Annex 2 Informed consent

INFORMED CONSENT FOR PARTICIPATION IN CLINICAL RESEARCH PROTOCOLS FACULTY OF MEDICINE UNIVERSIDAD DE ANTIOQUIA

Project title: Non-technical skills training and checklists versus standard training with checklists in boarding school students, randomized controlled clinical trial.

Date: 03/11/2020

Name: Mario Andrés Zamudio Burbano

Address: Calle 64 # 51D 154

Telephones: 5167469 - 44441333 ext. 3326

Email: mario.zamudio@udea.edu.co

Place of work: Anesthesia Service - University of Antioquia

Site where the study will be carried out: simulation center, Faculty of Medicine, University of Antioquia.

Entities that support the research: University of Antioquia

Research sponsoring entity: None

Mr. Participant: You are being invited to participate in an investigation into the best simulation educational strategy. Firstly, the use of checklists that are aids for doctors to make decisions in different contexts, are currently considered the best strategy. Secondly, training in checklists and non-technical skills, which also includes communication, leadership, role management, among other strategies.

In principle, the study will not change the training objectives of your rotation of the last semester of medicine, the same planned scenarios are used for your training with the same simulation tools.

What is intended to be evaluated in this study is training on checklists and more training in non-technical skills is superior to training with checklists only, for internship students. In any case, at the end of the study you will receive both trainings.

Study procedures.

After agreeing to participate in the research, you will be randomly assigned to one of the two research groups. Randomly it is like tossing a coin, if it falls heads, you will be assigned to the training group on non-technical skills and checklists, if seal falls you will be assigned to the training group on checklists; In either case, after completing the study you will receive both trainings.

Participation in this research does not carry great risks and uses educational tools similar to those of your scheduled clinical rotation.

Research risks

Your admission to this study is completely voluntary, as well as the option of withdrawal at any time. The data or all the information obtained from you, such as your name, the ID number, the age and what the researchers write down will be hidden from all people who are not involved in the investigation, that is, they will be kept strictly confidentiality. Participation does not mean any additional expense for you other than time.

Study alternatives. If you decide not to participate in the study, this will have no impact on your current rotation, neither training nor evaluation. If you initially decide to participate in the study and eventually decide to withdraw from it, it will not have any repercussions either.

Participant benefits. Your participation in the study will not receive any type of financial compensation, however, it would have the benefit of receiving non-technical skills training and checklists that can benefit your professional practice. Their participation will allow it to be verified if the use of a new educational tool is really useful and effective, which could benefit other students in the same level of training in the future, if it is shown that the new method is superior to the conventional one.

Apart from the inconvenience of the time it takes to read this document and decide voluntarily to participate, there are other additional commitments.

Participant's commitments

1. Participate in all virtual platform activities that takes approximately 2 hours.
2. Participate in all simulation activities that take 8 hours.
3. Inform any of the researchers or the ethics committee of the Faculty of Medicine of any damage or adverse event that may arise.

The researcher assumes the following commitments:

1. Follow up throughout the process.

2. Be pending and solve the problems that arise during the study period.

3. Answer and clarify any questions about the procedures, risks, benefits and other matters related to the investigation.

4. Request the evaluation by the respective specialists or services you need in case of any adverse event.

5. Keep the data of the participants hidden from personnel who are not related to the research, that is, confidentiality.

6. The research is duly approved by the bioethics committee of the Faculty of Medicine of the University of Antioquia. It will also be duly registered in the University Research System of the University of Antioquia and in the International Database of Clinical Trials (Clinicaltrials.gov). The

researchers are medical graduates from certified universities with valid registration to practice the profession and work as teachers at the institution.

7. Disclose the results of the investigation once it is completed.

8. Provide real-time information on the status of the study.

9. Disseminate the results and conclusions among all the participants.

The fact of signing this document does not imply the waiver of the legal rights that may exist.

Expected results

The results will be published in a magazine that reaches teachers or doctors from different parts of the world to achieve a more effective and safe practice and medical education. These results will serve to take advantage of new educational resources in the training of health professionals who can provide greater safety and quality to the care of their patients. The dissemination of the results may lead to the widespread use of these techniques in the population with benefits and reduced risks.

People to contact for information

Name: Mario Andrés Zamudio Burbano, Address: Calle 64 # 51D 154 Telephones: 5167469 - 44441333 ext. 3326 Email:mario.zamudio@udea.edu.co. Place of work: Anesthesia service - University of Antioquia. Contact Ethics Committee Faculty of Medicine, University of Antioquia.

Acceptance of participation in the Study

I, _____, with citizenship card number _____ of_____, confirm that I have read, the information for the previous study has been explained to me and that I have had the opportunity to ask questions and they have been solved. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any explanation, without my academic training or legal rights being affected. I understand that the study researchers, the institutional ethics committee and the judicial authorities will be the only people who will be able to observe the recordings collected in the study. I agree to the collection, processing,

I agree to participate in the study described above.

Firm: _____

Date:

Principal investigator or who requests consent:

Name:

Firm: _____

Date:

Witness 1

Name:

Relationship with the participant:

Residence address:

Firm: _____

Date:

Witness 2

Name: Relationship with the participant:

Residence address:

Firm: _____

Date: