

Signing an REB of Record Study Agreement in CTO Stream: A User Guide for REB of Record Host Institution Representatives

Background:

The REB of Record Study Agreement (or Schedule E to the Participation Agreement), formally delegates REB review and oversight responsibilities to the REB of Record. This agreement is executed on a study-specific basis and signed by the Host Institution of the REB of Record (REB Host), the Institution Representative (i.e., legal signing authority) and the Principal Investigator at the participating site. This agreement must fully executed before the study can begin at any site that is delegating REB oversight from their local REB to the REB of Record.

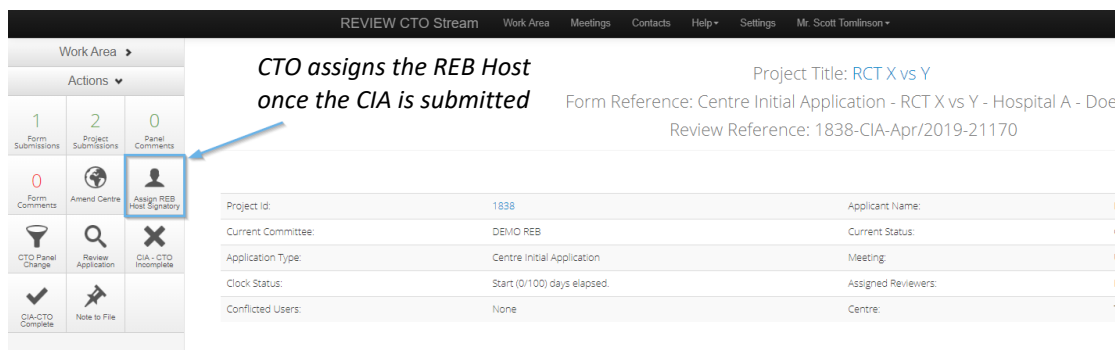
Previously, the REB of Record agreement was administered outside the CTO Stream system with wet-ink signatures. However, this meant it was possible for Centre Initial Applications (CIAs) to receive ethics approval in CTO Stream before the REB of Record agreement was fully executed, leading to a delay of the start of the study at the site. To better facilitate the administration of these agreements and reduce delays, all signatures will now be done within CTO Stream.

In addition to CTO’s usual screening criteria, **all CIAs must now have all three signatures in place** (REB of Record Host, Institution Representative and PI at the participating site) before CTO can screen the CIA through to the REB of Record. Once the REB Host signature is applied, it is possible the CIA is marked as incomplete by CTO and sent back to the study team for changes. In this case, **the REB host signature is not required on the re-submission** of the form.

Process for signing CIA as REB of Record Host

Step 1: CTO Assigns REB Host Institutional Representative once CIA is submitted by study team

Once CTO assigns the REB Host Institutional Representative in CTO Stream, the assigned individual will receive an email from the CTO Stream system with the subject, *“REB Host Institutional Representative Signature Required – [Study Title]”*. This email will serve as notice that a new site has joined the study and requires approval from the REB host in CTO Stream. This email comes from donotreply@infonetica.net.



