Proposal #HS-19-00919

University of Southern California Institutional Review Board
1640 Marengo Street, Suite 700
Los Angeles, California 90033-9269
Telephone: (323) 442-0114
Fax: (323) 224-8389
Email: irb@usc.edu

Date: Dec 13, 2019, 01:16pm

To: Vaia Lida Chatzi
Associate Professor
PREVENTIVE MEDICINE
Lisa Wolff
Study Coordinator
OCCUPATIONAL & ENVIRONMENTAL HEALTH
2001 N Soto St
230-18
Los Angeles, CA 90032 USA

From: University of Southern California Institutional Review Board
1640 Marengo Street, Suite 700
Los Angeles, California 90033-9269
(323) 442-0114

TITLE OF PROPOSAL:
Hepatotoxic effects of perfluoroalkyl substances: a new epidemiological approach for studying environmental fatty liver disease-R01 (Hepatotoxic effects of perfluoroalkyl substances-R01)

Action Date: **12/13/2019** Action Taken: **Approve**

Committee: Institutional Review Board Chairman

Note: The University of Southern California Institutional Review Board (IRB) designee reviewed your project and was APPROVED on 12/13/2019.

The materials submitted and considered for review of this project included:
1. iStar application, dated 11/22/2019
2. Protocol, undated (uploaded 11/18/2019)

The National Institutes of Health (NIH) and the Office for Human Research Protections (OHRP) do not consider research involving ONLY coded private information or specimens to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are BOTH met: the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals and the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased.

Based on the information submitted for review, this study is not human subjects research. If research is conducted, a separate IRB approval must be obtained.

This review and opinion is based only on the information provided to the IRB Office and is not valid if the proposed project is not exactly as described, or if additional information (including grants, contracts or other information) have been withheld.

This project is not subject to requirements for continuing review.

Attachments:

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** or school approval. IRB approval does not convey approval to commence research in the event that other requirements have not been satisfied.

This is an auto-generated email. Please do not respond directly to this message using the "reply" address. A response sent in this manner cannot be answered. If you have further questions, please contact your IRB Administrator or IRB/CCI office.