

ANNEX V. ASSENT FORM FOR MINORS (8 TO 17 YEARS)

MEXICAN SOCIAL SECURITY INSTITUTE

Unit of Education, Research and Health Policies

Health Research Coordination

Assent form for minors aged 8 to 17 years

Item	Information
Study title	Efficacy and safety of central venous catheter placement in the internal jugular vein using ultrasound-guided technique versus anatomical landmark technique in critically ill paediatric patients: a randomised clinical trial.
Institutional registration number	R-2019-1002-028.

Study objective and procedures

We want to compare two ways of placing a small plastic tube in your neck, by means of a puncture, so that the medicines and fluids needed for your treatment can be given. We will form two groups of children and you will belong to only one group. In the first puncture group, a small puncture is made in the neck to place a small plastic tube in a vein in the neck. In the second puncture group, an ultrasound machine is used to see the vein, and then a puncture is made in the neck to place the small plastic tube. The doctor who performs the procedure will be very careful and will clean your neck thoroughly before the puncture. In either group, you may feel pain only at the time of the puncture; if the pain continues, we will give you medicine to relieve it.

Hello, my name is _____, and I work at the Mexican Social Security Institute. We are currently carrying out a study to compare two ways of placing a small plastic tube in a vein in the neck to administer different types of fluids and medicines. Because of your illness, you need this procedure. We want to assess which of the two techniques is better, but we need your approval to do this, and we would like to ask for your support.

Your participation in the study would consist of the following: because of your illness, you need a small plastic tube, called a catheter, to be placed for your treatment in the Paediatric Intensive Care Unit. This can be placed in two ways. In the first option, a puncture is made in the vein in the neck and the small plastic tube is placed in the vein. In the second option, an ultrasound machine is used to help us see the vein and then we puncture the vein to place the plastic tube. We want to know which puncture is better so that, in the future, the neck puncture technique that gives the greatest benefit to children can be used. The doctors who place this type of tube have a lot of experience and will take care of you at all times. If any complication occurs, they will have everything necessary to resolve any problem.

Your participation in the study is voluntary. This means that, even if your father or mother has said that you may take part, if you do not want to do so, you may say no. It is your decision whether or not to take part in the study. It is also important for you to know that, if at any time you no longer wish to continue in the study, there will be no problem. If you do not want to answer a particular question, there will also be no problem.

This information will be confidential. This means that we will not tell anyone your answers or results without your authorisation. Only the people who are part of this study team will know them. Only if you authorise us will we tell your parents what you tell us. If you agree to participate, please place an (x) in the box below that says “Yes, I want to participate” and write your name. If you do not want to participate, leave it blank.

☐ Yes, I want to participate

Name: _____

Name and signature of the person obtaining assent: _____

Date: _____

Code: 2810-009-014