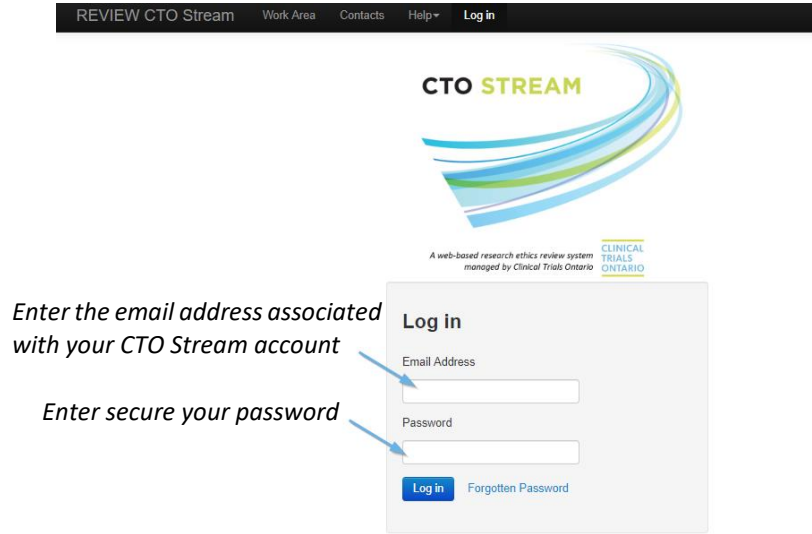
The screenshot shows the CTO Stream interface. On the left is a sidebar with an 'Actions' menu. One of the actions is 'Assign REB Host Signatory', which is highlighted with a blue box and a blue arrow. The main content area displays a notification: 'CTO assigns the REB Host once the CIA is submitted'. To the right of the notification, there is a header for 'Project Title: RCT X vs Y' and 'Form Reference: Centre Initial Application - RCT X vs Y - Hospital A - Doe'. Below this is a table with project details:

Project Id:	1838	Applicant Name:	
Current Committee:	DEMO REB	Current Status:	
Application Type:	Centre Initial Application	Meeting:	
Clock Status:	Start (0/100) days elapsed.	Assigned Reviewers:	
Conflicted Users:	None	Centre:	

Note: CTO recommends that REB Hosts create an inbox rule using the above email subject and sender address, to keep all requests in the same folder.

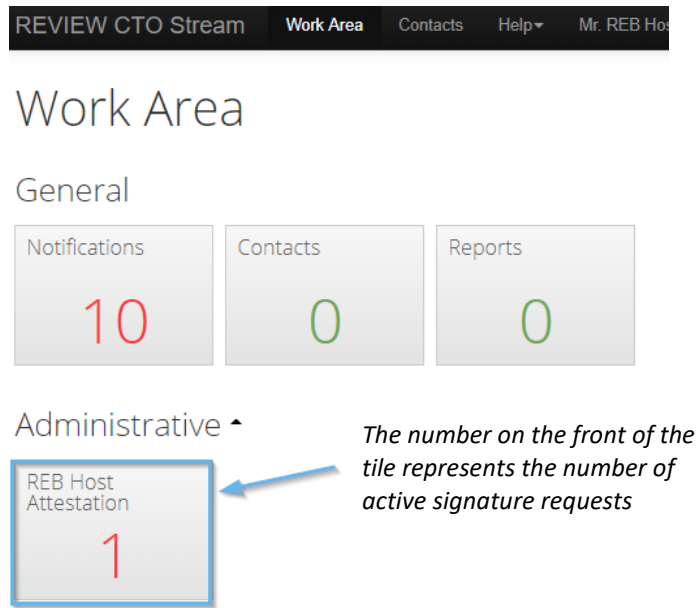
Step 2: REB Host logs into CTO Stream account

Once the REB Host receives the email notification from CTO Stream notifying them that their signature is required on the CIA, they should log in to their CTO Stream account at <https://review.ctostream.ca>.



