Kingdom of Saudi Arabia Ministry of Education Taibah University College of Dentistry Research Ethics Committee TUCD-REC



المملكة العربية السعودية وزارة التعليم جامعة طيبة كلية طب الأسنان لجنة أخلاقيات البحوث

03/01/2024 - 21/06/1445

Study Reference No.:

« TUCDREC/051223/TAIDhelai »

Subject: Approval of the study entitled <u>« Evaluate the use of the Virtual reality distraction technique to Reduce Pain and Anxiety in Pediatric dental Patients during local Anesthesia Administration »</u> by the Ethics Committee

Dear Thiyezen Abdullah AlDhelai

Please be advised that Taibah University, College of Dentistry Research Ethics Committee (TUCDREC) has reviewed and discussed your application to conduct the research mentioned above with yourself as the Principal Investigator.

TUCDREC has decided the following for your protocol:

Conditional Approval

■Unconditional Approval

Deferred

Rejected

The **TUCDREC** expects to be informed regarding the progress of the study and any serious adverse events occurring during the study, any amendment/addendum in the protocol and patient information/informed consent. You may not initiate any changes in the approved research protocol without the prior TUCDREC review and approval except when it is necessary to eliminate imminent and apparent hazards to study subjects.

While The TUCDREC has provided this decision. The committee, however, takes this occasion to draw to your attention that this document is purely ethical and in no shape or form, is it to be understood to mean the conduction of or the end of the search to be conducted.

This TUCDREC is organized and operated according to the Saudi National Regulation of the National Bioethics Committee, the Guidelines of the Declaration of Helsinki, the International Conference of Harmonization ICH, and the United States Codes of Federal Regulations. The TUCDREC is registered in the Office of the Human Research Protection under the IORG #: IORG0008371 which Expires on: 26th May 2023, and Federal Wide Assurance under the FWA #: FWA00023781, which Expires on 28th January 2026, IRB# 00010037.

Coordinator of TUCD-REC

Chairman of TUCD-REC

Dr. Ahmed Yaseen Alqutaibi
Associate Prof.

Dr. Ahmad Abdulkareem Alnazzawi Associate Prof.