UCSF Benioff Children's Hospital
Oakland

IRB AFFILIATION

NOTE TO FILE

The Institutional Review Boards for The University of California, San Francisco (UCSF) [FWA00000068] and UCSF Benioff Children's Hospital Oakland (BCH Oakland) [FWA00000094) have integrated as of May 1, 2020.

There will be a transition period (5/1/20 – 12/31/21) where both FWA's remain active. During this time protocols under FWA00000094 will administratively transfer to FWA00000068.

Once the study is administratively transferred, the new IRB contact details will be:

https://irb.ucsf.edu/contact-us

Human Research Protection Program, Box 0962
3333 California Street, Suite 315
San Francisco, CA 94143

The UCSF IRB Rosters can be located at:

https://irb.ucsf.edu/irb-rosters-meeting-dates

Based on the FDA's FAQ for the 1572, it is not necessary to update the 1572 with this new information:

https://www.fda.gov/media/78830/download

7. When must a 1572 be updated or a new 1572 completed and signed by an investigator to reflect new or changed information?

There are two instances when it is necessary for an investigator to complete and sign a new 1572: when an investigator is participating in a new protocol that has been added to the IND and when a new investigator is added to the study (21 CFR 312.53(c)).

If there are other changes to information contained on a signed and dated 1572 (e.g., an IRB address change, the addition of new subinvestigators, the addition of a clinical research lab), the investigator should document the changes in the clinical study records and inform the sponsor of these changes, so that the sponsor can appropriately update the IND. The 1572 itself does not need to be revised and a new 1572 need not be completed and signed by the investigator. The sponsor can accumulate certain changes and submit this information to the IND in, for example, an information amendment or a protocol amendment.