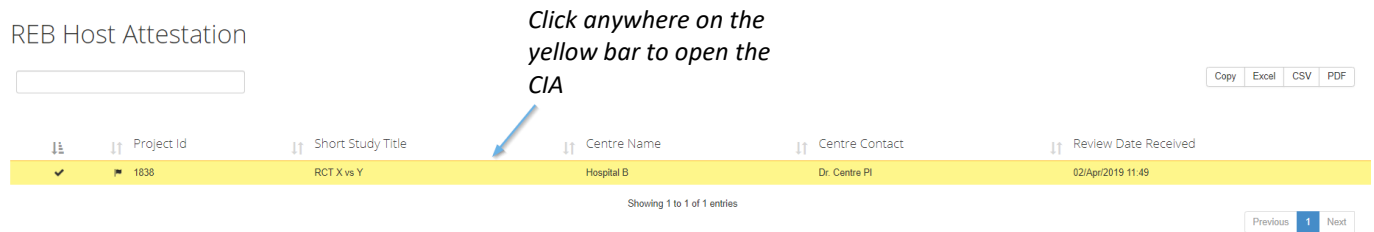
Step 3: REB Host Work Area

When the REB Host logs into the system they will be automatically directed to the 'Work Area'. Within the Work Area is an Administrative tile called, "REB Host Attestation" which will display a red number reflecting the number of active signature requests currently awaiting signature in CTO Stream. Click anywhere on this tile to view the CIA applications within.



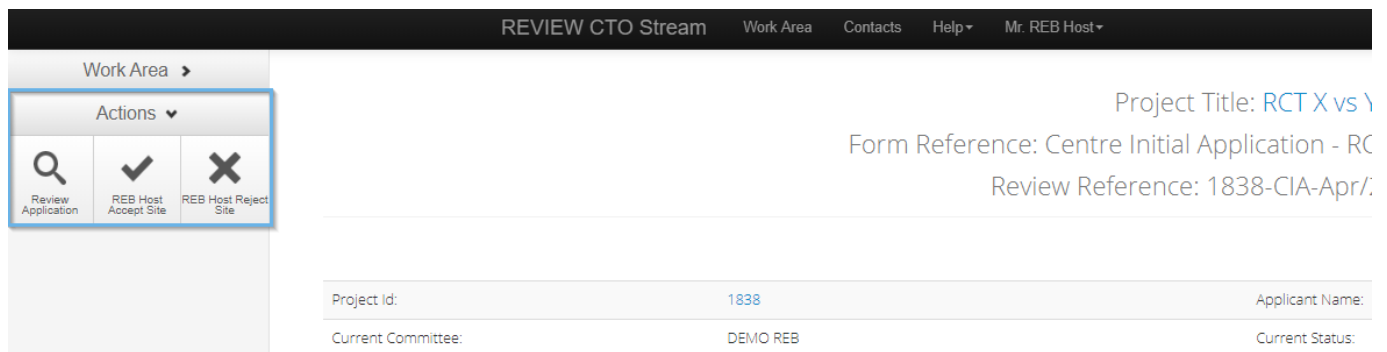
Step 4: REB Host accesses CIA submission within CTO Stream

Inside the REB Host Attestation tile is a list of all CIA submissions waiting for signature from the REB Host. Click anywhere on the yellow bar containing the CIA you wish to open and sign-off.

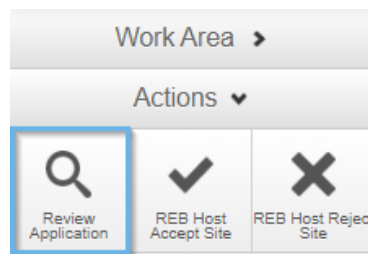


Step 5: REB Host Accepts or Rejects signature request

Once inside the CIA submission has been opened, you will be taken to the submission timeline. At the top left-hand side of the screen are three action buttons (Review Application, REB Host Accept Site and REB Host Reject Site) Each action is described below.

