BAYLOR SCOTT & WHITE RESEARCH INSTITUTE
Baylor University Medical Center
Dallas, TX

CONSENT FORM AND PRIVACY AUTHORIZATION

PROJECT TITLE: Establishing Outcomes of Once-Daily ICS/LABA/LAMA Plus PRN Respiratory Therapy Treatments in Hospitalized Patients with COPD Exacerbations (SUNDIAL-COPD)

PRINCIPAL INVESTIGATOR ("PI"): Mark W. Millard MD

TELEPHONE NUMBER: 214-820-6856

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering taking part in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future. Taking part in this study is voluntary.

Key Information –

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1. WHY HAVE I BEEN ASKED TO TAKE PART IN THIS STUDY?

You are being asked to take part in this research study because you have been diagnosed as having chronic obstructive pulmonary disease (COPD) and are now admitted to the hospital for worsening of your condition.

2. WHY IS THIS STUDY BEING DONE AND HOW LONG WILL IT LAST?

The purpose of this study is to

- Test the safety of TRELEGY ELLIPTA and see what effects (good and bad) that it has on COPD.
- Find out what effects (good and bad) that TRELEGY ELLIPTA has on you and others with COPD.

We think that you will be in the study for up to 2 months.

3. WHAT WILL I BE ASKED TO DO IN THIS STUDY?

If you decide to take part in this study, you will be asked to give permission to look at your medical records, and take the drug TRELEGY ELLIPTA as instructed.

4. WHY MIGHT I WANT TO TAKE PART IN THIS STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope that the information learned from this study will benefit other patients with this disease in the future.

The possible benefits of taking part in this study are the same as receiving treatment for COPD without being in this study.

5. WHY MIGHT I NOT WANT TO TAKE PART IN THIS STUDY?

You may have side effects while on the study.

The most common side effect(s) that people with COPD experience from taking TRELEGY ELLIPTA include upper respiratory infections, pneumonia, headache, backache, constipation and diarrhea (≥1%).

The most common side effect(s) that people with Asthma experience from taking TRELEGY ELLIPTA include upper respiratory infections, sinusitis, headache, and backache (≥2%).

There may be a risk of loss of confidentiality.

The researchers do not know all of the side effects that could happen. For a complete description of known risks, refer to the Detailed Information section of the consent form.

6. WHAT OTHER OPTIONS ARE THERE?

You may choose not to take part in this study. You may choose to receive TRELEGY ELLIPTA without taking part in the study.

Please talk to your regular doctor about these and other options.

7. HOW WILL TAKING PART IN THE STUDY AFFECT ME FINANCIALLY?

There is no additional cost to you if you take part in this study.

For additional information about possible costs, please refer to the section of the consent form titled "**Additional Financial Information"** and ask the study team about any expected additional costs or insurance problems.

Detailed Information Section

What is the Status of the Drugs (Devices or Procedures) Involved in This Study?
TRELEGY ELLIPTA is approved by the US Food and Drug Administration for the long-term treatment of COPD. Although this is an approved drug, it is not normally used by physicians for the treatment of sudden worsening of COPD.

How Many People Will Take Part In This Study?

About 80 people will take part in this study at this location.

What Will I Be Asked To Do?

Procedures that are being done that are considered a part of regular care for this condition that may be done even if you do not join this study. For this study data will be collected from these procedures which are done as part of your regular care.

While you are hospitalized as part of your regular care, your medical charts will be reviewed to collect information. You will be asked to do breathing tests and will be asked questions from a questionnaire about your health. The research team may do a follow-up phone call with you after you leave the hospital to ask about your health. If you are a woman of child-bearing age, a pregnancy blood test may be performed as determined by the study doctor.

Study Visits

SCREENING
If you are found eligible to take part in this study, someone from the research study staff will approach you to provide information about the study. You will be given the opportunity to ask questions and decide if you would want to take part in the study. If you agree you will be asked to sign a consent form.

For this study, data will be collected from your medical charts and a breathing test to look at your breathing patterns will be done.

