1 PURPOSE

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

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Study personnel lists in the electronic protocol management system will be updated when:

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

3.1.2 A principal investigator's employments status is changed to a status requiring additional approval to remain principal investigator.

4 RESPONSIBILITIES

4.1 The RCB Operations Director or designee and the HRPP staff will carry out these procedures.

5 PROCEDURE

5.1 The RCB Operations Director will provide notification of a terminated user or principal investigator's change in status to the HRPP staff. After notification, the following procedures are to be carried out:

5.1.1 If the terminated user is a Principal Investigator on an active study:

5.1.1.1 The HRPP staff will send correspondence to the PI's Department Chair and other key personnel on the study list using TEMPLATE: Correspondence: Terminated Personnel – Principal Investigator which states:

5.1.1.1.1 A new qualified Principal investigator is to be selected within 10 working days 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.

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

5.1.2.1 The HRPP staff will send correspondence to the Principal Investigator using TEMPLATE: Correspondence: Terminated Personnel – Study Staff which states:

5.1.2.1.1 A Personnel Change Request 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 up-to-date at the time of Continuing Review or Administrative Check-in, no further submissions will be processed.

5.1.3 If the notification is a change in employment status of a Principal Investigator so that he/she is no longer eligible to be a PI in accordance with TAMU SAP 15.01.01.M5.01.

5.1.3.1 The HRPP staff will send correspondence to the Principal Investigator and his/her Department Chair using TEMPLATE: Correspondence: Principal Investigator – Change in Status which states:

        5.1.3.1.1   To remain the Principal Investigator on the study the PI must submit written approval from the Department Head and Dean within 10 working days; or

        5.1.3.1.2   A new qualified Principal Investigator is to be selected within 10 working days by submitting a modification to the study; or

        5.1.3.1.3   The Principal Investigator may request study closure.

        5.1.3.1.4   Study is administratively closed if none of the options above are implemented.

    5.1.4   If the notification of terminated user or change in status is incorrect refer the individual to Human Resources or their department manager.

6 MATERIALS

    6.1   TEMPLATE - Correspondence: Terminated Personnel – Principal Investigator

    6.2   TEMPLATE - Correspondence: Terminated Personnel – Study Staff

    6.3   TEMPLATE - Correspondence: Principal Investigator – Change in Status

7 REFERENCES

    7.1   TAMU SAP 15.01.01.M5.01