



UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

Date: April 27, 2020

From: Kip Kantelo, Director

Re: Clarification of IRB Approval Periods

Federal regulations at 21 CFR 56.109(f), 45 CFR 46.109(e), and corresponding sections of other agencies' regulations generally require continuing review by an Institutional Review Board (IRB) "at intervals appropriate to the degree of risk, not less than once per year." Federal guidance ([here](#) and [here](#)) further allows the retention of a consistent expiration date from year-to-year, subject to a 30-day window.

Instead of using the above regulatory language, current University of California, San Diego (UCSD) IRB procedures and approval letters variously use the terms "365 days" and a "1-year anniversary date." The UCSD IRB database is also programmed to calculate a 365-day period without adjusting for leap years, while also maintaining the approval date anniversary rather than the expiration date anniversary.

Study teams and sponsors have raised concerns that UCSD approval periods straddling the 2019 leap year are two days shorter and/or have a gap between approval periods. We have also received questions about the gap on approval letters between the date a continuing approval is "released" and the date of "review and approval."

The HRPP does not have quick options for correcting the database or approval letters, particularly with the disruptions of the COVID-19 pandemic and efforts to deploy a new database. **Please use this memo as a Note to File for approvals covering any portions of the period from March 1, 2019-March 1, 2021.**

This memo serves to clarify the following, regardless of dates in the database or the wording on letters:

- A continuing review that occurs within one year of the approval date satisfies regulatory requirements and is valid for activity at UCSD, whether that year is 365 days or 366 days.
- The "release" and "review and approval" fields on approval letters are mis-labelled.
 - IRB records reflect that the actual review date is on or before the "release" date.
 - The "review and approval" date reflects the start date of the new approval period.

The following example illustrates how study teams should proceed:

- IRB completes its review and releases approval on 05/01/2019.
 - Study team can conduct research from 05/01/2019 through 11:59 pm on 04/30/2020.
- IRB completes continuing review of the same study and releases approval on 04/15/2020.
 - Study team can also conduct research from 05/01/2020 through 11:59 pm on 04/30/2021.

Note that this memo does not address variations on continuing review requirements introduced by the Revised Common Rule or if the IRB decides an approval period of less than one year is warranted. For any questions, please contact 858-246-HRPP (4777) or hrpp@ucsd.edu.