

Circumstances when IRB approved active protocols may be closed by the PI and/or the IRB

In April 2006, the University of Kentucky (UK) Institutional Review Board (IRB) and the Office of Sponsored Projects Administration (OSPA) agreed to eliminate the policy, which required protocols to remain under IRB approval while a sponsored program account (ledger 4) remained active.

If a study is open and the only activity remaining is analysis of data collected during the study, the study may be closed by the PI if either of the following conditions exist:

- the data is de-identified and there are no subject identifying codes or links to the de-identified data; or
- the data for studies approved after January 21, 2019 with identifiers, is encrypted; or
- for FDA-regulated studies, there are no outstanding data queries or other investigator/site responsibilities in the trial

If a study has been open for a period of three or more years and there have been no subjects enrolled in the study, the IRB may request that the study be closed.

If at Continuation or Annual Administrative Review the investigator reports to the IRB that the study has been open for a period of three or more years and there have been no subjects enrolled into the study, the IRB may request study closure, unless justified (e.g., study involving a rare condition). A notification of closure is sent to the investigator.

Procedures for closing a study fall into three categories:

- Final review (FR);
- Study Closure due to non-response or Lapse of approval due to non-response to requests for continuation or final review (See Continuation Review SOP); o Non-response from PI to IRB requests for revisions (a vote of 2, 3, or 4);
- Study Closure due to study never being initiated (i.e., non-enrollment, no data collection from records, and/or no specimens having been obtained).

A copy of this handout may be downloaded from the ORI Survival Handbook webpage under the section Recordkeeping <https://www.research.uky.edu/office-research-integrity/irb-survival-handbook>. For details on additional study closure circumstances, see the IRB/ORI "Study Closure" Standard Operating Procedure (SOP) available on ORI's SOP web page: http://www.research.uky.edu/ori/human/SOPs_&Policies.htm#4

If you have questions regarding this information please contact the Office of Research Integrity (ORI) at Ph: 859-257-9428 or IRBSubmission@uky.edu.