 hr)	Theo-Dur, TheoCap	100 mg, 200 mg, 300 mg, 450 mg
6402	theophylline (24 hr)	Theo-Time, Theo-24, Uniphyl, Theochron, Quibron-T	100 mg, 200 mg, 300 mg, 400 mg, 600 mg
5102	ticagrelor	Brilinta	90mg
5104	ticlopidine	Ticlid	250mg
212	timolol	Blocadren	5 mg, 10 mg, 20 mg
218	timolol-hydrochlorothiazide*	Timolide	10/25 mg
3107	tolazamide	Tolinase	250mg, 500mg
3108	tolbutaminde	Orinase	500mg
113	torsemide	Demadex	5 mg, 10 mg, 20 mg, 100 mg
310	trandolapril	Mavik	1 mg, 2 mg, 4 mg
412	trandolapril/verapamil*	Tarka	1/240 mg, 2/180 mg, 2/240 mg, 4/240 mg
114	triamterene	Dyrenium	50 mg, 100 mg
108	triamterene/hydrochlorothiazide*	Dyazide, Maxide	37.5/25 mg, 50/25 mg, 75/50 mg
607	valsartan	Diovan	40 mg, 80 mg, 160 mg, 320 mg
614	valsartan-hydrochlorothiazide	Diovan-HCT	80/12.5 mg, 160/12.5 mg, 160/25 mg, 320/12.5 mg, 320/25 mg
408	verapamil	Calan, Isoptin, Verelan, Coer, Covera HS	40 mg, 80 mg, 100 mg 120 mg, 200 mg, 180 mg, 240 mg, 300 mg, 360 mg
5001	warfarin	Coumadin, Jantoven	1mg, 2mg, 2.5mg, 3mg, 4mg, 5mg, 6mg, 7.5mg, 10mg
6302	zafirlukast	Accolate	10 mg, 20 mg
6303	zileuton	Zyflor CR, Zyflo	600 mg, 1.2 g

Drug Codes for Antihypertensive Agents

Diuretics – *Class Code = 100*

Code	Generic Name	Brand Names	Strengths Available
101	amiloride	Midamor	5 mg
102	amiloride/hydrochlorothiazide*	Moduretic	5/50 mg
103	bumetanide	Bumex	0.5 mg, 1 mg, 2 mg
104	chlorothiazide	Diuril	250 mg, 500 mg
105	chlorthalidone	Hygroton and others	25 mg, 50 mg, 100 mg
106	furosemide	Lasix	20 mg, 40 mg, 80 mg
107	hydrochlorothiazide	Hydrodiuril & others	12.5 mg, 25 mg, 50 mg
108	triamterene/hydrochlorothiazide*	Dyazide, Maxide	37.5/25 mg, 50/25 mg, 75/50 mg
109	indapamide	Lozol	1.25 mg, 2.5 mg
110	metolazone	Mykrox, Zaroxolyn	2.5 mg, 5 mg, 10 mg
111	polythiazide	Renese	1 mg, 2 mg, 5 mg
112	spironolactone/hydrochlorthiazide*	Aldactazide	25/25 mg, 50/50 mg
113	torsemide	Demadex	5 mg, 10 mg, 20 mg, 100 mg
114	triamterene	Dyrenium	50 mg, 100 mg
115	Ethacrynic acid	Edecrin	25 g

* list specific strength of each ingredient

Beta Blockers – *Class Code = 200*

Code	Generic Name	Brand Names	Strengths Available
201	acebutolol	Sectral	200 mg, 400 mg
202	atenolol	Tenormin	25 mg, 50 mg, 100 mg
203	betaxolol	Kerlone	10 mg, 20 mg
204	bisoprolol	Zebeta	5 mg, 10 mg
205	metoprolol tartrate	Lopressor	25 mg, 50 mg, 100 mg
206	metoprolol succinate (extended release)	Toprol XL	25 mg, 50 mg, 100 mg, 200 mg
207	nadolol	Corgard	20 mg, 40 mg, 80 mg, 120 mg, 160 mg
208	penbutolol	Levatol	20 mg
209	pindolol	Visken	5 mg, 10 mg
210	propranolol	Inderal	10 mg, 20 mg, 40 mg, 60 mg, 80 mg
211	propranolol long-acting	Inderal LA	60 mg, 80 mg, 120 mg, 160 mg
212	timolol	Blocadren	5 mg, 10 mg, 20 mg
213	atenolol-chlorthalidone	Tenoretic	50/25 mg, 100/25 mg
214	bisoprolol-hydrochlorothiazide*	Ziac	2.5/6.25 mg, 5/6.25 mg, 10/6.25 mg
215	metoprolol-hydrochlorothiazide*	Lopressor HCT	50/25 mg, 100/25 mg, 100/50 mg

