ST. LOUIS COLLEGE of PHARMACY

Informed Consent to Participate in a Research Study

Participant's Name: _____

Principal Investigator (PI): Suzanne Bollmeier, PharmD, BCPS, AE-C **PI's Phone Number:** 314-446-8525

Title of Project: COPD Severity and Adherence to GOLD Guidelines in the Community Pharmacy Setting

You may be able to be in a research study. This form gives important information about the study. It describes its purpose(s) and the possible risks and benefits of taking part.

Please read this information carefully. Talk to the pharmacist researcher. Please ask about all words you do not understand. Ask any questions you have. If you decide to participate, you will be asked to sign this form. Before signing, be sure that you understand what the study is about and your possible risks and benefits.

You are invited to be in a study conducted by Dr. Suzanne Bollmeier and others.

1. **Why is this study being done?**
   The purposes of this study are to:
   - Assess the severity of chronic obstructive pulmonary disease (COPD) symptoms of people like yourself
   - Compare the breathing medicine(s) prescribed by doctors with best-practice recommendations
   - Compare how patients take their breathing medicine with how it is prescribed by their doctor

2. **If I choose to be in the research study, what will I be asked to do?**
   You will be asked to:
   - Visit privately with your pharmacist who fills your breathing medications.
     - Complete a short form with questions about your:
       - general and lung health
       - breathing, like shortness of breath or last COPD flare-up
       - tobacco use now and in the past
   - Give your permission for the study team to:
     - Contact your doctor(s) to see your lung tests results. Note: If there are no prior tests, you will NOT have to take any additional tests as part of this study.
     - Review your answers to the study questionnaire.
     - See your pharmacy prescription records for your medications.

3. **How long will I be in the study?**
   We estimate the private study visit with the pharmacist will take no more than 30 minutes.

4. **How many other participants will be in the study?**
   We plan to enroll 875 people with COPD from 35 pharmacies across Missouri.

5. **What are the costs to me?**
   There is no direct cost to be in the study. There may be an extra trip to the pharmacy for your study visit.

6. **What are the possible risks to me if I am in the study?**
   There may be certain risks and discomforts with this research study. For example:
   - *Breach of confidentiality.* There is a very slight chance:
     - Somebody not involved in the study might see your responses.
     - Another customer might overhear you talking with the pharmacist.
   - *Unknown risks.* We cannot predict all risks. The PI will answer any questions you have about these potential risks.

7. **What will be done to minimize my potential risks?**
   We will make every effort:
   - To make sure your talk with the pharmacist is private.
   - That the form is completed in an area away from other customers.

   Your private information will:
   - be kept on a secure computer system.
   - be shared with study team only in a private, secure email system.
   - be destroyed after the study is over.
   - only be shown to those directly involved in the study.
   - not be identifiable in any publications; only group information will be reported.

8. **What will happen if I am disturbed or upset by participating in this study?**
   St. Louis College of Pharmacy study team prevent or limit any possible discomforts from being in this study. Please contact Dr. Suzanne Bollmeier at 314-446-8525 and/or the Chair of the Institutional Review Board (IRB) at St. Louis College of Pharmacy, Dr. Peter Hurd at 314-446-8441 if you are upset by anything related to the study.

9. **Are there benefits to taking part in the study?**
   - There are no direct health benefits to you from being in the study.
   - The pharmacists on the study team have many years of experience helping patients with lung medicines.
     - A summary of your health and medicine review will be sent to your doctor.
     - If you note problems taking your medicines, your doctor and pharmacist will be told, so they can help you.
     - Your doctor might receive suggestions to improve your breathing. After reviewing the suggestions, your doctor may or may not make changes in your medicines.
   - We hope results from this study will help doctors and pharmacists better care for people with COPD.

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10. Are there any options to participating in this research?

Being in the study is completely voluntary. Your pharmacist and doctor would continue to care for you as before. There are no penalties for refusing.

If you decide to be in the study, you may change your mind later. Let your pharmacist know or send a letter to Dr. Bollmeier at the address in #12 below.

11. What about my privacy and confidentiality?

The researchers will do all they can to protect your privacy and information. The research team will only use and share your information in the ways explained on this form.

If you have any questions or concerns about your privacy and the use of your personal health information, please contact Dr. Peter Hurd, the Chair of the Institutional Review Board (IRB) at St. Louis College of Pharmacy at 314-446-8441.

12. Who do I call if you have any questions or problems?

Please contact the Principal Investigator to:

- Obtain more information about the study
- Ask a question about the study procedures
- Leave the study before it is finished
- Share a concern about the study

Dr. Suzanne Bollmeier
Mailing Address: 4588 Parkview Place
St. Louis, MO 63110
E-mail Address: sbollmeier@stlcop.edu
Telephone: 314-446-8525

Principal Investigator:

If you want to talk to someone else, or have questions or concerns about your rights as a research participant, please call Dr. Peter Hurd of St. Louis College of Pharmacy's IRB at 314-446-8441.

13. The PI may withdraw you from the study without your consent, if considered appropriate.

14. You will be given a copy of this signed consent form for your records.

15. If you do not decide to sign this form, you cannot take part in this study. You may still get your prescription(s) filled at this pharmacy.

16. If you sign this form:

- Your signature and this form will not expire as long as you wish to participate.
- You may drop out of this study at any time. No additional information will be collected from you.

17. To cancel your permission, you may call Dr. Bollmeier or send an email or letter at the phone number or address above, in #12 above. If you cancel your permission:

- the research team may only use and share information already collected.
- you will not continue in the study.

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SIGNATURES OF ADULT PARTICIPANTS
Research Participant: I have read this consent form and have been given the chance to ask questions. I agree to participate in this research described above, titled: **COPD severity and adherence to GOLD guidelines in the community pharmacy setting**. Signature: _____ Printed Name: _____ Date of Signature: _____

Principal Investigator (or Designee): I have given this research participant information about this study that I believe is accurate and complete. The participant has indicated that he or she understands the nature of the study and the risks and benefits of participating. Signature: _____ Title: _____ Printed Name: _____ Date of Signature: _____