

INSTITUTIONAL REVIEW BOARD ADMINISTRATION

December 17, 2021

Re: Known issue with stamped documents in Kualii IRB (Note to File)

Dear UCSD and/or RCHSD Principal Investigator:

This information is being provided as a note to file in response to common requests relating to a known issue in Kualii IRB with the stamping of approved documents from researchers and sponsors. Please forward this letter to sponsors as needed.

On or about December 1, 2021 the Office of IRB Administration became aware of an issue in Kualii IRB where approved documents being stamped by the Kualii system were having the beginnings and ends of the stamp cut off. The primary effect of this was that often the last two to three digits of the year in the expiration date were being cutoff. This is clearly not desirable and the issue has been brought to the attention of Kualii for fixing.

On December 17, 2021 the Office of IRB Administration in coordination with our local IT support were able to deploy a short-term fix to the issue while we await a long-term fix from Kualii. The fix is implemented immediately and requires no additional action on the part of the IRB to re-stamp the documents.

If a consent form with the cutoff stamp was used to enroll subjects, please be assured that these documents have been reviewed and approved by the UC San Diego IRB and are valid for use with subjects in human subjects research studies meeting all criteria for approval as laid out in the applicable regulations and policies governing such research.

If further proof of approval is needed, the version number in the stamp applied by Kualii on the affected documents can be referenced in the approval letter issued by the UC San Diego IRB in Kualii showing the approval and expiration dates of the study.

I hope the above information will answer your and your study sponsor's questions. If there are other questions around this issue raised by sponsors, please refer your sponsor to me at 858-229-8978 or bmooso@ucsd.edu.

Sincerely,



Ben Mooso
Director