

ENHANCED **C**ONTINUITY **O**F PHARMACY **C**CARE
for CARDIOVASCULAR and PULMONARY DISEASES

**RESEARCH ASSISTANT
OPERATIONS MANUAL**

NIH: Ro1 HLo82711
Barry Carter, PI
The University of Iowa

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I. Introduction

The purpose of this document is to outline the duties of the Research Assistant for the NIH-funded research study “Enhanced Continuity of Pharmacy Care for Cardiovascular or Pulmonary Diseases” (R01 HL082711) conducted at the University of Iowa.

The responsibilities of the Research Assistant are described in detail in this manual. Detailed descriptions of the responsibilities of the Research Nurse, Pharmacy Case Managers and Project Manager can be found in their respective operations manuals.

II. Overview of Study Protocol

1. Each day, the Research Nurse will screen the IPR system for patients admitted to the hospital.
2. The Research Nurse will visit patients that seem to meet study enrollment criteria, explain the study and try to get informed consent.
3. The Research Nurse will notify the Project Manager of all new patients that sign consent.
4. The Research Nurse will collect demographic information from the patient and go through all the baseline forms with the patient.
5. The Project Manager will randomize the patient to the usual care, minimal intervention or enhanced intervention group.
6. The Project Manager will inform the Pharmacy Case Manager of each patient that is randomized to either of the two intervention groups. A flowsheet of the pharmacist intervention is shown in Figure 1.
7. For all intervention patients, the Pharmacy Case Manager will:
 - a. Review the admission medication history taken by the unit pharmacist and call the patient’s community pharmacy to verify the medication list is correct.
 - b. Conduct a brief introductory visit with the patient within 24 hours of their enrollment into the study. Resolve any discrepancies discovered when verifying admission medications with the community pharmacy.
 - c. Visit the patient at least every two days while s/he is in the hospital. During these visits the Pharmacy Case Manager will address any concerns the patient might have and begin teaching the patient about their probable discharge medications. Do special counseling at multiple visits if possible.
 - d. Track the patient throughout their hospital stay to monitor for medication problems and to determine the timing of discharge.
 - e. Regularly contact the medical service in charge of the patient’s care and the unit pharmacist in order to determine timing of discharge, identify a

potential discharge care plan and resolve any medication issues that the Pharmacy Case Manager discovered.

- f. Complete discharge teaching, give patient discharge medication list and wallet card.
 - g. Notify the project manager of the patient's discharge. The project manager will notify the Pharmacy Case Manager that the patient is in the minimal intervention group.
8. Patients in the minimal intervention group will not have additional follow-up by the Pharmacy Case Manager.
9. For patients in the enhanced intervention group the Pharmacy Case Manager will:
 - a. Create and fax a discharge summary/care plan to the community physician and community pharmacist.
 - b. Call the patient for follow-up 3-5 days after discharge and send a summary of the 3-5 day follow-up phone call via fax or email to the inpatient medical team, community physician, and community pharmacist.
 - c. Continue making follow-up phone calls with the patient at least weekly until all identified problems are resolved and continue contacting the community physician and community pharmacist as needed.
10. The Research Assistant will fax a Pharmacy Structure Survey to every unique primary pharmacy used by patients enrolled in the study.
11. The Research Assistant will notify each patient's community physician and community pharmacy of the patient's enrollment.
12. The Research Nurse will call all patients 30 days after discharge and again 90 days after discharge to collect survey information.
13. The Research Assistant will contact the community physician and community pharmacy by fax at least 90 days after each patient is discharged or after the Research has completed the 90 day phone call, whichever is LATER. The Research Assistant will fax the following items to the patient's community physician and community pharmacy and request that responses be faxed back to the research office.
 - a. A request for medical record or pharmacy record data on the patient for the 90 day period following hospital discharge
 - b. A survey regarding communication between the community physician and the community pharmacy (usual care and minimal intervention patients only)
 - c. A survey regarding communication between the community physician and the community pharmacy AND communication with the Pharmacy Case Manager (enhanced intervention patients only)

III. Communication Procedures among Team Members

- Key members of the research team (the Project Manager, Research Nurse, Pharmacist Case Managers and Research Assistant) will each be provided with a cellular telephone. Communication among team members should primarily be conducted via cell phone or in-person.
- Team members should not send email containing protected health information or patient names.
- The Project Manager will notify the Research Nurse and the Pharmacist Case Manager (for intervention patients only) when a patient is enrolled in the study.
- The two pharmacist case managers should communicate via phone daily for patient updates.

- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] [REDACTED]

IV. Documentation Procedures

The Project Manager, Research Nurse and Pharmacy Case Managers will each be provided with a Tablet personal computer. Each computer will undergo security review by UIHC Department of Pharmacy Staff. College of Pharmacy IT staff will provide a link to the database on each tablet computer.

The study's Access database will be stored on the College of Pharmacy's shared drive, with access to the database files controlled by College of Pharmacy IT department. The database will be composed of major tabs for the Project Manager, Research Nurse, and Pharmacy Case Managers. Each major tab overlays multiple sub-tabs for individual data collection forms.

The Project Manager, Research Nurse and Pharmacy Case Managers will each have access to both the study database and to wireless services at UIHC. Using wireless services, these team members will enter data directly into the study database via their tablet computers.

Certain pages of the database will not be accessible to all team members in order to maintain the blindness of patient randomization:

- The Research Nurse will be restricted from viewing all of the Pharmacy Case Manager tabs.
- Both the Research Nurse and both Pharmacy Case Managers will be restricted from viewing the Randomization page under the Project Manager tab.

The Research Nurse will return the signed patient consent forms and release of information forms to the Research Assistant. The Research Assistant will create a folder for the patient bearing the patient's name and store folders alphabetically by last name in a locked file cabinet.

Data collected via fax from the community physician and community pharmacy surveys will be double-entered into the database by the Research Assistant and by a student in the research office.

The Research Assistant will collect medical and pharmacy record information from community providers and compile an abstract for each patient after the patient has completed the study. The Research Assistant will scan the abstract into the computer. The Research Assistant, in consultation with the Project Manager, will distribute each abstract to one of the study's Evaluators.

Evaluators will complete a hard copy form and return it to the Project Manager. Data will be double-entered into the database by the Research Assistant and by a student in the research office.

Team members should not include any patient identifiers in e-mail correspondence or in e-mail attachments. Instead, the phone or the shared database should be used when communicating about patients.

V. Pharmacy Structure Survey

The Research Assistant will fax the following items to each unique pharmacy used by a study patient:

- A fax cover sheet listing the items included in the fax
- The IRB-approved and stamped cover letter to the pharmacist
- The Pharmacy Structure Survey

Each primary pharmacy will only be sent the survey when the first patient that uses that pharmacy is enrolled in the study. The survey will not be re-sent for subsequent study patients who use that pharmacy.

The Research Assistant will obtain the following information from the Excel log of physician and pharmacy IDs, located at [REDACTED]

- The name of the pharmacist-in-charge should be entered onto the fax cover sheet.
- The pharmacy study ID should be entered into the header of each page of the survey.

Pharmacies will be asked to return the completed survey via fax to the Research Assistant (319-). The Research Assistant will re-fax the survey and cover letter to each pharmacy that does not return the Pharmacy Structure Survey within two weeks. Survey data will be double- entered into the study's database by the Research Assistant and student data entry personnel. The Research Assistant and Project Manager will be able to query the database to determine which surveys have not been returned.

The date that each survey is faxed out should be documented in the Excel log of physician and pharmacy IDs, located at [REDACTED]

The textual content of the cover letter for the Pharmacy Structure Survey follows. The cover letter should be printed in the form approved by the IRB and showing the IRB stamp. The survey itself is located in the Research Assistant's electronic folder.

FAX COVER SHEET

DATE:

Number of pages: 9

TO:

Fax:

FROM:

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Please review and complete the following documents from the Iowa Continuity of Care study:

1. A consent letter asking you to complete a survey about the structure of your pharmacy.
2. The pharmacy structure survey itself.

Completion of the survey indicates your willingness to participate. We would appreciate your completing the survey and **FAXING** it to us as quickly as possible.

Please feel free to contact me if you have any questions.

[REDACTED]
[REDACTED]

FOR THE PHARMACIST-IN-CHARGE

December 4, 2007

Dear Pharmacist:

We are inviting you to participate in a research study. The purpose of the study to test whether enhanced continuity of pharmacy care including increased communication between inpatient and outpatient settings will improve therapy and reduce the number of serious ADEs, hospitalizations and unscheduled office visits in selected patients. This experimental-design study will enroll 1,000 patients hospitalized at the University of Iowa Hospitals & Clinics over a 4-year period and follow each patient for 90 days after discharge.