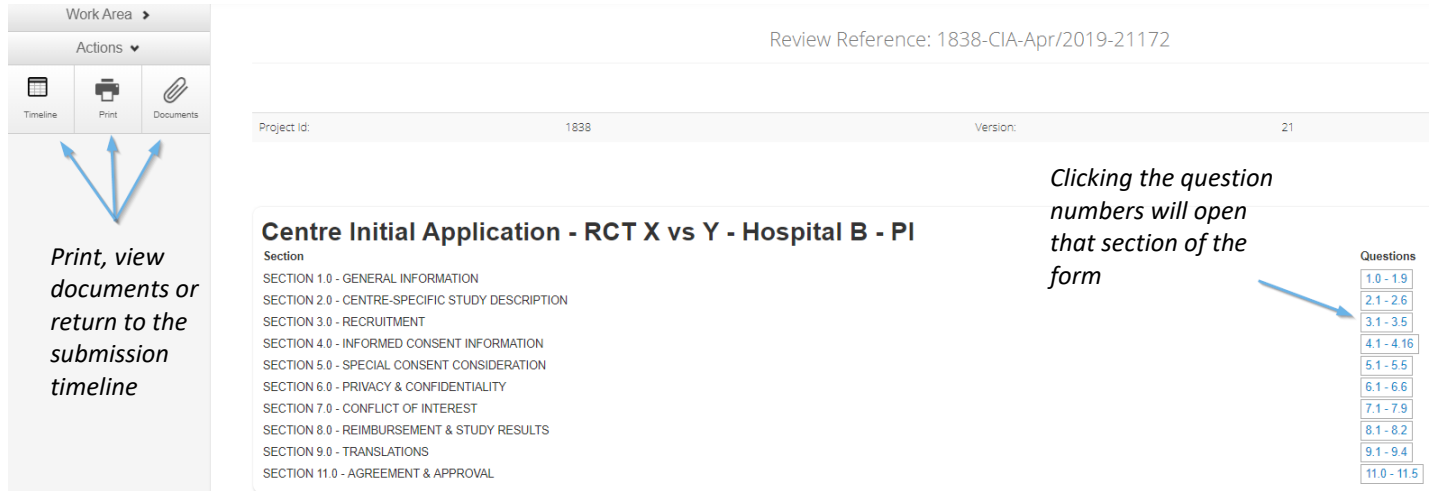


5a: Review Application

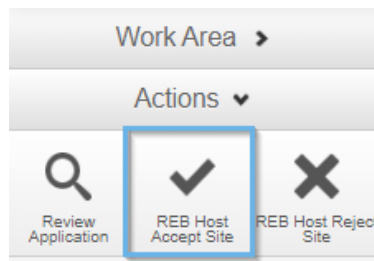


If desired, the REB Host can review the contents of the CIA application by pressing the 'Review Application' button. This takes you to the table of contents view for the form and from here you can open any section of the form you wish to view by clicking the corresponding question numbers for that section on the right side of the

screen. The Action Menu displays three actions which allow you to view the uploaded documents, print or return to the submission timeline.



