University of California
San Francisco

Human Research Protection Program

Institutional Review Board (IRB)
Quality Improvement Unit (QIU)
Gamete, Embryo and Stem Cell Research Committee (GESCR)

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Dear Principal Investigator:

RE: UCSF Benioff Children's Hospital Oakland Integration with UCSF IRB

As a result of the integration of Benioff Children's Hospital Oakland (BCH Oakland) and the University of California, San Francisco (UCSF), the Institutional Review Board (IRB) operations are actively transitioning to UCSF. It is expected that the transition will be complete by March 2021.

This letter is to provide study sponsors with information about the integration, membership, and function of the Institutional Review Board (IRB) at the University of California, San Francisco (UCSF). The IRB is within the Human Research Protection Program (HRPP), along with the Quality Improvement Unit (QIU).

UCSF holds Federalwide Assurance (FWA) number 00000068. BCH Oakland has been added as a component to this FWA. UCSF has five registered IRBs, including the newly convened Oakland Committee (IRB Registration #00012543), all of which meet the DHHS 45 CFR 46 Subpart E and FDA 21 CFR 56 regulation requirements for IRB registration.

For sponsored studies, the IRB applies the FDA regulations found in 21 CFR parts 50 and 56 which includes, by guidance, the International Conference on Harmonization-Good Clinical Practice Guidelines (ICH-GCP) guidance (E6).

During the transition, the BCH Oakland FWA (00000094) remains active and the BCH Oakland IRB approval letters are valid through the date of expiration.

The new Oakland IRB Committee will meet at the Oakland campus and is primarily comprised of IRB Members who are based at BCH Oakland. Current IRB member rosters are available on the HRPP website. IRB members are assigned studies based on their expertise. If an IRB member has a conflict of interest, he or she will not participate in the deliberation and voting of that protocol. Please refer to the Investigator Conflict of Interest guidance on the HRPP website for additional information.

All IRB reviews are conducted on the IRB electronic submission system, iRIS. Additional information can be found on the iRIS frequently asked questions (FAQ) website. Further, information and guidance regarding the

IRB's processes and guidance is available on the IRB website. During the 11-month transition, all BCH Oakland protocols will be transferred from CYBER IRB to iRIS.

Once a study has transferred to iRIS, the ongoing reviews of that protocol will be subject to the published UCSF IRB recharge rates.

If you have any other questions about the Committee membership or function, please call the office at (415) 476-1814 and ask to speak with the Director of the HRPP.

Thank you,

Edward Kuczynski, MA
Director, Human Research Protection Program