We are inviting you to participate in this study since we have enrolled a patient who is served by your pharmacy. Below are the study procedures and what you will be asked to do.

1. We would like you to complete a Pharmacy Structure Survey that tells us about the structure and service in the pharmacy where you work. You will complete ONE of these surveys during the study.
2. If the patient is in the control group, you will not be asked to do anything different. You will receive the usual discharge summary information from the treating physician in the hospital.
3. If a patient is in the minimal intervention group, you will receive a call from the study pharmacist to confirm the patient's medication list at hospitalization. You will also receive the usual discharge summary information.
4. If a patient is in the enhanced intervention group, you will receive a call from the study pharmacist to confirm the patient's medication list at hospitalization. You will receive the usual discharge summary information. You will also receive a discharge medication summary from the inpatient pharmacist. This summary will include discharge medications, dosages, plans to achieve specific therapeutic goals and plans for when these medications need to be filled or refilled. The summary will also identify any drug-related problems. This summary will also be sent to the patient's community physician. You will be encouraged to attempt to achieve these specified therapeutic goals.
5. For every patient enrolled, we will ask you to complete a brief (1-2 page) questionnaire asking about your level of communication with the patient's community physician and hospital pharmacist. You will receive this questionnaire approximately 90 days after the patient is discharged from UIHC. You or the pharmacy where you work will receive a \$50 compensation for each patient-specific questionnaire that you return.
6. Periodically, a research assistant will visit your pharmacy to obtain relevant patient-specific data from your records, including medication lists and refill histories while in the study. (Each patient will sign informed consent to allow us to obtain this information in compliance with the HIPAA requirements for research).

At this time, if you agree to participate in the study, please complete the Pharmacy Services Survey and return it to us via fax at your earliest convenience. Our fax number appears on the front page of the survey. Returning the completed survey will indicate your willingness to participate in the study. If you do not want to participate, please return the first page of the blank form indicating that to us. You are free to not answer any questions you would prefer not to answer. If we do not hear from you, our research assistant will ask you to complete the questionnaire when he/she comes to your pharmacy.

We will keep the information you provide confidential, however, federal regulatory agencies and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. We will use a code number for you and for your pharmacy and will not refer to you or the pharmacy by name. We will maintain a link to the name of your pharmacy and to your name so that we can compare your responses based on the patient's physician's responses, but that link will be destroyed at the end of the study, and your identity will remain anonymous. If we write a report about this study we will do so in such a way that you and your pharmacy cannot be identified. There are no known risks from being in this study. You will not benefit personally, and there is no compensation for your completing this survey. However, we hope that others may benefit in the future from what we learn as a result of this study.

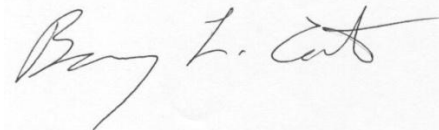
Taking part in this research study is completely voluntary. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

We will do everything possible to minimize any work for you or your staff. Your participation in this study will help us to identify a strategy to improve our communication with care providers following hospitalization, and we believe this will enable you to better care for your patients. If you have any questions, please feel free to contact Dr. Gail Ardery, the study's project manager, at [REDACTED]

Sincerely,



Paul James, M.D.
Professor and Iowa Academy of Family
Physicians Endowed Chair in Rural Medicine



Barry L. Carter, Pharm.D.
Professor

V. Notification of Community Providers

For each patient that is enrolled in the study, the Research Assistant will fax the following items to the patient's community physician and community pharmacist:

1. A fax cover sheet informing the provide about the contents of the fax
 - a. The Research Assistant should either write or type in the provider contact information and the name of the patient.
2. A letter informing each provider about the patient's participation in the study (see sample letters below)
 - a. The Research Assistant will write in the provider name and the name of the patient.
3. A copy of the patient's signed informed consent form and signed release of information form
 - a. The Research Assistant will make two photocopies of the informed consent and release of information forms:
 - i. One copy will be used for faxing and should not be stapled.
 - ii. The second copy should be stapled. Write in the patient's hospital ID number on the top of the front page. At least weekly, carry these forms to the University of Iowa Hospitals Medical Records Department in the west wing of the hospital, 2nd floor.

Copies of these documents are included below.

NOTIFICATION LETTER TO COMMUNITY PHYSICIANS

Date:

RE:

Dear Dr.

