CommonSpirit

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE: Non-Ventilated Prone Positioning in COVID-19 Population

PROTOCOL #: 1766880-1

PRINCIPAL INVESTIGATOR: Marie Hodges

SUB-INVESTIGATORS: Nishant Varghese, Michael Guffey, Marie Hodges, Christi Knapp, Jenny Li, & Dr. Geraldine B. Jones

RESEARCH SITES: Baylor St. Luke's Medical Center

PHONE NUMBER: 480-313-8821

WHAT YOU SHOULD KNOW ABOUT THIS STUDY

General Information

A person who takes part in a research study is called a research or study participant. In this consent form "you" always refers to the research participant.

You are being asked to be in a research study. Your participation is completely voluntary. If you decide not to take part in this study, your doctor will continue to treat you for your normal medical care. The decision to join or not join the research study will not cause you to lose any medical benefits. The purpose of this research study is to manage patients requiring oxygen diagnosed with COVID-19, to avoid the need for increased of respiratory intervention and escalation of care in the ICU. The results will contribute to the growing body of knowledge related to COVID-19 management. Your participation in this study will continue until either of the following occur: the participant is discharged or transferred from the acute care floor, or 14 days have passed. During this time, you will be asked to self-prone (lay on your stomach) every 2 hours by the nursing staff, including both day and night shifts; these procedures are described in more detail below. The key risks and discomforts associated with these procedures include skin breakdown (sores), drop in oxygen level, difficult breathing and need for a breathing tube. Some possible benefits may include improved ability to breathe and avoiding worsening trouble breathing. These procedures and their risks and benefits are described in more detail below. Instead of being in this research study, your diagnosis of **COVID-19** may be treated by usual treatment for patients diagnosed with COVID-19, which does not include proning (lying on your stomach every 2 hours).

You should not join this research study until all of your questions are answered.

INTRODUCTION TO RESEARCH STUDIES

We are asking you to take part in a research study. It is up to you to choose if you want to participate. Please take your time to make your decision. You may take home a copy of this consent form to think about or discuss with family and friends before making your decision. You can also discuss it with your personal doctor(s). This form may have words you do not know. Please ask the study staff to explain any words or information that you do not understand.

If you choose to take part in the research study you will be asked to sign and date this consent form and a separate "Authorization for Use or Disclosure of Protected Health Information for Research" form. The authorization form will tell you how your information will be used and to whom it will be given during the research study. You will be given a copy of all signed documents.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- Your condition may not get better or may get worse during this study.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.

A. WHY IS THIS RESEARCH BEING DONE?

This research study is being done to investigate the effectiveness of proning patients diagnosed with COVID-19 who have been assigned the status of acute care and require oxygen by a nasal cannula.

On a COVID-19 non-ICU acute care, telemetry-monitored unit, there will be two sets of patients: patients that will receive the intervention of proning plus standard of care, and patients that receive standard of care, but not the proning intervention. The patients that will be proned will be identified by a door slot "slider" that is purple. Timing devices will be placed at the nurses' station, and checklists to indicate proning times will be placed inside the room with a patient identification sticker. The researchers will be following the proning protocol for acute care patients provided by CommonSpirit Health (CSH).

B. WHY AM I BEING ASKED TO PARTICPATE?

You are being asked to take part in this study to explore the effectiveness of proning of non-ventilated COVID-19 hypoxemic patients hospitalized in a telemetry-monitored, acute care unit.

C. HOW MANY PEOPLE WILL PARTICIPATE?

Up to 96 people will participate in this study at Baylor St. Luke's Medical Center.

D. HOW LONG WILL I BE IN THIS STUDY?

If you choose to participate in the study, you will be in the study for a maximum of 14 days or until discharged or transferred from the acute care unit.

E. WHAT WILL HAPPEN TO ME DURING THIS STUDY?

If you choose to take part in this study, the following will occur.

