**electronic Protocol Accrual Auditing Committee (ePAAC) Procedures**

**Notification & Response:**

1. ePAAC Coordinator will request the electronic database, Clinical Oncology Research system (CORe) to generate the Request for Information report.
   a. Electronic database is doing a search for the following criteria:
      i. Protocols that have been IRB approved for six months, but have not yet been activated.
      ii. Protocols which have been activated, but have had no accruals in the last six months.
      iii. Protocols that have been activated, but have had less than or equal to three accruals in the last six months.

2. ePAAC Coordinator will send out notifications through the electronic database (CORe) to the Principal Investigator (PI), Study Manager and Additional Contact.

3. PI is responsible for responding back to the ePAAC notification by the designated deadline.
   a. The PI can solicit help when filling out the form from either the Study Manager or Additional Contact but only the PI can electronically sign and submit the document.
   b. ePAAC Coordinator will receive an ePAAC Notification of Completed Response email from the electronic database (CORe) once the document has been submitted.
   c. If no response has been received from the PI, a follow-up notification is sent through the electronic database (CORe).

**Meeting Preparation:**

4. ePAAC Coordinator will update the electronic database (CORe) with the Meeting Category, Meeting Date and Response Category for each protocol.

5. ePAAC Coordinator will run a draft Meeting Agenda through the electronic database (CORe).

6. ePAAC Coordinator will review each protocol to make sure that there are no discrepancies in accrual or in the PI’s response.
   a. If discrepancies, then the ePAAC Coordinator will reach out to the PI for additional information.
     i. PI should respond back to clear up any unresolved issues before the ePAAC meeting.

7. ePAAC Coordinator will run the final Meeting Agenda.

**Meeting Process:**

8. Committee will meet to review the PI’s response to the ePAAC query and make a determination.

9. PI, Study Manager, and Additional Contact will be notified of the Committee’s decision via the electronic protocol system (PDOL).
a. Determination letters may be sent to the PI for closure, withdrawal, clarification or further justification if requested.

b. The PI will need to submit a request to the Institutional Review Board (IRB) via the electronic protocol system (PDOL) requesting closure or withdrawal by the designated deadline.

10. ePAAC Coordinator updates the electronic system (CORe) regarding meeting outcome.

**Appeals Process (Face-to-Face Meeting):**

11. The PI may appeal the ePAAC’s determination by responding through a generic memo via the electronic protocol system (PDOL).
   a. The PI’s response should give a robust justification for why the protocol should be kept open.

12. ePAAC Coordinator will gather all appeals and enter this information into the electronic database (CORe) to create an ePAAC Appeals Agenda.

13. The PI along with his/her Department Chair or Division Head will be asked to attend an ePAAC Appeals Meeting.

14. The PI and Department Chair or Division Head will give a brief justification as to why the protocol should be allowed to remain open.

15. The Committee will hold a closed session to discuss and make a final determination on the PI’s appeal.

16. ePAAC Coordinator sends a generic memo via the electronic protocol system (PDOL) regarding the ePAAC’s determination.
   a. Further action may be required by the PI based upon the ePAAC determination. Instructions will be given in the memo.

17. ePAAC Coordinator updates the electronic system (CORe) regarding appeal outcome.

**Contact Information:**

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