

USC



University of Southern California Institutional Review Board
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Date: Apr 15, 2020, 04:03pm
 Action Taken: **Approve**
 Principal Investigator: [Ali Gholamrezanezhad](#)
 RADIOLOGY
 Faculty Advisor:
 Co-Investigator(s): [Catherine Song](#)
 KECK SCHOOL OF MEDICINE
[Bhushan Desai](#)
 RADIOLOGY
 Project Title: **Impact of COVID-19 on medical students**
 Study ID: **UP-20-00314**
 Funding:

The University of Southern California Institutional Review Board (IRB) designee reviewed your iStar application and attachments on 4/15/2020.

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 dated 4/15/2020
2. Survey, uploaded 4/14/2020

NOTES to PI:

Per USC Policy, someone may not collect data about people he or she oversees in a professional capacity. Please ensure that someone on the study (represented in 2.1, with the required human subjects certification) is able to serve as an independent data collector. Further, data must be stripped of any identifying information before being provided to people who have the supervisory relationship in order to protect the confidentiality of the participant responses.

INFORMATION SHEET

Consent and recruitment documents are not required to be uploaded for exempt studies; however, researchers are reminded that USC follows 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. Therefore, please utilize the Information Sheet Template available on the IRB website (<http://oprs.usc.edu>) and revise the language to be specific to your study. This document will not be reviewed by the IRB. It is the responsibility of the researcher to make sure the document is consistent with the study procedures listed in the application.

Funding source(s): N/A – no funding source listed

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

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

[Clinical Research Guidelines COVID-19 Update 03-19-2020.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 ICMJE 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 or contact Jean Chan (jeanbcha@usc.edu, 323-442-2825).

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://www.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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