

# Informed Consent

## **INVITATION TO PARTICIPATE**

You are being invited to participate in this research project because you are an adult who has one of the medical problems we are studying. These medical problems are Congestive Heart Failure (CHF), Chronic Obstructive Pulmonary Disease (COPD or Emphysema), and Cancer (Ca).

Research studies include only patients who choose to take part. Please take your time to make a decision about whether you want to participate. Discuss it with your friends and family. Please feel free to ask us to answer any questions you or they may have.

## **WHY IS THIS STUDY BEING DONE?**

PhoenixCare is a three year project. It is an attempt to learn more about how we in health care can assist patients achieve the best quality of life while living with a serious chronic illness. The goal is to help patients learn to better manage the physical, social, and spiritual needs brought on by their illness.

The purpose of this study is to find out how these three diseases (CHF, COPD/ Emphysema, Cancer) affect people over time, and what we can do to help them manage the illnesses better. To do this, we want to understand how the symptoms, treatments and services you have affect your life, and what you do to take care of yourself.

## **HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

About 500 people will take part in this study.

## **WHAT IS INVOLVED IN THIS STUDY?**

Of all the people who agree to participate, about half (250 or 50%) will have visits to their home by a PhoenixCare team member, usually a nurse. If you agree to participate, you will be randomly assigned to get visits, or not to get visits. Like the flip of a coin, you will have an equal chance to be in either of the two groups of patients- those receiving home visits and those not receiving home visits.

### 1. INTERVIEWS

Everyone who agrees to participate will be asked a set of questions surrounding their illness. We will ask you these questions in person the first time. After that, we will call

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you about every three (3) months to ask you the study related questions in a telephone interview.

2. INFORMATION ABOUT HEALTH CARE SERVICES

If you agree to participate, we will ask your Health Plan to give us information about the types of services you use for your illness. This information will be kept confidential.

3. HOME VISITS

Half (50%) of the people who agree to participate in the study will receive visits to their home by a PhoenixCare Team Member. Both the group visited by a PhoenixCare Team Member, and the group not visited by a Team Member, will continue to get all their usual health care services through their own doctor and Health Plan.

If you are in the group visited by a PhoenixCare Team Member

Home visits will be provided to the participants randomly placed in the home visit group. These home visits will be in addition to the care you receive from your doctor and Health Plan. The visits do not cost you or you Health Plan anything. The nurse, and others in the team will teach you about your medications, your disease, how to stay healthier and how to find other services you might want. They will visit you and call you on the phone regularly to check on how you are doing.

**HOW LONG WILL I BE ON THE STUDY?**

The study will start on July 1, 1999 and continue through December 31, 2001. As long as you continue to be eligible, we would hope you would be a participant in the study, up to the whole time.

**WHAT ARE THE RISKS OF THIS STUDY?**

There are minimal risks to you if you participate in the study. All medical care remains under the direction of your personal physician and your health plan. Patients do not "give up" any care to participate in the study. You do give up some of your time to be interviewed. For those who receive visits, PhoenixCare nurses will provide education on symptom and disease management. If you act on information which is misunderstood or inaccurate, however, there is the possibility harm could occur.

**WHAT ARE THE REPRODUCTIVE RISKS OF THE STUDY?**

There are no reproductive risks to this study.

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**ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?**

You may or may not benefit directly from the study. We hope the information we learn from this study will benefit other patients in the future who have a disease like yours. Everyone who participates will have the opportunity to discuss their condition with an interviewer every three months. Half of all who participate will learn more about how to manage their illness from PhoenixCare Team Member home visits.

**WHAT OTHER OPTIONS ARE THERE?**

You may decide now that you do not want to be included in this study, and you can refuse to participate. If you agree to participate in this study, you can change your mind later, and quit from the study. No matter which you decide, you will still have your usual doctor and all the usual benefits of your Health Plan.

**WHAT ABOUT CONFIDENTIALITY?**

All information will be kept strictly confidential.

All the various types of information collected will be put together at the end of the study. It will be used for statistical, informational, and publication purposes in scientific journals or presentations at scientific meetings. The reports will discuss groups of individuals participating in the study, and will not disclose your individual identity. No specific data will be connected with you.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the GSRMC Institutional Review Board, the Robert Wood Johnson Foundation, or other study sponsors.

**WHAT ARE THE COSTS?**

There is no cost to you or your Health Plan.

**IS THERE COMPENSATION FOR PARTICIPATING?**

You will receive no payment for participating in this study.

**WHAT HAPPENS IF I AM INJURED?**

In the case of injury or illness resulting from this study, emergency and ongoing medical treatment will continue to be available through your Health Plan. No funds have been set aside to compensate you in the event of injury. This does not waive your rights in the event of negligence.

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**WHAT ARE MY RIGHTS AS A PARTICIPANT?**

Taking part in this study is voluntary. You may choose not to participate. If you do participate, you may leave the study at any time. Whatever your decide, it will not affect your relations with your doctors, your Health Plan, Arizona Health Care Cost Containment System (AHCCCS) eligibility, or any other medical benefits that you are entitled to.

**CAN I BE REMOVED FROM THE STUDY?**

If you are no longer eligible to participate in the study, you will be removed from the study without your consent.

**WHOM DO YOU CALL IF YOU HAVE QUESTIONS?**

For questions related to the study, contact the primary researcher, Carol Lockhart, Ph.D., at 1510 E. Flower Street, Phoenix, AZ 85014, Phone: (602) 287-7050.

If you have any questions about your rights as a research participant, contact the Good Samaritan Regional Medical Center Institutional Review Board Chairman, Joseph J. Frank, Ph.D. at 602-271-9472, Monday through Friday, from 9AM to 5PM. This study has been approved by the GSRMC IRB.

**WHERE CAN YOU GET MORE INFORMATION?**

You can get more information by calling The PhoenixCare Program at (602) 287-7050. You can write to The PhoenixCare Program at 1510 E. Flower Street, Phoenix, AZ 85014. You can also reach the Program on the Internet at [www.phoenixcare.org](http://www.phoenixcare.org).

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