Beta Blockers – *Class Code = 200* (cont)

Code	Generic Name	Brand Names	Strengths Available
216	nadolol-bendroflumethiazide*	Corzide	40/5 mg, 80/5 mg
217	propranolol LA-hydrochlorothiazide*	Inderide LA	40/25 mg, 80/25 mg
218	timolol-hydrochlorothiazide*	Timolide	10/25 mg
219	Nebivolol	Bystolic	2.5 mg, 5 mg, 10 mg, 20 mg

* list specific strength of each ingredient

Alpha/Beta Blockers *Class Code = 200*

Code	Generic Name	Brand Names	Strengths Available
220	carvedilol	Coreg	3.125 mg, 6.25 mg, 12.5 mg, 25 mg
221	labetalol	Normodyne, Trandate	100 mg, 200 mg, 300 mg
222	carvedilol extended release	Coreg CR	10 mg, 20 mg, 40 mg, 80 mg

ACE Inhibitors – *Class Code = 300*

Code	Generic Name	Brand Names	Strengths Available
301	benazepril	Lotensin	5 mg, 10 mg, 20 mg, 40 mg
302	captopril	Capoten	12.5 mg, 25 mg, 50 mg, 100 mg
303	enalapril	Vasotec	2.5 mg, 5 mg, 10 mg, 20 mg
304	fosinopril	Monopril	10 mg, 20 mg, 40 mg
305	lisinopril	Zestril, Prinivil	2.5 mg, 5 mg, 10 mg, 20 mg, 30 mg, 40 mg
306	moexipril	Univasc	7.5 mg, 15 mg
307	perindopril	Aceon	2 mg, 4 mg, 8 mg
308	quinapril	Accupril	5 mg, 10 mg, 20 mg, 40 mg
309	ramipril	Altace	1.25 mg, 2.5 mg, 5 mg, 10 mg
310	trandolapril	Mavik	1 mg, 2 mg, 4 mg
311	benazepril-hydrochlorothiazide*	Lotensin HCT	5/6.25 mg, 10/12.5 mg, 20/12.5 mg, 20/25 mg
312	captopril-hydrochlorothiazide*	Capozide	25/15 mg, 25/25 mg, 50/15 mg, 50/25 mg
313	enalapril-hydrochlorothiazide*	Vaseretic	5/12.5 mg, 10/25 mg
314	fosinopril-hydrochlorothiazide*	Monopril-HCT	10/12.5 mg, 20/12.5 mg
315	lisinopril-hydrochlorothiazide*	Prinzide, Zestoretic	10/12.5 mg, 20/12.5 mg, 20/25 mg
316	moexipril-hydrochlorothiazide*	Uniretic	7.5/12.5 mg, 15/12.5 mg, 15/25 mg
317	quinapril-hydrochlorothiazide*	Accuretic	10/12.5 mg, 20/12.5 mg, 20/25 mg

* list specific strength of each ingredient

Calcium Channel Blockers – *Class Code = 400*

Code	Generic Name	Brand Names	Available Strengths
401	amlodipine	Norvasc	2.5 mg, 5 mg, 10 mg
402	diltiazem	Cardizem, Dilacor, Tiazac	30 mg, 60 mg, 90 mg, 120 mg, 180 mg, 240 mg, 300 mg, 360 mg, 420 mg
403	felodipine	Plendil	2.5 mg, 5 mg, 10 mg
404	isradipine	DynaCirc	2.5 mg, 5 mg, 10 mg
405	nicardipine	Cardene	20 mg, 30 mg, 45 mg, 60 mg
406	nifedipine	Adalat, Procardia	10 mg, 20 mg, 30 mg, 60 mg, 90 mg
407	nisoldipine	Sular	8.5 mg, 10 mg, 17 mg, 20 mg, 25.5 mg, 30 mg, 34 mg, 40 mg
408	verapamil	Calan, Isoptin, Verelan, Coer, Covera HS	40 mg, 80 mg, 100 mg 120 mg, 200 mg, 180 mg, 240 mg, 300 mg, 360 mg

ACE Inhibitor/Calcium Channel Blocker Combinations *Class Code = 300, 400*

Code	Generic Name	Brand Names	Available Strengths
410	amlodipine/benazepril*	Lotrel	2.5/10 mg, 5/10 mg, 5/20 mg, 5/40 mg, 10/20 mg, 10/40 mg
411	enalapril/felodipine *	Lexxel	5/2.5 mg, 5/5 mg
412	trandolapril/verapamil*	Tarka	1/240 mg, 2/180 mg, 2/240 mg, 4/240 mg

* list specific strength of each ingredient

Calcium Channel Blocker;Angiotensin II Receptor Blocker Combination
Class Code = 400, 600

Code	Generic Name	Brand Names	Available Strengths
420	amlodipine/valsartan*	Exforge	5/160 mg, 10/160 mg, 5/320 mg, 10/320 mg
421	amlodipine/valsartan/hydrochlorothiazide	Exforge HCT	5/160/12.5 mg, 10/160/12.5 mg, 5/160/25 mg, 10/160/25 mg, 10/320/25 mg
422	amlodipine/olmesartan	AZOR	5/20 mg, 5/40 mg, 10/20 mg, 10/40 mg

* list specific strength of each ingredient

Alpha blockers – *Class Code = 500*

Code	Generic Name	Brand Names	Available Strengths
501	doxazosin	Cardura	1 mg, 2 mg, 4 mg, 8 mg
502	prazosin	Minipress	1 mg, 2 mg, 5 mg
503	terazosin	Hytrin	1 mg, 2 mg, 5 mg, 10 mg
504	prazosin/polythiazide	Minizide	1/0.5 mg, 2/0.5 mg, 5/0.5 mg

Angiotensin II receptor antagonists (ARB) – *Class Code = 600*

Code	Generic Name	Brand Names	Available Strengths
601	candesartan	Atacand	4 mg, 8 mg, 16 mg, 32 mg
602	eprosartan	Teveten	400 mg, 600 mg
603	irbesartan	Avapro	75 mg, 150 mg, 300 mg
604	losartan	Cozaar	25 mg, 50 mg, 100 mg
605	olmesartan	Benicar	5 mg, 20 mg, 40 mg
606	telmisartan	Micardis	20 mg, 40 mg, 80 mg
607	valsartan	Diovan	40 mg, 80 mg, 160 mg, 320 mg
608	candesartan-hydrochlorothiazide	Atacand HCT	16/12.5 mg, 32/12.5 mg, 32/25 mg
609	eprosartan-hydrochlorothiazide	Teveten-HCT	600/12.5 mg, 600/25 mg
610	irbesartan-hydrochlorothiazide	Avalide	150/12.5 mg, 300/12.5 mg, 300/25 mg
611	losartan-hydrochlorothiazide	Hyzaar	50/12.5 mg, 100/12.5 mg, 100/25 mg
612	olmesartan medoxomil-hydrochlorothiazide	Benicar HCT	20/12.5 mg, 40/12.5 mg, 40/25 mg
613	telmisartan-hydrochlorothiazide	Micardis-HCT	40/12.5 mg, 80/12.5 mg, 80/25 mg
614	valsartan-hydrochlorothiazide	Diovan-HCT	80/12.5 mg, 160/12.5 mg, 160/25 mg, 320/12.5 mg, 320/25 mg
615	Azilsartan Medoxomil	Edarbi	40 mg, 80 mg

