GUIDANCE: Continuing Review Progress Report Instructions

Researchers can find instructions for submitting continuing reviews, or final reports, in the HRP 451- CHECKLIST – RUTH Continuing Review-Final Reports, which can be found in the RUTH checklist library This supplemental guidance pertains to the brief narrative summary of research progress.

In addition to including an explanation of each item left unchecked in Question 5 of the Continuing Review SmartForm in RUTH, please include:

- Enrollment Progress:
  - Briefly summarize the status of enrolled/active participants, including whether they have completed study activities or if not, what study activities remain.
  - If your study only involves the collection and analysis of *existing data,* please summarize the accrual of patient data here relative to the target sample size in your approved submission.
  - If there was over enrollment, please provide an explanation for the difference and whether any modifications will be made to compensate or update the original study. Please file a separate Reportable New Information (RNI) submission to report this occurrence and the proposed corrective actions.
  - If you are reporting withdrawals, including those lost to follow up, please give an explanation and note if dropouts or withdrawals occurred at a greater frequency than expected. If so, please explain what will be done to improve the situation and whether the protocol will be modified to improve retention and completion rates.
  - Summarize the demographics of participants to date and whether the protocol's sample diversity aims are being met. If the protocol lists the inclusion of non-English speakers, give the linguistic breakdown of participants to date.

- Study Progress:
  - The estimated date of study completion (to the point of reporting initial findings, not necessarily publication).
  - Describe the research activities that remain to be done before the project can be closed.
  - If this study involves a retrospective chart review component, indicate the date range, from the approved HRP-503, for which this study is approved to generate data and confirm that no data have been collected outside of this range.
  - Please explain if the study is experiencing delays or difficulties that may prolong the project.

- Findings
  - Provide a summary of initial findings and/or publications.

- If the study has already lapsed, please include a "late memo", and file an RNI.