5b: REB Host Accept Site

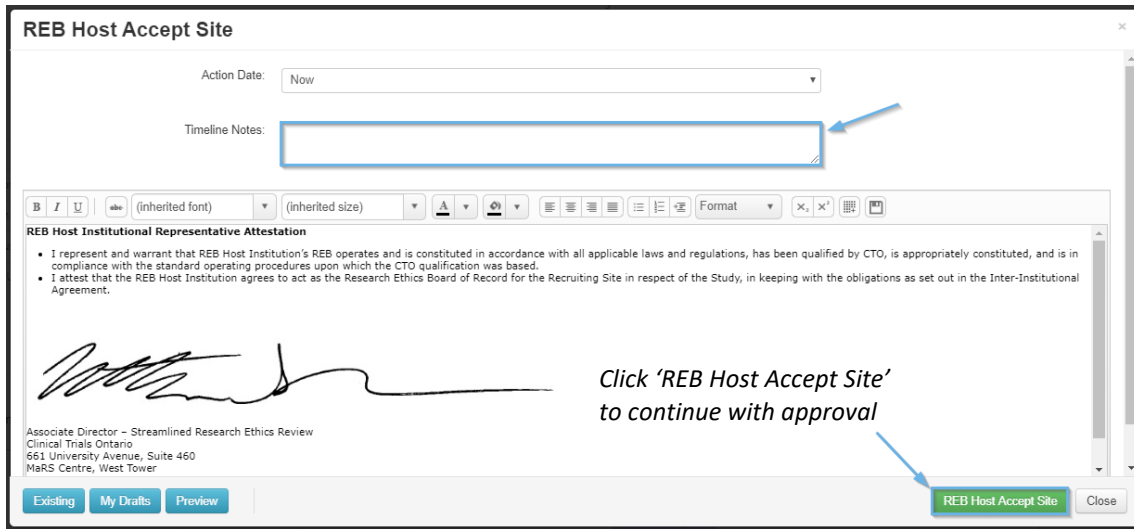


To accept the study on behalf of the REB of Record the REB Host must press the ‘REB Host Accept Site’ action button. Once the button is pressed a document template will appear in a pop-up window with the attestation language and electronic signature of the REB Host. (Note: this template should not be modified).

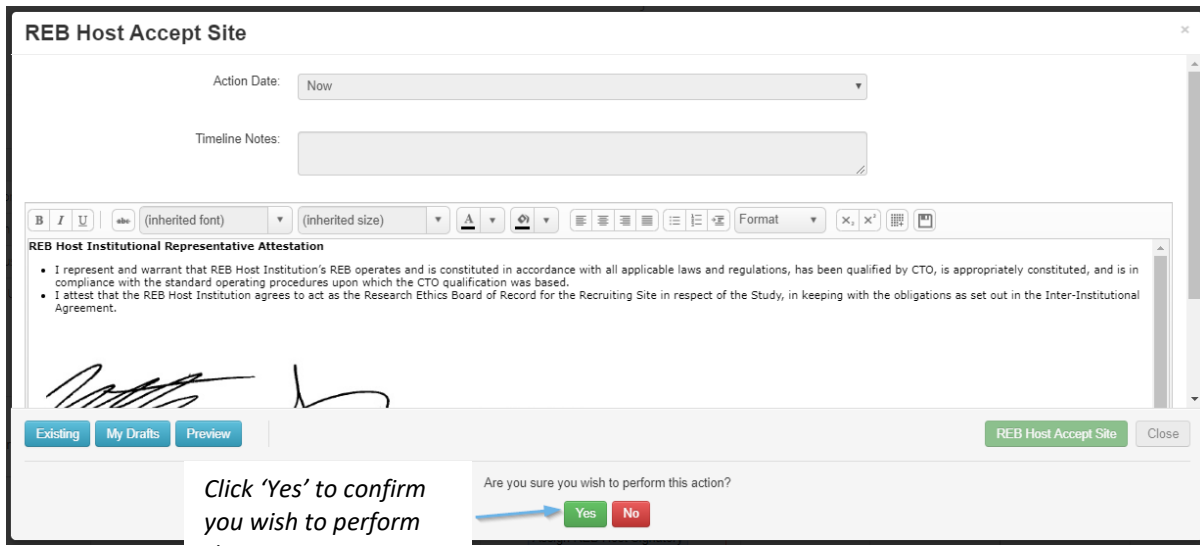
The attestation language reads:

1. *I attest that the REB Host Institution agrees to act as the Research Ethics Board of Record for the Recruiting Site in respect of the Study, in keeping with the obligations as set out in the Inter-Institutional Agreement or REB of Record Agreement.*

To continue with the site approval, press the green ‘REB Host Accept Site’ button at the bottom right-hand corner of the pop-up window.

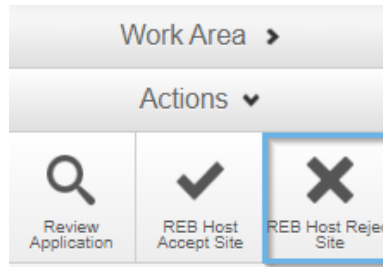


Next click 'Yes' to confirm that you wish to perform this action. You also have the option to create a "Timeline Note" that will be displayed along with your decision on the submission timeline for the CIA.



