



University of Southern California Institutional Review Board  
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Email: [irb@usc.edu](mailto:irb@usc.edu)

Date: Jan 09, 2023, 04:12pm  
Action Taken: **Approve**  
Principal: [Tamara Chambers, MD](#)  
Investigator: OTOLARYNGOLOGY, HEAD & NECK SURGERY  
Faculty Advisor:  
Co-Investigator(s): [Joshua Lin, MS3](#)  
KECK SCHOOL OF MEDICINE  
[Neil Luu, MD](#)  
LAC + USC Medical Center  
[Matthew Lin](#)  
KECK SCHOOL OF MEDICINE  
Project Title: [Sources ENT Interest](#)  
Study ID: **UP-22-01066**  
Funding:

The University of Southern California Institutional Review Board (IRB) designee reviewed your iStar application and attachments on **01/09/2023**. Based on the information submitted for review, this study is determined to be **Exempt from 45 CFR 46 according to §46.104(d) as category (2)**.

As research which is considered Exempt according to §46.104(d), this project is not subject to requirements for continuing review. You are authorized to conduct this research as approved.

If there are significant changes that increase the risk to subjects or if the funding has changed, you must submit an amendment to the IRB for review and approval. For other revisions to the application, use the "Send Message to IRB" link.

**The materials submitted and considered for review of this project included:**

1. iStar application UP-22-01066, dated 12/14/2022
2. ENT Interest Protocol 11.16.22.docx(0.01)
3. Exempt Sheet 11.16.2022.doc(0.01)
4. InterestInENT\_revised.pdf(0.01)

**Principal Investigator Responsibilities:**

As the Principal Investigator, you are required to ensure that this research and the actions of all project personnel involved in conducting the study will conform with all federal, state, local and institutional standards and for obtaining all necessary approvals before commencing research. Please be sure that you have satisfied all applicable requirements, for example: conflicts of interest, credentialing, data security, sponsor approval, school district or school approval. IRB approval does not convey approval to commence research in the event that other requirements have not been satisfied.

**Information Sheet and Recruitment:**

It is the responsibility of the principal investigator to follow the principles of the Belmont Report, which requires all potential participants to be informed of the research study, their rights as a participant, confidentiality of their data, etc. per USC IRB policy. Consent and recruitment documents are not required to be uploaded to the iStar application for exempt studies. Please utilize the attached Information Sheet for Exempt Research template and Guidance for Recruitment materials. The documents should include the information specific to your study. These documents will not be reviewed by the IRB. It is the responsibility of the researcher to make sure the documents are consistent with the study procedures listed in the application.

**NOTES to PI:**

1. The investigator must not record information in such a manner that the identity of the human subjects can readily be ascertained directly or through identifiers linked to the subjects and must not contact or re-identify the subjects.
2. Matthew Lin's CITI certificates are about to expire (2/4/2023). Please renew before expiration date.

Attachments [11 Information-Sheet-for-Exempt-Studies-07-27-2019 \(4\).doc](#)

: [2019-10-31\\_guidance-for-recruitment-tool-final.pdf](#)

Social-behavioral health-related interventions or health-outcome studies must register with **clinicaltrials.gov** or other International Community of Medical Journal Editors (ICMJE) approved registries in order to be published in an ICJME journal. The ICMJE will not accept studies for publication unless the studies are registered prior to enrollment, despite the fact that these studies are not applicable "clinical trials" as defined by the Food and Drug Administration (FDA). For support with registration, go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or contact Jean Chan ([jeanbcha@usc.edu](mailto:jeanbcha@usc.edu), 323-442-2825).

Approved Documents: [view](#)

**Important**

The principal investigator for this study is responsible for obtaining all necessary approvals before commencing research. Please be sure that you have satisfied applicable requirements, for example conflicts of interest, bio safety, radiation safety, biorepositories, credentialing, data security, sponsor approval, [clinicaltrials.gov](http://clinicaltrials.gov) or school approval. IRB approval does not convey approval to commence research in the event that other requirements have not been satisfied.

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