

PO/ISO Review of Protocol

Investigators are encouraged to meet with the PO/ISO prior to initiating submission so that issues can be addressed ahead of time.

1. Investigator or staff enter new project into eRRRP.
2. Investigator signs/submits in eRRRP indicating project is ready for review
3. eRRRP generates email to PO and ISO that a new project needs review.
4. PO and ISO conduct preliminary review within 10 working days of receiving email notification.
 - a. Preliminary review is a method to find problems with the submission. It is not a method to solve all issues or to go back and forth with the PI.
 - b. If issues are encountered, PO or ISO then logs comments which become part of the record.
 - c. Comments should not be addressed at this point of the review.
5. PO and ISO sign off and a preliminary report is generated to the IRB. Emails are generated to PI and IRB.
 - a. Email sent to IRB liaison.
 - i. IRB liaison logs report into eIRB and schedules review of protocol by IRB.
 - ii. IRB determines status of protocol
 - iii. Approval by IRB.
 - b. Email sent to Investigator.
 - i. If comments – Investigator should work on addressing the comments (continue to step 6)
 - ii. If no comments – investigator waits for IRB approval then continues to step 6
6. Investigator logs into eRRRP and continues submission to R&D Committee. At this point comments feature is available for responding to comments.
7. Investigator addresses comments by PO/ISO via eRRRP.
8. Protocol is assigned to R&D
9. Protocol is reviewed by R&D
10. PO and SIO grant final approval once all comments are addressed
11. ACOS releases project.

Amendments:

If an amendment requires a change in the transmission or management of data or authorization status then it must be reviewed by ISO and PO prior to approval. This will be accomplished by the SIO office sending all of the materials for review to the ISO and PO by email. At this point, there is no method of tracking amendments in eRRRP.