UCSF Research Record Retention Requirements Summary

University of California, Office of the President, recommends retention of research records for at least three (3) years after completion of the research (UCOP Contract and Grant Manual, section 18-272). Additional requirements include:

- FDA regulated research: "An investigator shall retain records … for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified." (21CFR312.62.c)
- FDA regulated research for investigational drugs and devices being developed for marketing submission in the US and European Economic Union (EEU) member countries and/or Japan: Records "…should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product." (ICH GCP 4.9.5)
- Pediatric research: Research records where children are the research subjects should be kept until the subjects are 25 years of age (General Counsel recommendation, UCOP Contract and Grant Manual, section 18-272).
- In vitro studies or research including pregnant women: Research records for in vitro studies or where pregnant women are included as research subjects should be kept for 25 years after completion of the research (General Counsel recommendation, UCOP Contract and Grant Manual, section 18-272).

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