

## PATIENT INFORMATION SHEET

**Title of Research Study:** The Lung Attack Alert Study(TLAL Study)

**Principal Investigator:** Dr. Mohit Bhutani, MD, FRCPC  
Department of Medicine, University of Alberta

Dr. Brian Rowe, MD, MSc, CCFP(EM)  
Department of Emergency Medicine, University of Alberta

**Background:** You have been seen and treated in the Emergency Department(ED) for a worsening of your lung condition. Your lung condition is called Chronic Obstructive Pulmonary Disease (COPD). This worsening is called an Acute Exacerbation of COPD (AECOPD). Your Emergency Department (ED) doctor has determined that you are safe to be discharged home.

The ED is conducting a study to help improve communication between your family doctor and the ED in patients who have COPD.

Following completion of this study, we hope to improve the outpatient treatment of patients with COPD who have an AECOPD across the region and try to reduce the rate of relapse and improve the long term management by improving communication between the ED and your family doctor.

**Purpose:** To improve the quality of treatment for adult patients (over 40 years of age) with COPD, who are sent home from the emergency department.

**Participating in this study will involve:** If you agree to participate, our study coordinator will take your name and telephone number in order that we can contact you later. You will also be provided with reading materials that are to help you better understand COPD. These are from the Canadian Thoracic Society and the Canadian Lung Association.

At 30 days after your discharge from the ED, our study coordinator will contact you and see how you are recovering. A series of questions will be asked, and the total time for the phone interview will be less than 15 minutes. This will be repeated at 90 days after discharge.

**Possible Benefits:** The possible benefits to you for participating in this study are that we are planning to follow you 2 times over the next 3 months. You will be contacted by phone by someone on the study team on day 30 and 90 after your discharge from ED. This contact will provide you with an opportunity to discuss your COPD with a health

care professional.

**Possible Risks:** Your treatment will not be affected by this study. As far as we know, we do not think there are any risks to you from taking part in this study.

**Confidentiality:** Personal records relating to this study will be kept confidential and locked in a secured area. Only the study investigators and their research staff will access to your records. Any report published as a result of this study will not identify you by name. GlaxoSmithKline (GSK) of Canada is providing financial support for this study; however, they will not have access to study data

**Voluntary Participation:** You are free to withdraw from the study at any time, and your continuing medical care will not be affected in any way. If the study is not undertaken or if it is discontinued at any time, the quality of your medical care will not be affected. Patients who do not enroll in the study will be treated with standard care by the emergency physician. If any knowledge gained from this or any other study becomes available which could influence your decision to continue in the study, you will be promptly informed. There will be no monetary costs to you for participating in this study.

**Compensation for Injury:** If you become ill or injured while participating in this study, necessary medical treatment will be available at no additional cost to you. By agreeing to this follow-up you are not releasing the investigators, institution and/or the supporting drug company from their legal and professional responsibilities.

**Further Information:** If you have concerns about any aspect of this study, you may contact the Patient Concerns Office at (780) 342-8080. They have no affiliation with the study investigators. Please contact any of the individuals identified below if you have any questions or concerns: Dr. Mohit Bhutani at (780) 407-1832 or Dr. Brian Rowe at (780) 407-6707.

### **Patient Consent**

**Title of Research Study:** The Lung Attack Alert Study(TLAL Study)

**Principal Investigators:** Dr. Mohit Bhutani, MD, FRCPC  
Department of Medicine, University of Alberta  
Dr. Brian Rowe, MD, MSC, CCFP(EM)  
Department of Emergency Medicine, University of Alberta

Part 2 (to be completed by the research subject):

Do you understand that you have been asked to be in a research study?      Yes      No

Have you read and received a copy of the attached Information Sheet?      Yes      No

Do you understand the benefits and risks involved in taking part in this research study?      Yes      No

Have you had an opportunity to ask questions and discuss this study?      Yes      No

Do you understand that you are free to refuse to participate or withdraw from the study at any time? You do not have to give a reason and it will not affect your care.      Yes      No

Has the issue of confidentiality been explained to you? Do you understand who will have access to your records?      Yes      No

This study was explained to me by: \_\_\_\_\_

I agree to take part in this study.

\_\_\_\_\_/\_\_\_\_\_/20\_\_\_\_\_  
Signature of Research Participant      Date      Witness

\_\_\_\_\_  
Printed Name      Printed Name

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

\_\_\_\_\_/\_\_\_\_\_/20\_\_\_\_\_  
Signature of Investigator or Designee      Date

**THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT  
FORM AND A COPY GIVEN TO THE RESEARCH SUBJECT.**