Guidelines:

- The patient will be educated about self-proning, and instructed to self-prone every 2 hours. The nursing staff will document patient position on the checklists every 2 hours.
- Upon initiation of the initial proning, the patient will be monitored by the RN for adverse effects for 15 minutes (such as inability to tolerate position or signs of respiratory distress).
- If the patient tolerates the proning well, the procedure can continue and the RN will set the timer for 2 hours, enter the patient's oxygen saturation into the medical record, and document the position (prone or supine) on the checklist. Oxygen saturation will be documented at least every 4 hours per unit protocol.
- The 2 hour timer will be reset each set of 2 hours by the nursing staff, and the intervention will continue for 14 days or until discharged or transferred from the acute care unit.
- The checklists will be placed in a binder at the nurses' station at the end of each shift and collected daily by a member of the research team.
- This intervention for each "proned" patient will continue until either of the following occur: either the patient is discharged home or transferred from the acute care unit, or 14 days have passed.
- A retrospective chart review will be completed by the research team to gather information about length of stay on the acute care, telemetry monitored unit, as well as the need for increase of respiratory care; which is defined as a need for oxygen requirements above 6 liters of oxygen on nasal cannula.

F. WHAT ARE THE RISKS OF THIS STUDY?

Everyone taking part in the study will be watched carefully for any side effects (such as increased difficulty breathing, skin breakdown). You may have side effects while on the study. However, the research team doesn't know all the side effects that may happen. Side effects may be mild or very serious. In some cases, side effects can be serious, long lasting, or may never go away. See list below for possible side effects.

You should talk to your doctor about any side effects that you have while taking part in the study.

Risks and Discomforts
The risks associated with self-prone positioning include:

- Most Common – Skin breakdown (sore)
- Less Common – drop in oxygen level
- Rare – needing a breathing tube to assist you with breathing

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Other risks and side effects include:

- prone position discomfort
- difficulty sleeping or interrupted sleep

G. WHAT ABOUT UNFORESEEN RISKS OF PARTICIPATION?

In addition to the risks described above, there may be unknown risks, or risks that we did not anticipate, associated with being in this study.

H. ARE THERE BENEFITS TO BEING IN THE STUDY?

Taking part in this study may offer certain benefits such as improved ability to breathe. However, there are no guarantees that you will benefit from taking part in this study.

I. WHAT HAPPENS IF I AM INJURED OR HURT DURING THE STUDY?

Every effort to prevent any injury resulting from this study will be taken by the Principal Investigator. Necessary care, emergency treatment, and professional services will be available to you, just as they are to the general community.

By signing this consent you do not give up any of your legal rights.

J. HOW CONFIDENTIAL ARE MY RECORDS?

The Principal Investigator and researchers follow institutional policies and procedures to protect your privacy and confidentiality.

Before your health information is sent to a data coordination center, **your name and other identifying information will be removed and replaced with a number**.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

K. WHAT IF I OR MY DOCTOR DECIDES TO STOP THE STUDY EARLY?

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study Principal Investigator without your consent for any reason, including:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;

L. Compensation for Participation

You will not be compensated for participating in this study.

M. WHO IS FUNDING THIS STUDY?

The sponsor, Baylor St. Luke's Medical Center Friends of Nursing Foundation is paying for supplies and statistician expenses to perform the research study.

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N. ARE THERE ANY CONFLICTS OF INTEREST?

- Conflict of interest guideline was followed as required by Common Spirit Health policy.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You **will not** have any additional costs for being in this research study**.**

You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

- You or your insurance company may be billed for:
    - Any standard medical care given during this research study

O. WILL I RECEIVE NEW INFORMATION ABOUT THE STUDY WHILE PARTICIPATING?

During the course of the research study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from taking part in the research or new alternatives to participation that might cause you to change your mind about continuing in the study.

P. WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact **the Principle investigator** Marie Hodges, at 480-313-8821.

Should you have any questions about your rights, including any concerns or complaints, as a research participant, you may call the Institutional Review Board which is concerned with protection of volunteers in research projects at:

CommonSpirit Health Research Institute
Institutional Review Board (CSHRI IRB)
198 Inverness Drive West
Englewood, Colorado 80112
Telephone: toll-free 1-844-626-2299
E-mail: CHIRB@catholichealth.net

SIGNATURE OF RESEARCH PARTICIPANT OR LEGAL REPRESENTATIVE

I am volunteering to take part in the research study described in this consent form. All my questions about this research study have been answered. My signature below indicates that I have read this consent form, the information in this consent has been explained to me, and that I have decided to take part in this research study.

_____ ___/___/____
Signature of **Adult Participant** (per State requirement) Date

_____
Printed Name

I discussed this study with the above named participant or legal representative. This person had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in this study.

_____ ___/___/____
Signature of **Person Obtaining Consent** Date

_____
Printed Name