* list specific strength of each ingredient

Centrally Acting Alpha 2 blockers – *Class Code = 700*

Code	Generic Name	Brand Names	Strengths Available
701	clonidine	Catapres	0.1 mg, 0.2 mg, 0.3 mg
702	clonidine topical patch	Catapres TTS	0.1 mg, 0.2 mg, 0.3 mg
703	guanabenz	Wytensin	4 mg, 8 mg
704	guanfacine	Tenex	1 mg, 2 mg
705	methyldopa	Aldomet	250 mg, 500 mg
706	methyldopa-hydrochlorothiazide	Aldoril	250/15 mg, 250/25 mg
707	clonidine-chlorthalidone	Clorpres	0.1/15 mg, 0.2/15 mg, 0.3/15 mg

* list specific strength of each ingredient

Peripheral Adrenergic Blocking Agents – *Class Code = 800*

Code	Generic Name	Brand Names	Strengths Available
801	reserpine		0.1 mg, 0.25 mg
802	reserpine-chlorthalidone	Demi-Regroton	
803	reserpine-chlorothiazide	Diupres	
804	reserpine-hydrochlorothiazide	Hydropres	0.125/25 mg, 0.125/50 mg
805	Ser Ap Es		

Vasodilators – *Class Code = 900*

Code	Generic Name	Brand Names	Strengths Available
901	hydralazine	Apresoline	10 mg, 25 mg, 50 mg, 100 mg
902	isosorbide dinitrate	Isordil	2.5 mg, 5 mg, 10 mg, 20 mg, 30 mg, 40 mg
903	isosorbide mononitrate	Imdur	10 mg, 20 mg, 30 mg, 60 mg, 120 mg
904	minoxidil	Loniten	2.5 mg, 10 mg
905	hydralazine-hydrochlorothiazide		25/25 mg, 50/50 mg, 100/50 mg
906	isosorbide dinitrate-hydralazine	BiDil	20/37.5 mg

* list specific strength of each ingredient

Aldosterone Receptor Blockers – *Class Code = 1000*

Code	Generic Name	Brand Names	Strengths Available
1001	eplerenone	Inspra	25 mg, 50 mg
1002	spironolactone	Aldactone	25 mg, 50 mg, 100 mg

* list specific strength of each ingredient

Direct Renin Inhibitor – *Class Code = 1100*

Code	Generic Name	Brand Names	Strengths Available
1101	aliskiren	Tekturna	150 mg, 300 mg
1102	aliskiren-hydrochlorothiazide	Tekturna HCT	150/12.5 mg, 150/25 mg, 300/12.5 mg, 300/25 mg
1103	aliskiren-valsartan	Valturna	150/160 mg, 300/320 mg

ICARE STUDY
Drug Codes for Hyperglycemic Agents

Insulins– *Class Code = 2000*

Code	Generic Name	Brand Names	Strengths Available
2001	Aspart	Novolog	100U/ml
2002	Aspart Protamine	Novolog Mix	70/30 – 100U/ml
2003	Detemir	Levemir	100U/ml
2004	Glargine	Lantus	100U/ml
2005	Glulisine	Apidra	100U/ml
2006	Lispro	Humalog	100U/ml
2007	Lispro Protamine	Humalog Mix	50/50, 75/25
2008	Isophane	Humulin N, Novolin N	100U/ml
2009	Regular	Humulin R, Novolin R	100U/ml, 500U/ml
2010	Regular:Isophane	NPH	Novolin 70/30, Humuilin 50/50, Humulin 70/30

Alpha-glucosidase inhibitors– *Class Code = 2100*

Code	Generic Name	Brand Names	Strengths Available
2101	Acarbose	Precose	25mg. 50mg, 100mg
2102	Miglitol	Glyset	25mg, 50mg, 100mg

Amylin analogues– *Class Code = 2200*

Code	Generic Name	Brand Names	Strengths Available
2201	Pramlintide	Symlin	60 and 120

Biguanides– *Class Code = 2300*

Code	Generic Name	Brand Names	Strengths Available
2301	Metformin	Glucophage, Fortamet, Appformin, Glumetza	500mg, 750mg, 850mg, 1000mg

