

## QuickGuide: How to Respond to a Request for Modifications from CTO

CTO pre-screens the initial study-wide application submitted for projects before the REB of Record has been assigned. For projects using the clinical trial forms, the initial study-wide application is called the “Clinical Trial Initial Application (CTIA)”. For projects using the observational forms the initial study-wide application is called the “Observational Study Initial Application (OSIA)”. Once CTO deems the CTIA/OSIA is complete, it is released to the REB of Record. CTO also pre-screens all Participating Site Initial Application (PSIA) submissions.

If during the pre-screen CTO determines changes are required to the CTIA or OSIA, the application is sent back to the study team for changes and the form status changes to “CTO Revisions Required”. If the PSIA application is sent back for changes during pre-screening, the form status changes to “CTO Revisions Requested” (Figure 1).

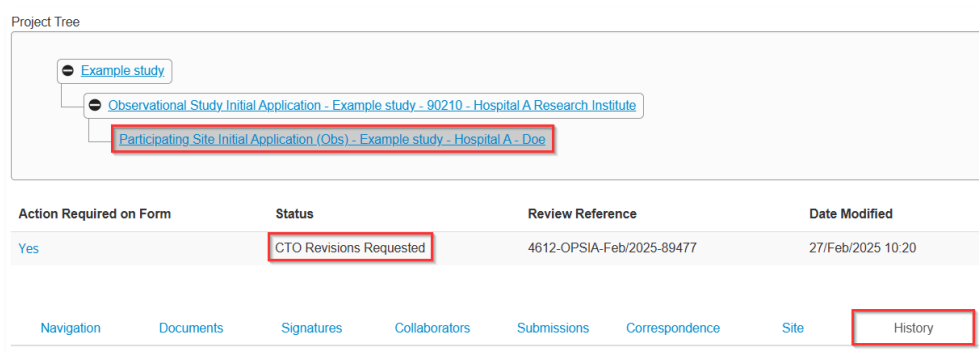


Figure 1

In either case an email notification is sent to the study team to notify them CTO has requested changes to the application, and a CTO Incomplete letter is issued containing a list of the required changes and clarifications. **CTO Incomplete letters are not attached to email notifications sent out by the system; they must be downloaded from the History tab of the application form in the system (Figure 2).**

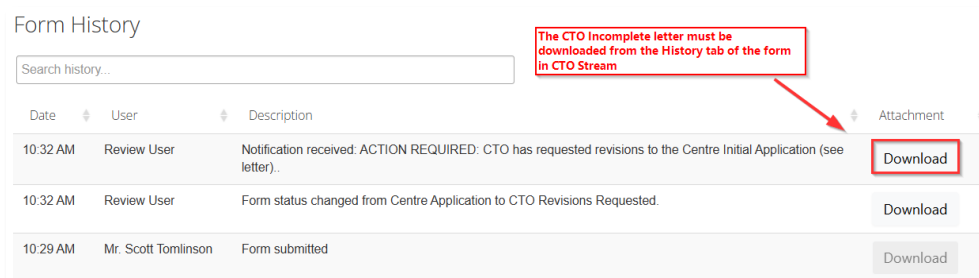


Figure 2

### To re-submit your application to CTO:

1. Ensure your answer to question 1.0 is “Yes” (Figure 1) to indicate you are re-submitting the form, unless the CTO screening letter instructs you otherwise.
  - a. Changing the response to question 1.0 to “Yes” causes a new section of the form to appear called, “Re-submission Information”.



Figure 1