Assessments and procedures at screening

- Assignment of screening number
- Data collection from your medical charts
- Breathing measurement tests to measure your lung function (spirometry and inspiratory flow rate (PIFR))
- Breathing measurement tests (Spirometry)

ENROLLMENT (within 24 hours of admission)
The following assessments will be done the morning or following morning of admission into study:

- Data collection from your medical charts, including Medical History, medications and any side effects

- Questions will be asked from the St. George's Respiratory questionnaire, which may take about 15 minutes of your time.

TREATMENT (Enrollment to Discharge)
TRELEGY ELLIPTA (fluticasone furoate 100 mcg, umeclidinium 62.5 mcg, and vilanterol 25 mcg inhalation powder) will be given on the morning of enrollment into the study, or the morning after enrollment. Treatment will continue daily until discharge. Treatments will be administered by a respiratory therapist daily in the morning between 6 AM and 12 PM. If enrolled in the study you will receive nebulized short-acting beta-2 agonist (SABA) treatments of albuterol sulfate (2.5mg) as needed during hospitalization. You will receive prednisone 40 mg tablet daily for the first 7 days from enrollment, subtracting 1 day for each consecutive day you may have received systemic corticosteroid treatment prior to enrollment as part of your regular care.

DISCHARGE
Upon discharge, you will receive a full TRELEGY ELLIPTA inhaler containing 30 doses with instructions to take 1 puff daily in the morning for 30 days. The left over TRELEGY ELLIPTA used in the hospital will be taken and thrown away on your discharge from the hospital.

The following procedures/assessments will be done before hospital discharge:

- Breathing measurement tests to measure your lung function (spirometry and inspiratory flow rate (PIFR))
- Data collection from your medical charts, including Medical History, medications and any side effects
- Questions will be asked from the St. George's Respiratory questionnaire, which may take about 15 minutes of your time.

If for any reason, some of the research assessments at discharge are not performed, the study team may (at investigator's discretion) schedule a follow-up with you in the research clinic to obtain the missed assessments.

30 DAY POST DISCHARGE/WITHDRAWAL FOLLOW-UP
You will receive a follow-up phone call from a study coordinator to ask about your health. This phone call may take up to 10-15 minutes.

Medical Charts will be reviewed to assess if you were readmitted within 30 days of discharge.

If you decide to withdraw before discharge from the hospital, you will still receive a follow-up phone call (10-15 minutes duration), and your medical charts will be reviewed for data collection 30 days after the study withdrawal.

After you are finished with this study, the study doctor, sponsor and the institution will not continue to provide the study medicines to you.

How Long Will I Be In This Study?

You will be in this study for up to 2 months.

The researcher may decide to take you off this study if any of the following occur:

- He/She feels that it is in your medical best interest.
- Your condition worsens.
- New information becomes available.
- This study is stopped by the sponsor.

You can stop taking part in this study at any time. However, if you decide to stop taking part in this study, we encourage you to talk to the researcher and your regular doctor first.

What Are The Risks of This Study?

While on this study, you are at risk for these reactions, sometimes bad, which are listed below. You should discuss these with the researcher and/or your regular doctor. There also may be other reactions that we cannot predict. These unknown reactions could also be to your unborn child if you are pregnant or become pregnant while on this study. Other medicines may be given to make them less serious and uncomfortable. Many of these reactions go away shortly after the TRELEGY ELLIPTA is stopped, but in some cases, they can be serious or long lasting and permanent. These are unknown at this time.

Risks and reactions related to the TRELEGY ELLIPTA we are studying include:

Patients with COPD: Most common adverse reactions (incidence ≥1%) are upper respiratory tract infection, pneumonia (infection of the lung), bronchitis (inflammation of the airways), oral candidiasis (infection of the mouth), headache, back pain, arthralgia (joint pain), influenza (infection of the respiratory system), sinusitis (inflammation of the sinuses), pharyngitis (infection of the throat), rhinitis (inflammation of the nose), dysgeusia (change of sense of taste), constipation, urinary tract infection, diarrhea, gastroenteritis (inflammation of the gut), oropharyngeal pain (pain in mouth and throat), cough, and dysphonia (abnormal voice).

Patients with Asthma: Most common adverse reactions (incidence ≥2%) are pharyngitis/nasopharyngitis (infection of the nose and throat), upper respiratory tract infection/viral upper respiratory tract infection, bronchitis, respiratory tract infection/viral respiratory tract infection, sinusitis/acute sinusitis, urinary tract infection, rhinitis, influenza, headache, and back pain.

