

CTO STREAM APPLICATION SIGNATURE REQUIREMENTS

Appendix 2: Signature Requirements for the CTO Stream REB Submissions

Exception: The Board of Record reserves the right to request the Lead Applicant or Principal Investigator signature at any time (i.e., if the re-submission or subsequent correspondence involves significant revisions related to safety information).

Note: Delegated signatories must be listed on the study delegation log prior to assuming this responsibility. A copy of the delegation log could be requested at the discretion of the Board of Record.

Type of Application	Required Signatures
Clinical Trial Initial Application or Observational Study Initial Application	
First time the Clinical Trial Initial Application or Observational Study Initial Application is submitted	Lead Applicant Lead Co-Applicant (if included in the application)
Subsequent correspondence to Clinical Trial Initial Application or Observational Study Initial Application (i.e., in response to requests for modifications from the REB)	Lead Applicant or Delegate
Study Wide Post Approval Form	
First time Study-Wide post approval form is submitted <u>For example:</u> <ul style="list-style-type: none"> • Study-Wide Amendment • Study-Wide Reportable Event • Study-Wide Continuing Review • Study-Wide Study Closure 	Lead Applicant
Study-Wide Amendment involving only a change to: <ul style="list-style-type: none"> • Contact details for Lead Applicant/Co-Applicant • Name/contact details of main contact 	Lead Applicant or Delegate
Subsequent correspondence to any post approval form (i.e., in response to requests for modification from the REB)	Lead Applicant or Delegate
Participating Site Initial Application	
First time Participating Site Initial Application is submitted	Principal Investigator Co- Investigator (if included in the application)

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	<p>For TOH/OHRI studies: Department Head / Department Approver</p> <ul style="list-style-type: none"> • Exceptions: <ul style="list-style-type: none"> ○ Division Head for studies from Department of Medicine and Department of Surgery ○ Deputy Scientific Director, Practice Changing Research of the Research Program Director if Department Head conflicts with the application. <p>For UOHI/OHIRC studies: Division Head</p> <ul style="list-style-type: none"> • Exceptions: <ul style="list-style-type: none"> ○ Chief Scientific Officer if Division Head conflicts with the application. ○ CEO if Chief Scientific Officer conflicts with the application. <p>Primary Representative</p>
<p>Subsequent correspondence to Participating Site Initial Application (i.e., in response to requests for modifications from the REB)</p>	<p>Principal Investigator or Delegate</p>
<p>Participating Site Post Approval Form</p>	
<p>First time Participating Site post approval form is submitted</p> <p>For example:</p> <ul style="list-style-type: none"> • Participating Site Amendment • Participating Site Reportable Event • Participating Site Continuing Review • Participating Site Study Closure 	<p>Principal Investigator</p>
<p>Participating Site Amendment to change Principal Investigator (PI): (e.g., the current PI is being replaced with a new PI)</p>	<p>Principal Investigator (new)</p> <p>For TOH/OHRI studies: Department Head / Department Approver</p> <ul style="list-style-type: none"> • Exceptions: <ul style="list-style-type: none"> ○ Division Head for studies from Department of Medicine ○ Deputy Scientific Director, Practice Changing Research of the Research Program Director if Department Head conflicts with the application.

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	<p>For UOHI/OHIRC studies: Division Head</p> <ul style="list-style-type: none"> • Exceptions: <ul style="list-style-type: none"> ○ Chief Scientific Officer if Division Head conflicts with the application. ○ CEO if Chief Scientific Officer conflicts with the application. <p>Primary Representative</p>	
Participating Site Amendment to change Co-Investigator (Co-I): (e.g., addition of a new Co-I or replacement of the current Co-I with a new Co-I)	Principal Investigator Co-Investigator (new)	
Participating Site Amendment involving only a change to: <ul style="list-style-type: none"> • Contact details for PA/Co-Applicant • Name/contact details of main contact 	Principal Investigator or Delegate	
Subsequent correspondence to any post approval form (i.e., in response to requests for modification from the REB)	Principal Investigator or Delegate	
<p><u>Exceptions to the signature process:</u></p> <p>The Board of Record reserves the right to request the Principal Investigator signature at any time.</p>		
Revision History		
Version Number	Effective Date	Summary of Changes
Version 4	April 30, 2025	Updated CTO application names and position titles for when the Department Head or Division Head are in conflict with the REB application.
Version 3	September 27, 2022	Updated instruction for TOH/OHRI Department Head signs for clarity; added instruction for UOHI/OHIRC Division Head sign off; added pagination
Version 2	January 12, 2022	Updated instruction for TOH/OHRI Department Head signs (replaced “supervisor” with “Dr. Bill Cameron”); updated Amendment descriptions for clarity
Version 1	October 2, 2019	Initial Version
This N2-CAREB SOP Addendum has been reviewed and approved by the OHSN-REB Administrative Committee.		