Once the action has been confirmed, an email notification will be delivered to CTO Staff informing them that the REB Host has accepted the new recruiting site. CTO will then proceed with screening the CIA through to the REB of Record. The CIA will no longer appear REB Host Attestation tile of the Work Area.

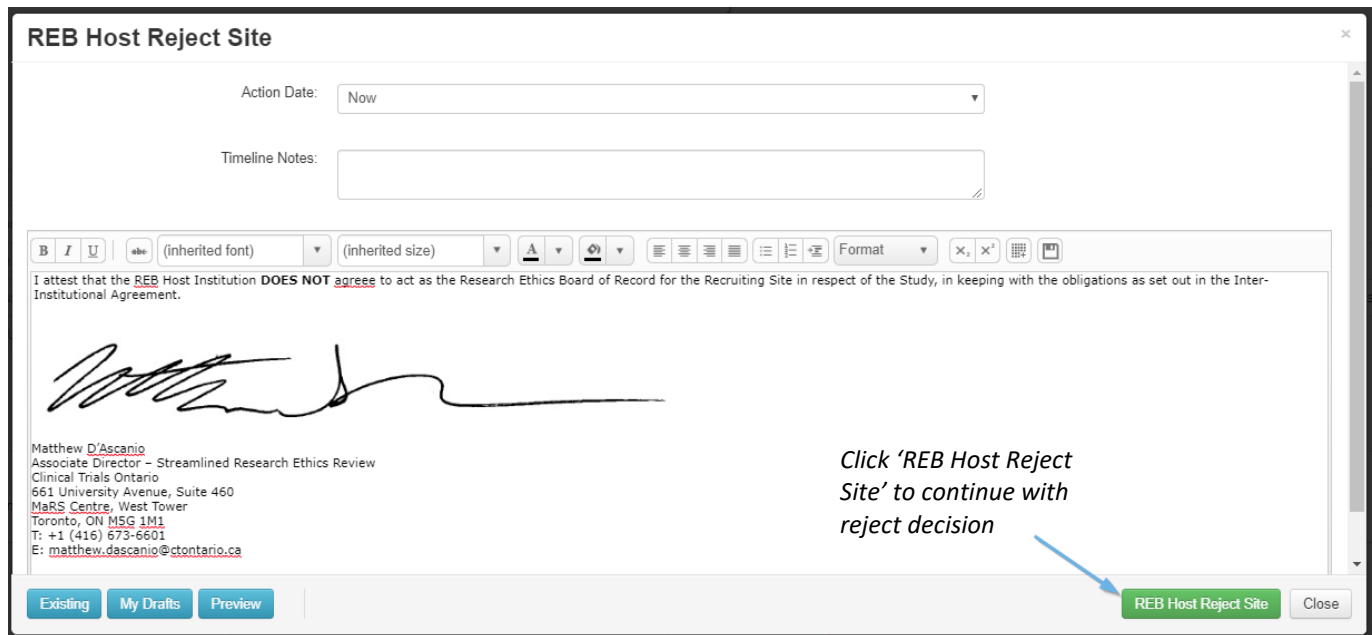
5c: REB Host Reject Site



Pressing 'REB Host Reject Site' will decline the study on behalf of the REB of Record. Once the button is pressed, a document template will appear in a pop-up window with an attestation saying,

*"I attest that the REB Host Institution **DOES NOT** agree to act as the Research Ethics Board of Record for the Recruiting Site in respect of the Study, in keeping with the obligations as set out in the Inter-Institutional Agreement."* (Note: this template should not be modified).

To continue with rejecting the recruiting site, press 'REB Host Reject Site' in the bottom right-hand corner of the pop-up window. Similar to the Approval decision, you will need to confirm you wish to perform this action.



Once the REB host rejects the site on behalf of the REB of Record, a notification will be sent to CTO Staff to inform them of the decision and the CIA will automatically be withdrawn.