	SOP: Terminated and Changed Status Users
	Section III: IRB Protocols
	Number: IRB III-016 — Date: 9/13/2025

SOP: Terminated and Changed Status Users

Section III: IRB Protocols

Number	Date
IRB III-016	9/13/2025

1. **PURPOSE**

   1.1. This SOP outlines the process to remove terminated users from the study application in the Cayuse electronic system and to verify principal investigator eligibility when there is a personnel status change requiring additional approvals.

2. **REVISION FROM PREVIOUS VERSIONS**

   2.1. None

3. **SOP STATEMENT**

   3.1. Study personnel lists in the Cayuse electronic system will be updated when:

      3.1.1. Study personnel with access to the Cayuse electronic system are terminated from the institution.

      3.1.2. A principal investigator's employment status changes to a status requiring additional approval to remain principal investigator.

4. **RESPONSIBILITIES**

   4.1. The research compliance staff assigned to the IRB carries out this procedure.

5. **PROCEDURE**

   5.1. The research compliance staff assigned to the IRB will provide notification of a terminated user or principal investigator's change in status to the IRB Chair. After notification, the following procedures are to be carried out:

      5.1.1. If the terminated user is a PI on an active study and their departure is reported ahead of time (10 business days or more prior to departure), the PI should immediately either identify a new PI and submit the appropriate protocol modification or submit the protocol closure form via TAMUK SOP: Monitoring for Study Closure (IRB SOP III-010). Research compliance staff will notify the IRB Chair immediately upon receiving notice of terminated user. The IRB Chair will be responsible for reviewing modifications within 24 hours of receipt of modification.

         5.1.1.1. The research compliance staff assigned to the IRB will send correspondence to key personnel on the study list which states within 10 business days:

            5.1.1.1.1. A new qualified Principal investigator is to be selected by submitting a modification to the study; or

            5.1.1.1.2. The Department Chair and/or other key study personnel may request study closure.

5.1.1.1.3. Study is administratively closed if neither of the options above are implemented.

5.1.1.2. If the PI's departure becomes known less than 10 business days from departure to the research compliance staff, the IRB Chair, or any member of the IRB, in coordination with the IRB Chair or research compliance staff assigned to the IRB will:

5.1.1.2.1. Issue a notice to stop all data collection and research the day prior to departure, or immediately if the day of departure is the same or before this process is implemented.

5.1.1.2.2. Procedures 5.1.1.1-4 are to be followed to install a new PI or close the study.

5.1.2. If the terminated user's study role is not the Principal Investigator:

5.1.2.1. The research compliance staff assigned to the IRB will send correspondence to the Principal Investigator which states:
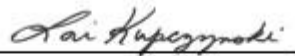
5.1.2.1.1. A modification is to be promptly submitted to the IRB to remove the terminated study personnel.

5.1.2.1.2. If the study personnel list is not updated with this modification within 10 working days, then no further submissions will be processed.

5.1.3. If the notification of terminated user or change in status is incorrect, refer the individual to the research compliance staff assigned to the IRB to correct the termination.

6. REFERENCES

6.1. None

Approved by: _Lori Kupczynski_
Lori Kupczynski, EdD
Special Assistant to the Vice President,
Office of Research and Innovation
Date: _8 September 2025_