Sometimes, delays or problems with communication to the primary care physician about medication changes for hospitalized patients can limit your ability to offer high quality health care. We have begun a program that we believe will improve communication about medications for hospitalized patients at the University of Iowa Health Care system. This research study is designed to enhance your ability to care for your patients through improved information sharing.

Your patient _____ has agreed to participate in a project called the Iowa Continuity of Care study. Your patient has agreed to allow us to obtain and review all of their medical and pharmacy records for 90 days following their discharge from UIHC. Please find attached a signed copy of their informed consent form, which indicates their willingness to participate in the study, and a signed copy of their consent for release of medical records.

You will be compensated \$50 for each of your patients in the study for the additional effort that this study may require. We will do everything possible to minimize any work for you or your staff.

Following are the general procedures for this project:

7. Your patient may end up in either a control group or one of two intervention groups. If the patient is in the control group or the minimal intervention group, you will not be asked to do anything different. You will receive the usual discharge summary information from the treating physician in the hospital.
8. If your patient is in the enhanced intervention group, you will also receive a discharge medication summary from the inpatient pharmacist. This summary will include all discharge medications, dosages, plans to achieve specific therapeutic goals and plans for when these medications need to be filled or refilled. The summary will also identify any drug-related problems that were detected for this patient. This summary will also be sent to the patient's community pharmacist. You will be encouraged to attempt to achieve these specified therapeutic goals.
9. For every patient enrolled, you will receive a brief (1-2 page) questionnaire asking about your level of communication with the patient's community pharmacist. If your patient is in the enhanced intervention group, the questionnaire will also include questions about your communication with the hospital pharmacist. You will receive this questionnaire approximately 90 days after the patient is discharged from UIHC.

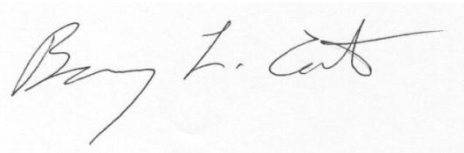
10. At the end of the study, a research assistant will visit your office to obtain the relevant data from your medical record. (Your patient has signed informed consent to allow us to obtain this information in compliance with the HIPAA requirements for research).

Your participation in this study will help us to identify a strategy to improve our communication with primary care physicians and we believe this will enable you to better care for your patients. If you have any questions, please feel free to contact Dr. Gail Arderly, the study's project manager, at [REDACTED]

Sincerely,



Paul James, M.D.
Associate Professor and
Iowa Academy of Family Physicians Endowed Chair in Rural Medicine



Barry L. Carter, Pharm.D.
Professor

NOTIFICATION LETTER TO COMMUNITY PHARMACISTS

Date

RE:

Dear Pharmacist:

Sometimes, delays or problems with communication to community pharmacies about medication changes for hospitalized patients can limit your ability to offer high quality health care. We have begun a program that we believe will improve communication about medications for hospitalized patients at the University of Iowa Health Care system. This research study is designed to enhance your ability to care for your patients through improved information sharing.

Your patient _____ has agreed to participate in a project called the Iowa Continuity of Care study. Your patient has agreed to allow us to obtain and review all of their pharmacy records for 90 days following their discharge from UIHC. Please find attached a signed copy of their informed consent form, which indicates their willingness to participate in the study, and a signed copy of their consent for release of medical records.

You will be compensated \$50 for each of your patients in the study for the additional effort that this study may require. We will do everything possible to minimize any work for you or your staff.

The following are the general procedures for this project:

11. Your patient may end up in either a control group or one of two intervention groups. If the patient is in the control group or the minimal intervention group, you will not be asked to do anything different. You will receive the usual discharge summary information from the treating physician in the hospital.
12. If your patient is in the enhanced intervention group, you will also receive a discharge medication summary from the inpatient pharmacist. This summary will include all discharge medications, dosages, plans to achieve specific therapeutic goals and plans for when these medications need to be filled or refilled. The summary will also identify any drug-related problems that were detected for this patient. This summary will also be sent to the patient's community physician. You will be encouraged to attempt to achieve these specified therapeutic goals.
13. For every patient enrolled, you will receive a brief (1-2 page) questionnaire asking about your level of communication with the patient's community physician. If your patient is in the enhanced intervention group, the questionnaire will also include questions about your communication with the hospital pharmacist. You

will receive this questionnaire approximately 90 days after the patient is discharged from UIHC.

