

CTSUS OPEN Rave Request Form

OMB #xxxx-xxxx
Expiration Date: xx/xx/xxxx

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (OMB#0925-0753). Do not return the completed form to this address.

Use this form to initiate the development of a new protocol in OPEN and Rave, or to update an Eligibility Checklist for an existing protocol.

Submit the completed form to the OPEN Registrar team (CTSUSOPENForms@westat.com). Please contact the OPEN team for any questions regarding the form. All questions marked with a red asterisk (*) must be completed.

For Rave protocols, an individual from the Lead Protocol Organization (LPO)¹ must notify CTSUS of the Rave production release date to configure the Rave production settings.

SECTION I – Protocol and Request Information		
1.1*	Protocol Name/Number: <i>(As specified by PIO)</i>	e.g. E2410
1.2*	Protocol Form Public ID(s): <i>(Please indicate the associated step # for each public ID)</i>	
1.3*	Protocol CRF Name:	
1.4*	Protocol CRF Version #:	
1.5*	LPO Name:	
1.6*	Date of Request:	Click here to enter a date.
1.7*	Type of Modification: <i>(Check all that apply)</i>	<input type="checkbox"/> New submission <input type="checkbox"/> Addition of questions <input type="checkbox"/> Deletion of questions <input type="checkbox"/> Question setup changes (such as data type, question order, help text) <input type="checkbox"/> Major wording changes (impacts responses) <input type="checkbox"/> Minor wording changes to questions (does not impact responses) <input type="checkbox"/> Change in valid values (addition, deletion, update) <input type="checkbox"/> Updates to the Rave information <input type="checkbox"/> Edit check updates

¹ LPO is used in this document to represent the lead organization for the protocol.

SECTION I – Protocol and Request Information

1.8	If this Request is for a Revision of the EC, Provide the Revised CDE ID #s:	
1.9*	Estimated OPEN Release Date:	Click here to enter a date.

SECTION II – OPEN and RSS Setup Information

2.1*	Specify RandoNode URL:	e.g. https://webapps.ecog.org/RandoNode/services/RandoNode					
2.2*	Indicate the Protocol Type: (Check one)	<input type="checkbox"/> Treatment <input type="checkbox"/> Prevention					
2.3*	List the Protocol's RSS Step Information. Select from the drop down list of step descriptions.	Reqd?	Step #	Count Accrual Step (select one)	Step Description	Specify Rave Transactions that OPEN will Handle:	
						Patient Initialization	
						Transfer EC Data	
		e.g. Yes	e.g. 1	<input checked="" type="checkbox"/>		e.g. Yes	e.g. Yes
				<input type="checkbox"/>	Select or type.		
		<input type="checkbox"/>	Select or type.				
		<input type="checkbox"/>	Select or type.				
		<input type="checkbox"/>	Select or type.				
2.4*	Is an Embedded Ancillary Protocol Associated with this Protocol?	<input type="checkbox"/> Yes <input type="checkbox"/> No					
2.5	If Yes, Indicate Whether the Embedded Ancillary Protocol is Optional or Mandatory:	<input type="checkbox"/> Optional <input type="checkbox"/> Mandatory					
2.6*	Is this a Slot Reservation Protocol?	<input type="checkbox"/> Yes <input type="checkbox"/> No					
2.7*	Is this a Rave Protocol:	<input type="checkbox"/> Yes <input type="checkbox"/> No (If No, skip to section V, only applies to legacy trials)					

SECTION III – Rave Information

3.1*	Name of the Rave Instance that will Host this Protocol:	e.g. ECOG-ACRIN			
3.2*	URL of the Rave Instance that will Host this Protocol:	e.g. https://ecog-acrin.mdsol.com			
3.3*	Rave Study Names: (Must match the protocol # in RSS)	PROD	e.g. E2410		
		UAT	e.g. E2410 (UAT)		
3.4*	OPEN-Rave ALS Version Used for the Protocol?	<input type="checkbox"/> 4.0 <input type="checkbox"/> 5.1/5.2 <input type="checkbox"/> 6.0			

3.5	<p>Use the OPEN-Rave Supplemental Checklist to ensure the Rave configurations and study setup are completed correctly. <i>(Not for submission to the CTSU)</i></p>	<p>CTSU-OPEN-Rave-RequestForm-SupplementalChecklist.docx</p>
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SECTION IV –Rave and RSS Setup Information

See the **Supplemental Checklist** for additional information regarding the integrations and the required testing.

4.1*	<p>Is this a Balance protocol?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, LPO should use Rave ALS version 6.0* or above)</p>
4.2*	<p>Is this a Rave-CTEP-AERS Integration Protocol? (should use the Standard CTSU AE, AER, LAE and LAER forms) (RSS caAERS Load Flag)</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, LPO should use Rave ALS version 5.1 or above) *This is required for all new CTEP IND trials</p>
4.3*	<p>Does this protocol use TSDV based on site auditing? (TSDV Flag)</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, LPO should use Rave ALS version 5.2* or above) *This is required for all new Rave trials</p>
4.4*	<p>Does this protocol use central monitoring? (CM Flag)</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, LPO should use Rave ALS version 6.0* or above) *This is required for all new CTEP IND trials</p>
4.5*	<p>Will this trial be available on the Data Quality Portal (DQP Flag)</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No *This is required for all new Rave trials</p>
4.6*	<p>Is this an ePRO protocol?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
4.7*	<p>Will this protocol use CTSU imaging portal?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>

SECTION V – LPO Comments

5.1	<p>Comments: <i>(Optional)</i></p>	
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SECTION VI – LPO Contact Information

6.1*	<p>LPO OPEN Contact: <i>(The contact at the LPO for the protocol's OPEN configuration questions)</i></p>	<p>Name: Click here to enter text. Phone: Click here to enter text. E-Mail: Click here to enter text.</p>
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SECTION VI – LPO Contact Information

6.2*	LPO Rave Contact: <i>(The contact at the LPO for the protocol's Rave configuration questions)</i>	Name: Click here to enter text. Phone: Click here to enter text. E-Mail: Click here to enter text.
6.3*	LPO Sign Off: <i>The LPO ensures the accuracy of this form and that all integration testing per the supplemental checklist is completed prior to study activation in OPEN and Rave</i>	Name: Click here to enter text. Date: Click here to enter a date.

SECTION VII – Form Download (To be Completed by CTSU)

7.1*	CTSU Reviewer Name:	
7.2*	Date of Form Download:	Click here to enter a date.