

Two 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) adopted two new circumstances permitting IRB approved protocols to be closed by the Principal Investigator (PI) and/or the IRB.

Since that time, the IRB and 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. Accordingly, the two previously described circumstances under which IRB approved protocols can be closed by the Principal Investigator (PI) and/or the IRB have been revised. They now stand as follows:

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 the data is de-identified and there are no subject identifying codes or links to the de-identified data.

A memorandum from the PI must be submitted to the Office of Research Integrity (ORI) in order to close a study when the only activity remaining is analysis of data collected during the study and the data are de-identified (there can not be any subject identifying codes or links to the de-identified data). The memorandum must contain all of the following information:

- a request for inactivation of IRB approval
- confirmation that all subjects have been enrolled
- assurance that data collection is complete
- confirmation that only data analysis, as approved in the protocol, of already collected data remains
- assurance that data are de-identified (provide explanation what this means)
- assurance that there are no subject identifying codes or links to the de-identified data

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 requires that the study be closed.

If at continuation 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 require that the PI submit a withdrawal request memo. A notification of closure letter is sent to the investigator.

The PI must complete and submit a final review report form with the requested materials to the IRB unless:

- 1. He/she never initiated the study; or,**
- 2. A review (initial or continuation) has been conducted within the last six months and no subjects have been enrolled since the last review.**

A copy of this handout may be downloaded from the ORI Educational Materials, Regulations and Policy Guidance web page under the topic "Closure of a Study":
<http://www.research.uky.edu/ori/human/guidance.htm>. 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 Helene Lake-Bullock in the Office of Research Integrity (ORI) at Ph: 257- 9428 or hbullo@uky.edu