Dipeptidyl peptidase 4 inhibitor – *Class Code = 2400*

Code	Generic Name	Brand Names	Strengths Available
2401	Sitagliptin	Januvia	25mg, 50mg, 100mg
2402	Sitagliptin/simvastatin (OFF-MARKET)	Juvasync	100-10mg, 100-20mg, 100-40mg
2403	Saxagliptin	Onglyza	2.5mg, 5mg
2404	Linagliptin	Tradjenta	5mg

Biguanide/dipeptidyl peptidase 4 inibitor– *Class Code = 2500*

Code	Generic Name	Brand Names	Strengths Available
2501	Sitagliptin/metformin	Janumet	50/500mg, 50/1000mg 100/1000mg
2502	Sitagliptin/metformin XR	Janumet XR	50/500mg, 50/1000mg 100/1000mg
2503	Linagliptin-metformin	Jentadueto	2.5/500mg, 2.5/850mg, 2.5/1000mg
2504	Sexagliptin/metformin XR	Kombiglyze	2.5/1000mg 5/500mg, 5/1000mg

meglitinides– *Class Code = 2600*

Code	Generic Name	Brand Names	Strengths Available
2601	Nateglinide	Starlix	60mg, 120mg
2602	Repaglinide	Prandin	0.5mg, 1mg, 2mg

Biguanide/meglitinide– *Class Code = 2700*

Code	Generic Name	Brand Names	Strengths Available
2701	Metformin/repaglinide	Prandimet	500/1mg, 500/2mg

Thiazoladinediones– *Class Code = 2800*

Code	Generic Name	Brand Names	Strengths Available
2801	Pioglitazone	Actos	15mg, 30mg, 45mg
2802	Rosiglitazone	Avandia	2mg, 4mg, 8mg

Biguanide/Thiazoladinediones– *Class Code = 2900*

Code	Generic Name	Brand Names	Strengths Available
2901	Pioglitazone/metformin	ActoPlus	15/500mg, 15/850mg 15/1000mg, 30/1000mg,
2902	Rosiglitazone/metformin	Avandamet	2/500mg, 2/1000mg, 4/500mg, 4/1000mg

Incretin Mimetics– *Class Code = 3000*

Code	Generic Name	Brand Names	Strengths Available
3001	Exanatide	Byetta	5mcg, 10mcg
3002	Liraglutide	Victoza	18mg/3ml

Sulfonylureas– *Class Code = 3100*

Code	Generic Name	Brand Names	Strengths Available
3101	Chlorpropamide	Diabinese	100mg, 250mg
3102	Glimeperide	Amaryl	1mg, 2mg, 4mg
3103	Glipizide	Glucotrol	5mg, 10mg
3104	Glipizide XR	Glucotrol XR	2.5mg, 5mg, 10mg
3105	Glyburide	Diabeta, Micronase	1.25mg, 2.5mg, 5mg
3106	Glyburide – micronized	Glynase	1.5mg, 3mg, 6mg
3107	Tolazamide	Tolinase	250mg, 500mg
3108	Tolbutaminde	Orinase	500mg

Sulfonylurea/biguanide– *Class Code = 3200*

Code	Generic Name	Brand Names	Strengths Available
3201	Glipizide/metformin	Metaglip	2.5/250mg, 2.5/500mg, 5/500mg
3202	Glyburide/metformin	Glucovance	1.25/250mg, 2.5/500mg, 5/500mg

Sulfonylureas/thiazoladinediones – *Class Code = 3300*

Code	Generic Name	Brand Names	Strengths Available
3301	Glimepiride/pioglitazone	Duetact	2/30mg, 4/30mg
3302	Glimepiride/rosiglitazone	Avandaryl	1/4mg, 2/4mg, 4/4mg,2/8mg, 4/8mg

Sodium-glucose co-transporter 2 (SGLT2) – *Class Code = 3400*

Code	Generic Name	Brand Names	Strengths Available
3401	Canagliflozin	Invokana	100mg, 300mg
3402	Dapagliflozin	Farxiga	5mg, 10mg