Reproductive Risks: Because the drugs in this study could harm an unborn baby, you should not become pregnant while on this study. You should not nurse your baby while in this study. Ask about counseling and more information about preventing pregnancy.

The study drug has not been adequately studied on pregnant women and the effects on the fetus/unborn child are unknown.

Non Medical Risks and Discomforts

A non-medical risk is the potential loss of confidentiality or disclosure of your protected health information (PHI). PHI is any health information that is collected about you, including your history and new information collected during this study. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

There may be risks or discomforts that are not yet known.

Conflict of Interest

Your doctor may be an investigator in this study. If so, s/he is interested both in your medical care and in the conduct of this research. Before you sign up for this study or at any time during the research, you may discuss your care with another doctor who is not associated with this research project. You are not under any obligation to take part in any research study offered by your doctor.

The people working on this study may be paid for their work on this research study from money provided by the company sponsoring this research study. The people working on this study may be paid for other work that is unrelated to this study, such as consulting with the sponsor company or speaking at educational programs at the request of the sponsor company or other companies that may have an interest in this study. The people working on this study may have public stock holdings as an investment in the company sponsoring this research study.

What About Confidentiality?

You have a right to privacy. This means that all the information about you from this study will only be shown to the people working on this study. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used. All information about you from this research project will be kept in a locked office or other locked area. Information that is kept on computers will be kept safe from access by people who should not see it.

The privacy law requires that Baylor Scott & White Research Institute ("BSWRI") and your doctors and other health care providers and facilities that have provided services to you, which could include physicians that work for the Scott & White Clinic, HealthTexas Provider Network or Texas Oncology, P.A., Baylor University Medical Center, Scott & White Medical Center – Temple and other health care providers depending on where you have received care (collectively, "Your Health Care Providers") get your permission before giving any of your health information to other people. There are people who need to review your information to make sure this study is done correctly. These people may look at or copy your information while they are doing this review. When you sign this form you give permission to BSWRI and Your Health Care Providers to give other people information about your health as needed for the research project. These groups include people who work for BSWRI (including the Institutional Review Board), Baylor Scott and White Health, the US Food and Drug Administration, the Office for Human Research Protections and the Association for the Accreditation of Human Research Protection Programs. This also includes the following groups of people who are working with the sponsor of this study: GlaxoSmithKline plc. (GSK). Even though we usually remove your name from the

information, the people who get this information may be able to figure out who you are. The kinds of health information that might be given to these people include results from tests. This information might also include notes and other information in your medical records. We may ask for these notes and other information in your medical records from Your Health Care Providers. This means that the records of your care and information about you maintained by Your Health Care Providers may be given to the people mentioned above and, by signing this form, you are agreeing that Your Health Care Providers may release this information to these people.

You do not have to give this permission and it is all right to refuse to sign this form. Your doctor will still treat you and your insurance company will still pay your medical bills (according to their policy) even if you do not give your permission for BSWRI and Your Health Care Providers to release this information. However, since it is important for the people listed above to have access to your information, if you do not sign this form, you cannot be in this study.

If you give permission to BSWRI and Your Health Care Providers to give other people information about your health and the other people are not part of the group that must obey the privacy law, your health information will no longer be protected by the privacy law. However, we will take all reasonable measures to protect your information from being misused.

If you change your mind and later want to withdraw your permission, you may do so. You must notify BSWRI in writing at 3434 Live Oak St., Dallas TX 75204. Please be sure to tell us the name of this study and the PI for this study for which you are withdrawing your permission. BSWRI will provide your withdrawal notice to Your Health Care Providers promptly after BSWRI receives your withdrawal notice. While not required, you should also talk to your PI and Your Health Care Providers and make sure they are aware you are withdrawing your permission. If you withdraw your permission, it will not apply to information that was given to others by BSWRI before you withdrew or to information given to others by Your Health Care Providers before Your Health Care Providers receive your notice withdrawing your permission. If you withdraw your permission, you will no longer be able to take part in this study.

