USC

Proposal #HS-20-00396

University of Southern California Institutional Review Board
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Date: Aug 20, 2020, 01:30pm

To: Nathanael Heckmann
Assistant Professor of Clinical Orthopaedic Surgery
ORTHOPAEDIC SURGERY
Emi Hirsh
Research Coordinator I
Clinical Translational Science Institute

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

TITLE OF PROPOSAL:
Examination of Distal Femoral Replacement in Non-oncologic Cases (Examination of DFR)

Action Date: **8/20/2020** Action Taken: **Approve**

Committee: Institutional Review Board Chairman

Note: The University of Southern California Institutional Review Board (IRB) designee reviewed your iStar application and attachments on 08/20/2020.

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) & (4).

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 05/07/2020
2. DFR Variables.xlsx(0.01), uploaded 4/9/2020
3. DFR Questionnaire.pdf(0.01), uploaded 4/10/2020

NOTES TO PI:

1. This approval does not include accessing data from the Clinical Data Warehouse.

2. The IRBA has made minor changes to the following sections of the application based on the attached email correspondence with the study team: 2.1 (to indicate the PI [since his name is on the information sheet] and RAs Chung and Qureshi are obtaining consent; and to add Brian Chung as study personnel); 5.1 (to change the application from expedited to exempt, for which it qualifies); 9.1.1 (to indicate this study does not involve direct in-person interactions with participants); 11.1 (to add in the prospective study procedures and indicate that REDCap will be used to obtain consent [via information sheet] and signed HIPAA authorization from participants in advance to the phone survey and chart review procedures); and 26.5 (to indicate that once direct identifiers are destroyed at the completion of the study, the remaining de-identified data can be retained for future research use).

PRINCIPAL INVESTIGATOR RESPONSIBILITIES
Individuals who are knowledgeable about the protocol must obtain consent from subjects for participation in a study. Specifically, they must be able to describe the purpose, procedures, benefits, risks, and alternatives to participation in the study. They must be able to answer subjects' questions about the protocol and about risks of the research procedures and alternatives. The PI must identify all individuals who will obtain consent and attest that they fit the above criteria. The PI is ultimately responsible for ensuring that ethically and legally valid consent is obtained from all research subjects.

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. Please utilize the attached Information Sheet For Exempt Research and Guidance for Recruitment materials. The documents should include information specific to your study. These documents will not be reviewed by the IRB; however, it is the responsibility of the researcher to make sure the documents are consistent with the study procedures listed in the IRB application.

NOTE: In the event that this study is audited by the IRB, you are required to provide the Information Sheet and recruitment documents used for this study.

HIPAA AUTHORIZATION APPLICABLE:
Based on the documents submitted, the investigator is accessing, using or obtaining research subject/patient's identifiable health information that is governed by the HIPAA privacy federal regulations and a waiver of authorization is not applicable. You must obtain authorization from subjects using the current "USC HIPAA Authorization to Use Health Information for Research" template approved by the USC Office of Compliance.

PLEASE NOTE: If the subject notifies the investigator directly that the subject is revoking the authorization, the investigator must advise the IRB within 5 working days of the receipt of the revocation.

PARTIAL WAIVER OF HIPAA AUTHORIZATION (APPLICABLE FOR RECRUITMENT): This study meets the regulations outlined in 45 CFR 164.512 (i) (1) (i) and a request for a partial waiver of HIPAA authorization has been granted. The request for a waiver of authorization is approved solely for the purposes of obtaining protected health information to screen, recruit, and/or identify potential research subjects into the study. Please note that you may be asked to provide a copy of this waiver to obtain or access to this protected health information.

PLEASE NOTE: YOU MAY LOOK AT, BUT NOT RECORD HIV TEST RESULTS (California Health and Safety Code 120985).

Attachments: Correspondence with Study Team 8.20.2020 re HS-20-00396.pdf
2019-10-31_guidance-for-recruitment-tool-final.pdf
Information-Sheet-for-Exempt-Studies-07-27-2019.doc

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.