ICARE STUDY

Drug Codes for Cholesterol Agents

HMG – CoA Reductase inhibitors "statins"– *Class Code = 4000*

Code	Generic Name	Brand Names	Strengths Available
4001	Atorvastatin	Lipitor	10mg, 20mg, 40mg, 80mg
4002	Rosuvastatin	Crestor	5mg, 10mg, 20mg, 40mg
4003	Fluvastatin, Fluvastatin XL	Lescol, Lescol XL	20mg, 40mg, 80mg
4004	Lovastatin, Lovastatin XR	Mevacor, Altoprev	10mg, 20mg, 40mg, 60mg
4005	Pravastatin	Pravachol	10mg, 20mg, 40mg, 80mg
4006	Simvastatin	Zocor	10mg, 20mg, 40mg, 80mg
4007	Pitavastatin	Livalo	1mg, 2mg, 4mg

HMG – CoA Reductase Inh (statin)/Niacin combination– *Class Code = 4100*

Code	Generic Name	Brand Names	Strengths Available
4101	Lovastatin/Niacin	Advicor	20/500mg, 20/750mg, 20/1000mg, 40/1000mg
4102	Simvastatin/Niacin	Simcor	20/500mg, 40/500mg, 20/750mg, 20/1000mg, 40/1000mg

HMG–CoA Reductase Inh (statin)/Cholesterol Absorption Inh combination – *Class Code = 4200*

Code	Generic Name	Brand Names	Strengths Available
4201	Simvastatin/exetimibe	Vytorin	10/10mg, 20/10mg, 40/10mg, 80/10mg

HMG–CoA Reductase Inh (statin)/Calcium Channel Blocker combination – *Class Code = 4300*

Code	Generic Name	Brand Names	Strengths Available
4301	Atorvastatin/amlodipine	Caduet	10/2.5mg, 20/2.5mg, 40/2.5mg, 10/5mg, 20/5mg, 40/5mg, 80/5mg, 10/10mg, 20/10mg, 40/10mg, 80/10mg

HMG–CoA Reductase Inh (statin)/Dipeptidyl Peptidase-4 Inh combination – *Class Code = 4400*

Code	Generic Name	Brand Names	Strengths Available
4401	Simvastatin/Sitagliptan	Juvisync	10/100mg, 20/100mg, 40/100mg

Niacin (Rx) – *Class Code = 4500*
*Many over –the-counter products available. Only document prescribed products

Code	Generic Name	Brand Names	Strengths Available
4501	Niacin	Niaspan	500mg, 750mg, 1000mg

Cholesterol Absorption Inh combination – *Class Code = 4600*

Code	Generic Name	Brand Names	Strengths Available
4601	Exetimibe	Zetia	10mg

Omega - 3 Fatty acids – *Class Code = 4700*

*Many over –the-counter products available. Only document prescribed products

Code	Generic Name	Brand Names	Strengths Available
4701	Omega – 3 fatty Acids	Lovaza	1 gr

Bile Acid Sequestrants – *Class Code = 4800*

Code	Generic Name	Brand Names	Strengths Available
4801	Cholestyramine,	Questran,	4 gr
4802	Cholesteramine light	Questran Light, Prevalite	4 gr
4803	Colestipol	Colestid	1 gr tab, 5 gr granules
4804	Colesevelam	WelChol	625mg tab, 3.75g powder

Fibric Acids – *Class Code = 4900*

Code	Generic Name	Brand Names	Strengths Available
4901	Gemfibrozil	Lopid	600mg
4902	Fenofibrate	Lipofen, Lofibra, Tricor, Triglide	40mg, 48mg, 50mg, 54mg, 120mg, 145mg, 160mg
4903	Fenofibrate - Micronized	Lofibra, Antara	43mg, 67mg, 130mg, 134mg, 200mg

ICARE STUDY

Drug Codes for Antiplatelet and Anticoagulant Agents

Anticoagulants – *Class Code = 5000*

Code	Generic Name	Brand Names	Strengths Available
5001	Warfarin	Coumadin, Jantoven	1mg, 2mg, 2.5mg, 3mg, 4mg, 5mg, 6mg, 7.5mg, 10mg
5002	Enoxaparin	Lovenox	30mg, 40mg, 60mg, 80mg, 100mg, 120mg, 150mg, 300mg
5003	Daltaperin	Fragmin	2500U, 5000U, 7500U, 10,000U, 12,500U, 15,000U, 18,000U, 25,000U

