From: IRBMAIL@uthscsa.edu
To: Wang, Zhu
Subject: No IRB Approval is Required, Project is Not Human Research
Date: Friday, April 2, 2021 11:34:54 PM

Protocol number:
20210234NHR

Protocol title:
Predicting Outcomes in Children with Ulcerative Colitis

Dear Zhu Wang,

It was determined that your project does not require IRB approval because it is not human research as defined by DHHS regulations at 45 CFR 46 and FDA regulations at 21 CFR 56.

The proposed project does not include non-routine intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction, nor do the researchers obtain private, identifiable information about living individuals.

We will only make the determination for your engagement in the activity at UTHSA; however, additional project approval may be warranted at Conn. Children's Medical Center and U Mississippi Medical Center.

If the goals and/or activities of the project change during the course of the project, or if new activities are proposed that would constitute human subjects research, please re-contact the OIRB so that we may determine whether or not the revised plan involves human subject research activities.

Project/study sites:

- University of Texas Health Science Center at San Antonio

NOTE: All approved documents related to this submission will be available from your ORCA dashboard O.R.C.A. . If you require a formal letter of approval contact the Office of the IRB (OIRB). If your submission requires UT HEALTH SAN ANTONIO institutional activation, documents will be available after OCR provides this activation. For studies including an affiliate site (VA/UHS), a separate approval is required before beginning your research at the affiliate site.