You may not be allowed to look at your study-related health information during this study. However, at a later time, you will be able to look at this information. This later time will be sometime after this study is completed.

Unless permission is withdrawn, this permission will not expire at the end of this study.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Additional Financial Information

There will be no cost to you for being in this study. This means that you (or your insurance company) will not be billed for any of the drugs, devices, tests or visits that take place for the

study. If you see the same doctors for other clinical care, you or your insurance company will be responsible for those costs, the same as if you were not in the study.

The sponsor of the study will pay for:

- Study drug TRELEGY ELLIPTA
- All of the breathing tests (Spirometry) done specifically for the study
- Study Visits (phone calls, questionnaires)

You or your insurance company will pay for:

- Your hospitalization, tests and related care as part of your regular treatment

The sponsor of this study is paying Baylor Scott & White Research Institute (BSWRI) a specific amount of money for each person who agrees to take part in the study. This money is to cover the cost of doing the study and pay for such things as study supplies, staff salaries, etc.

You will not be paid for being in this study.

What if I am Injured or Become Ill While Taking part in this Study?

The people doing this research project will do everything they can to make sure you do not get hurt during the project. If you do get hurt, there are some things that you need to know:

- Baylor Scott and White Health, Baylor Scott and White Research Institute and Baylor University Medical Center have not set funds aside to pay you money if you are hurt. GlaxoSmithKline plc. (GSK) has not set funds aside to pay you money if you are hurt.
- If you have an emergency illness during the project, the people working with you will provide emergency care. You or your insurance company may need to pay for the emergency care if that happens.
- You have not given up any of your legal rights by signing this form.

The Centers for Medicare and Medicaid Services (CMS), the agency that administers the Medicare program, has stated that payments by clinical trial sponsors for injuries related to a trial are a form of liability insurance and must be reported to CMS. As a result, if [Sponsor] pays any medical expenses to treat a trial-related injury, and if you are covered by Medicare, [Sponsor] must report that payment to CMS. In order to do that, [Sponsor] must have certain individually identifiable information about you, such as your name, date of birth, Social Security number, Medicare claim number, date of injury and a description of the injury.

While GSK normally will not receive any individually identifiable information about you, GSK (or its delegate) will receive your individually identifiable information if (and only if) you are covered by Medicare and have incurred medical expenses that have been determined to be the result of a trial-related injury. If it receives your individually identifiable information, GSK (or its delegate) will only use that information to make legally required reports to CMS.

What are My Rights As a Subject?

Taking part in this study is voluntary. You may choose not to take part or may leave this study at any time. If you agree to take part and then decide against it, you can withdraw for any reason. At certain times during the treatment, it may be unsafe for you to withdraw, so please be sure to discuss leaving this study with the PI or your regular physician. Deciding not to be in this study, or leaving this study early, will not result in any penalty or loss of benefits that you would otherwise receive.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

Whom Do I Call if I have Questions or Problems?

If you have concerns, complaints or questions about this study or have a research-related injury, contact the Principal Investigator, Mark W. Millard MD at phone number 214-820-6856.

For concerns, complaints or questions about your rights as a research subject or if you simply wish to speak with someone who is not a part of the research staff, contact the IRB Office at 254-215-9697 (North Texas IRB Office).

Statement of Person Obtaining Consent:

I have explained to _____(printed name of subject) the purpose of this study, the procedures required and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to taking part in this study. I gave a copy of this consent to the subject.

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

Confirmation of Consent by Research Subject:

You are making a decision about being in this study. You will be asked to give your written consent if you want to be in this study. Giving consent is like giving permission. You should not give your permission to be in this study until you have read and understood all pages in this form. Make sure that all your questions about this study have been answered before you sign this form. When you sign this form, you are giving your permission to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence.

_____ (printed name of person obtaining informed consent) has explained to me the purpose of this study, the study procedures that I will have, and the possible risks and discomforts that may happen. I have read (or have been read) this consent form. I have been given a chance to ask questions about this study and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other

options. To the best of my knowledge, I am not in any other medical research. Therefore, I consent to take part as a subject in this study and authorize the activities described in this consent. I also acknowledge that I have received a copy of this consent form.

_____	_____	_____
Signature of Subject	Date	Time