Adenosine diphosphate inhibitor (thienopyridine) – *Class Code = 5100*

Code	Generic Name	Brand Names	Strengths Available
5101	Clopidogrel	Plavix	75mg, 300mg
5102	Ticagrelor	Brilinta	90mg
5103	Prasugrel	Effient	5mg, 10mg
5104	Ticlopidine	Ticlid	250mg

Factor Xa inhibitors – *Class Code = 5200*

Code	Generic Name	Brand Names	Strengths Available
5201	Rivaroxaban	Xarelto	10mg, 15mg, 20mg
5202	Apixaban	Eliquis	2.5mg, 5mg

Direct Thrombin inhibitors – *Class Code = 5300*

Code	Generic Name	Brand Names	Strengths Available
5301	Dabigatran	Pradaxa	75mg, 150mg

Salicylates – *Class Code = 5400*

Code	Generic Name	Brand Names	Strengths Available
5401	Aspirin	Ecotrin, Bufferin, Aspergum	81mg, 227mg, 325mg, 500mg, 650mg

Drug Codes for Asthma

Inhaled Corticosteroids – *Class Code = 6100*

Code	Generic Name	Brand Names	Strengths Available
6101	Beclomethasone	Beclovent, QVAR	42 mcg, 40 mcg, 80 mcg
6102	Budesonide	Pulmicort Flexhaler	90 mcg, 180 mcg
6103	Ciclesonide	Alvesco	80 mcg, 160 mcg
6104	Flunisolide	Aerobid	.25 mg
6105	Fluticasone Propionate	Flovent Diskus, Flovent, Flovent HFA	50 mcg, 100 mcg, 250 mcg, 44 mcg, 110 mcg, 220 mcg
6106	Mometasone	Asmanex Twisthaler/ Twist	220 mcg, 110 mcg

Long-Acting Beta-Agonists – *Class Code = 6200*

Code	Generic Name	Brand Names	Strengths Available
6201	Arformoterol Tartrate	Brovana	15 mcg
6202	Formoterol Fumarate	Foradil Aerolizer Inhaler	12 mcg
6203	Indacaterol Maleate	Arcapta Neohaler	75 mcg
6204	Salmeterol Xinafoate	Serevent Diskus	50 mcg

Leukotriene Modifiers -- *Class Code = 6300*

Code	Generic Name	Brand Names	Strengths Available
6301	Montelukast	Singulair	4 mg, 5 mg, 10 mg
6302	Zafirlukast	Accolate	10 mg, 20 mg
6303	Zileuton	Zyflor CR, Zyflo	600 mg, 1.2 g

Theophyllines (SR) – *Class Code = 6400*

Code	Generic Name	Brand Names	Strengths Available
6401	Theophylline (12 hr)	Theo-Dur, TheoCap	100 mg, 200 mg, 300 mg, 450 mg
6402	Theophylline (24 hr)	Theo-Time, Theo-24, Uniphyl, Theochron, Quibron-T	100 mg, 200 mg, 300 mg, 400 mg, 600 mg

Combinations- Inhaled Corticoidsteroid and LABA – *Class Code = 6500*

Code	Generic Name	Brand Names	Available Strengths
6501	Fluticasone/ Salmeterol	Advair Diskus, Advair HFA	100mcg-50 mcg, 250 mcg-50 mcg, 500 mcg-50 mcg, 45 mcg-21 mcg, 115 mcg-21 mcg, 230 mcg-21 mcg
6502	Fluticasone/ Vilanterol	BREO ELLIPTA	100 mcg-25 mcg
6503	Mometasone/ Formoterol	Dulera	100 mcg-5 mcg, 200 mcg-5 mcg
6504	Budesonide/ Formoterol	Symbicort	80 mcg-4.5 mcg, 160 mcg-4.5 mcg