SCRIPT 1: Standard Informed Consent Request

Characters:

Alejandro: Principal investigator of the e-Prone study, physician at the Intensive Care Unit (ICU).
Roberto: Family member/legal representative of a patient with moderate/severe Acute Respiratory Distress Syndrome (ARDS).

Location: ICU and a private room or space where the conversation can take place in a calm environment, free from interruptions and ensuring confidentiality. It should also be a comfortable place where the family member feels free to make an informed decision (principle of voluntariness).
Room Elements: 3 chairs, a table, artificial lighting, quiet environment, a pen, and the informed consent form.

ICU Context:

The scene begins in the ICU, where Alejandro approaches Roberto to invite him to the e-Prone clinical study.
Alejandro: Good morning, my name is Alejandro Bruhn. I'm a doctor working in this Intensive Care Unit, and part of my role also involves conducting medical research. Are you a family member of Mrs. Francisca? What is your name?

Roberto: Yes, I'm Roberto, Francisca's husband. Is something wrong?

Alejandro: Don't worry, everything is stable with Francisca. Are you here alone or with someone else? I'd like to invite you to the meeting room to give you some information about a research study we're conducting in our unit.

Meeting Room Context:

Alejandro: How are you doing? I imagine you must be worried about Francisca's condition. I'd like to ask for a few minutes of your time to tell you about a research study we're conducting with patients who have a respiratory illness similar to Francisca's. To participate, we must first inform the patient or their representative about the study so they can decide whether or not to take part. Since she is currently sedated, we need to inform you and ask if you agree to include her in the study.

Francisca is on mechanical ventilation due to a condition called Acute Respiratory Distress Syndrome (ARDS). One of the few interventions shown to be effective in such cases is the prone position—that is, placing patients face down. This simple intervention not only

improves oxygenation but has also been shown to increase survival. For that reason, the medical team treating Francisca has decided to place her in the prone position.

Studies show that prone positioning is effective if maintained for at least 16 continuous hours. However, the optimal duration beyond those 16 hours is unclear. In some places, patients are treated with prone positioning for 16 to 24 continuous hours, then repositioned face up, and the maneuver is repeated if necessary.

We call this strategy intermittent daily prone positioning. In other places, patients remain prone for longer periods—at least 48 hours—until a significant improvement in oxygenation is observed. This is known as continuous prolonged prone positioning. However, it is unknown which strategy is better. In this study, we aim to compare both strategies in patients who meet specific clinical criteria.

Francisca meets the criteria to be included in this study, and we'd like to invite her to participate. This study is being conducted in more than 50 ICUs across Latin America (Mexico, Argentina, Peru, Colombia, Uruguay), including over 20 hospitals in Chile.

Alejandro: Do you have any questions so far?

Roberto (attentive): No, none. The doctor already explained Francisca's condition. But what would happen to her if she enters the study?

Alejandro: If you agree, based on the information we are giving you, to allow Francisca to participate in the study (by signing this informed consent document), she will be randomly assigned to one of the two study groups: either the intermittent daily prone position group or the continuous prolonged prone position group.
If she is assigned to the first group, she will remain prone for 16 to 24 continuous hours, and then she will be repositioned face up. If necessary, a new prone session of similar duration will be repeated. If she is assigned to the second group, she will stay prone for at least 48 hours, or until her oxygenation improves significantly. All other aspects of Francisca's treatment will not be affected by the study and will be the same regardless of the assigned group.

It is important to note that we will monitor and collect data from Francisca for seven consecutive days. This doesn't mean she will be prone for seven days straight. If her respiratory condition improves, she will remain in the supine (face-up) position. If it worsens, the doctor may decide to reposition her in the prone position again.

Roberto (slightly concerned 5/10): Doctor, I don't quite understand. Does this mean Francisca will be turned more than once?

Alejandro: Not necessarily. Some patients only need one or two days of prone positioning and then improve, so the maneuver is not repeated. Others have persistent oxygenation issues and require multiple prone sessions. This can happen regardless of the study group she is assigned to. The main difference is that in the first group, prone sessions last a maximum of 24 hours, meaning the patient is repositioned daily—possibly resulting in more total rotations. In the second group, sessions are longer, so the total number of rotations may be fewer.

Roberto (more confident 8/10): I see. Now I understand. Thank you. Is that everything the study involves?

Alejandro: Yes. Apart from the prone positioning, the rest of the treatment will not be affected by the study. We will collect some routine clinical data during the first 7 days, then follow-up includes tracking hospitalization duration and vital status at day 28 and day 90. If the patient is discharged by then, we may need to follow up briefly by phone to assess general condition.

Roberto: I understand. But will you call her or me? Since I'm the one signing?

Alejandro: We'll ask for both her phone number and yours, so we have more ways to get in touch.
Do you have any other questions about what I've explained so far?

Roberto: Yes, doctor. What are the risks for Francisca if I decide to allow her participation?

Alejandro: It's important to understand that Francisca's condition is serious and that prone positioning is part of her treatment. Her illness and the use of the prone position both carry inherent risks, regardless of her participation in the study. Participating in the study does not involve additional risks beyond those already present, based on current information.

Roberto: I see. And does the study offer any direct benefit for Francisca?

Alejandro: Francisca may or may not benefit directly from the study—we can't say for sure. However, we believe the study will benefit future patients with the same condition by providing more information on how to best use prone positioning to treat this disease.

Roberto: If we choose to participate, is there any cost involved?

Alejandro: No, the study does not involve any cost to you, nor are there any financial incentives for participating.

Roberto: Doctor, and if I don't want Francisca to participate in the study, what will happen to her treatment and care?

Alejandro: It's important for you to know that participation is completely voluntary. If you decide not to allow Francisca's participation, she will still receive all the necessary treatment and care at the same standard as other patients with this illness. The use of prone positioning will remain at the discretion of the treating medical team.
Now, I'll give you a document where you can read in detail everything I've just explained. If you agree to participate and later change your mind, the intervention will be stopped. However, data collected up to that point will be stored anonymously for later analysis.
If you authorize participation, we will ask for your signature, and you will keep a copy of this informed consent document. It will also include my contact information and the contact of the ethics committee that approved the study.
Do you have any questions about what I've just explained?

Roberto (calm, 10/10): No, doctor. Everything is clear now. Do I need to sign the document right away, or can I review it in case I have more questions?

Alejandro: Of course, take your time to review it. How about we talk again in 30 minutes to clarify any questions and hear your decision?

Roberto: That sounds good. Thank you.

Alejandro: Thank you very much, Roberto.