Human Subjects Application Review Process

Roll back FAQs

A roll back is when an eResearch Human Subjects submission is manually moved to a different state in the review process.

1. What constitutes the need for a roll back?
   - If a submission has been mistakenly moved to another state due to data entry error, a manual roll back can be administered.
   - If it has been determined that a submission needs to be reviewed by an ancillary committee during review in an IRB, a manual roll back is currently necessary and can be administered.
   - If eResearch is not functioning properly and a submission is not making its natural progression through the system.

2. What are some cases where a roll back is not appropriate?
   - To prevent the need for a new submission. Examples include, but are not limited to:
     o If core committee staff wants to reopen an approved submission to add a previously un-reviewed document to be sent back to a reviewer.
     o A submission is in the state Withdrawn.
     o If a submission is in the approved state based on board vote, and it is later determined by the board that the study should be discontinued.

3. What type of submissions can be rolled back?
   - Adverse events/ORIOS
   - HUMs (parent studies)
   - SCRs (continuing reports and terminations)

4. What type of submission should not be rolled back?
   - Amendments should not be rolled back once they are in the state of approved because they replace the parent. If an amendment has to be rolled back based on the criteria listed in section 1 of this document, future submissions are subject to error. It is generally recommended that another amendment is submitted to address the errors of the approved amendment.

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