



INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS
FWA # 00006767 LUBBOCK/ODESSA IRB #00000096

May 23, 2017

Jirapat Teerakanok
Texas Tech University Health Sciences Center
3601 4th Street
Lubbock, TX 79430

Re: A Rare Case of Primary Esophageal Diffuse Large B Cell Lymphoma Presenting with Tracheoesophageal Fistula and Review

Dear Dr. Teerakanok,

This letter serves as official documentation that the single-patient case report you described in your email dated May 20, 2017, which was conducted at Texas Tech University Health Sciences Center does not require submission to the Institutional Review Board for review or approval. As you may know, the Texas Tech University Health Sciences Center IRB Policies and Procedures do not require IRB review or approval of single case studies. A research project is defined by the federal regulations as "a systematic investigation ...designed to develop or contribute to generalizable knowledge" (45 CFR 46 .102.d). We do not consider single-patient case reports to meet either the "systematic" or "generalizable" components of the definition. Because the TTUHSC IRBs are only charged with review of research projects that involve human subjects, and because we do not consider case reports to be research projects, the TTUHSC IRBs do not require review of these types of projects.

As a courtesy to the patient involved (and if it is possible) you might consider informing him or her that you are hoping to publish de-identified information about his/her case and document in the medical record that you held this discussion prior to submitting the manuscript. This is only a courtesy action, though, and is not required by any federal or state regulation or by local policy.

Please do not hesitate to contact me if you have additional questions.

Best regards,

A handwritten signature in black ink that reads "Karen Douglas".

Karen Douglas
Unit Manager
TTUHSC Lubbock/Odessa Institutional Review Board
3601 4th Street STOP 8146
Lubbock, TX 79430
806-743-4753