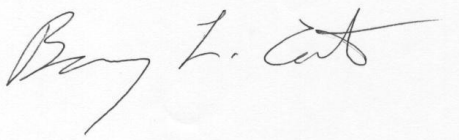
14. At the end of the study, a research assistant will visit your pharmacy to obtain the relevant data from your records. (Your patient has signed informed consent to allow us to obtain this information in compliance with the HIPAA requirements for research).

Your participation in this study will help us to identify a strategy to improve our communication with care providers following hospitalization, and we believe this will enable you to better care for your patients. If you have any questions, please feel free to contact Dr. Paul James at [REDACTED]

Sincerely,



Paul James, M.D.
Associate Professor and
Iowa Academy of Family Physicians
Endowed Chair in Rural Medicine



Barry L. Carter, Pharm.D.
Professor

XI. Faxes after 90 Days

The Project Manager will maintain a running log in the Research Assistant's folder of patients who have completed their 90 days call from the Research Nurse.

The Research Assistant will contact both the community physician and the community pharmacist via fax to include:

- A fax cover letter explaining the items that are included in the fax.
- The IRB-approved consent letter for the provider. Providers for usual care and minimal intervention patients receive one letter, while providers for enhanced intervention patients receive a different letter. Fill in patient and provider names.
- The appropriate survey form for the provider. Again, providers for usual care and minimal intervention patients receive a one-page survey, while providers for enhanced intervention patients receive a two-page survey. Fill in patient and provider study ID numbers. Fill in the date the patient was discharged from the hospital.
- A list of medical records being requested.
 - Fill in the patient name, date of hospital discharge and span of time for which records are being requested. The end date should be either the day that is 90 days after discharge OR the date of the Research Nurse's 90 day phone call, whichever is LATER.
- A reimbursement form

Providers will be asked to return the completed survey, reimbursement form, and medical record or pharmacy record data via fax to 319-_____.

The Research Assistant will electronically submit physician and pharmacist requests for reimbursement (\$50 for each returned questionnaire) within 24 hours of receipt (reimbursement form follows).

Survey data will be double-entered into the study's database by the Research Assistant and student data entry personnel. The Research Assistant and Project Manager will be able to query the database to determine which surveys have not been returned.

FAX COVER SHEET

6/10/09

Number of pages:

TO:

Fax:

FROM:

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

RE:

The above patient has completed participation in a research study at the University of Iowa, and we are now requesting your assistance with the following items:

1. Please provide us with the patient's medical record information that is listed on the following page. I have included copies of the patient's signed consent and release of information forms.
2. Please complete the survey about your communication with the patient's pharmacy. I have included a letter approved by the University of Iowa Institutional Review Board that formally requests your participation.
3. If you would like to receive \$50 for returning the survey, please complete and return the reimbursement form.

Please fax all of the information to me at 319-____-_____.

Do contact me if you have any questions.

Andrew Pretorius, B.S.

FAX COVER SHEET

6/10/09

Number of pages:

TO:

Fax:

FROM:

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

RE:

The above patient has completed participation in a research study at the University of Iowa, and we are now requesting your assistance with the following items:

4. Please provide us with the patient's pharmacy record information that is listed on the following page. I have included copies of the patient's signed consent and release of information forms.
5. Please complete the survey about your communication with the patient's physician. I have included a letter approved by the University of Iowa Institutional Review Board that formally requests your participation.
6. If you would like to receive \$50 for returning the survey, please complete and return the reimbursement form.

Please fax all of the information to me at 319-____-____.

Do contact me if you have any questions.

Andrew Pretorius, B.S.

PLEASE FAX THE FOLLOWING MEDICAL RECORD INFORMATION:

Patient Name:

Time span for data collection:

- Complete medication list with dates prescribed and discontinued (collect multiple lists, if available)
- Vital signs records
- All physician notes
- All nursing notes
- All physician consult notes and notes from specialists
- All hospital discharge summaries
- Laboratory data

Please send patient information via fax to Andrew Pretorius at **319**-____-_____.

For questions, please phone 319-____-_____.

COMMUNITY PHARMACY RECORD DATA TO BE FAXED

Patient Name:

Time span for data collection:

- List of documented allergies, reactions, intolerances or other problems with any medications
- List of all prescribed medications that includes:
 - i. Start date (if available)
 - ii. End date (if available)
 - iii. Dates of all refills
- Any paper chart records for the pertinent time period

Please send patient information via Fax to Gail Ardery at **319**-____-_____.

For questions, please phone 319-____-_____.

Primary Care Physician – Questionnaire

RE: _____

Dear Doctor _____:

We are writing to invite you to participate in a research study. The purpose of the study is to better understand systems that may improve communication between large hospitals and primary care providers.

We are inviting you to be in this study because your patient, _____, was recently hospitalized at the University of Iowa Hospital and Clinics (UIHC). Your patient receives their usual pharmacy services from _____. This patient has enrolled in the **Continuity of Care** study and has signed a release of information for us to obtain a copy of their medical records. We obtained your name and address from your patient.

If you agree to participate in the study, we would like you to complete the attached questionnaire. If we do not hear from you, our research assistant will ask you to complete the questionnaire when he/she comes to your office to collect a copy of the patient's records. If you do not want to participate, please return the blank form to us or let the research assistant know when he/she comes to your office. You are free to not answer any questions you would prefer not to answer.

We will keep the information you provide confidential, however, federal regulatory agencies and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. We will use a code number and not refer to you by name. We will maintain a link to your name so that we can compare your responses based on the patient's pharmacist's responses, but your identity will remain anonymous. If we write a report about this study we will do so in such a way that you cannot be identified.

There are no known risks from being in this study, and you will not benefit personally. However, we hope that others may benefit in the future from what we learn as a result of this study.

Taking part in this research study is completely voluntary. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

Please tear off this cover sheet, complete the attached survey and return it in the enclosed, self addressed, stamped envelope. You or your office staff will receive \$50 for every patient for whom you return a completed survey to the research team and assist with obtaining medical record data. You may receive the \$50 in the form of a check or you may decline it.

If you have any questions about the research study, please feel free to contact Dr. Barry Carter at _____ If you have questions about the rights of research subjects or research related injury, please contact the Human Subjects Office, _____

Thank you for your assistance with this important project. Completing the questionnaire will indicate your willingness to participate in the study.

Sincerely,

Paul A. James, M.D.
Professor and Head
IAFP Endowed Chair in Rural Medicine

Community Pharmacist – Questionnaire

RE: _____

Dear _____:

We are writing to invite you to participate in a research study. The purpose of the study is to better understand systems that may improve communication between large hospitals and primary care providers.

We are inviting you to be in this study because your patient, _____, was recently hospitalized at the University of Iowa Hospital and Clinics (UIHC). This patient has enrolled in the ***Continuity of Care*** study and has signed a release of information for us to obtain copies of their medical records and prescription data from you. This patient's primary doctor is _____. We obtained your name and address from your patient.

If you agree to participate in the study, we would like you to complete the attached questionnaire. If we do not hear from you, our research assistant will ask you to complete the questionnaire when he/she comes to your office to collect a copy of the patient's records. If you do not want to participate, please return the blank form to us or let the research assistant know when he/she comes to your office. You are free to not answer any questions you would prefer not to answer.

We will keep the information you provide confidential, however, federal regulatory agencies and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. We will use a code number and not refer to you by name. We will maintain a link to your name so that we can compare your responses based on the patient's physician's responses, but your identity will remain anonymous. If we write a report about this study we will do so in such a way that you cannot be identified.

There are no known risks from being in this study, and you will not benefit personally. However, we hope that others may benefit in the future from what we learn as a result of this study.

Taking part in this research study is completely voluntary. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

Please tear off this cover sheet, complete the attached survey and return it in the enclosed, self addressed, stamped envelope. You or your office staff will receive \$50 for every patient for whom you return a completed survey to the research team and assist us with obtaining the patient's pharmacy record data. You may receive the \$50 in the form of a check or you may decline it.

If you have any questions about the research study, please feel free to contact Dr. Barry Carter at _____ If you have questions about the rights of research subjects or research related injury, please contact the Human Subjects Office, _____

Thank you for your assistance with this important project. Completing the questionnaire will indicate your willingness to participate in the study.

Sincerely,

Barry L. Carter, Pharm.D.
Professor
College of Pharmacy and
Department of Family Medicine
Roy J. and Lucille A. Carver College of Medicine

Care Provider Reimbursement Form

Provider Name:

Home Address:

City, State, Zip

Social Security No.

_ _ _ / _ _ / _ _ _ _

U.S. Citizen (check one)

Yes

No

If not a U.S. citizen,

Country of citizenship:

Immigration status:

Please fax form with completed survey to:

Andrew Pretorius, Research Assistant

319-___-_____

If you have questions, please call 319-___-_____.

After the Research Assistant has returned the abstract form to the office and the data has been entered into the database, the Project Manager will assign the patient to a Pharmacist Evaluator.