

CTSU OPEN Rave Request Form

OMB# 0925-0753
Expiration Date: 07/31/2021

Public reporting burden for this collection of information is estimated to average **10** 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 7074, Bethesda, MD 20892-7974, ATTN: PRA (OMB#0925-0753). Do not return the completed form to this address.

**Corrected
time in
burden
statement
from 5 to 10
minutes per
SSA**

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 (CTSUOPENForms@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 CTSU 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>	
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:	
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
1.8	If this Request is for a Revision of the EC, Provide the Revised CDE ID #s:	
1.9 *	Estimated OPEN Release Date:	
SECTION II – OPEN and RSS Setup Information		
2.1	Specify RandoNode URL:	Remove Question

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

SECTION II – OPEN								
2.1*	Indicate the Protocol Type (Check one)	<div style="border: 2px solid red; padding: 2px; display: inline-block;">Remove question</div> <input type="checkbox"/> Treatment <input type="checkbox"/> Prevention						
2.2*	List the Protocol's RSS Step Information. Select from the drop down list of step descriptions.	Reqd?	Count	Step #	Step Description	Specify Rave Transactions that OPEN will Handle:		
		e.g. Yes	Accrual Step			Patient Initialization	Transfer EC Data	
				e.g. 1	<input type="text"/>	e.g. Yes	e.g. Yes	
					<input type="text"/>			
					<input type="text"/>			
2.3*	Is an Embedded Ancillary Protocol Associated with this Protocol?	<input type="checkbox"/> Yes <input type="checkbox"/> No						
2.4	If Yes, Indicate Whether the Embedded Ancillary Protocol is Optional or Mandatory:	<input type="checkbox"/> Optional <input type="checkbox"/> Mandatory						
2.5*	Is this a Slot Reservation Protocol?	<input type="checkbox"/> Yes <input type="checkbox"/> No						
2.6*	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:	
3.2*	URL of the Rave Instance that will Host this Protocol:	
3.3*	Rave Study Names: (Must match the protocol # in RSS)	PROD
		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 <input type="checkbox"/> 7.0
3.5	Use the OPEN-Rave Supplemental Checklist to ensure the Rave configurations and study setup are completed correctly. (Not for submission to the CTSU)	CTSU-OPEN-Rave-RequestForm-SupplementalChecklist.docx

SECTION IV –Rave and RSS Setup Information

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

4.1*	Is this a Balance protocol?	<input type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, LPO should use Rave ALS version 6.0* or above)
4.2*	Is this a Rave-CTEP-AERS Integration Protocol? (should use the Standard CTSU AE, AER, LAE and LAER forms) (RSS caAERS Load Flag)	<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
4.3*	Does this protocol use TSDV based on site auditing? (TSDV Flag)	<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
4.4*	<p>Does this protocol use central monitoring the source document portal for central monitoring? (CM Flag)</p> <p>Rephrased question 4.4 when the CM portal was renamed Source Document Portal.</p> <p>Add section below line on right</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> <p>If yes, provide: Step Number: <input type="text"/></p> <p>If this is <u>Not</u> a new activation, enter effective date, otherwise leave blank: Select Effective Date: Click or tap to enter a date.</p> <p>OR, use protocol activation date: <input checked="" type="checkbox"/></p> <p>Patient Selection Method: <input type="text"/></p> <p>Patient 1st X <input type="text"/> (Leave blank if 'All' or Manual is selected)</p> <p>Patient Next Y <input type="text"/> (Leave blank if 'All' or Manual is selected)</p>
4.5*	Will this trial be available on the Data Quality Portal (DQP Flag)	<input type="checkbox"/> Yes <input type="checkbox"/> No *This is required for all new Rave trials
4.6*	Is this an ePRO protocol?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.7*	Will this protocol use the CTSU Imaging Portal	Remove question

SECTION V – LPO Comments

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

6.1*	LPO OPEN Contact: <i>(The contact at the LPO for the protocol's OPEN configuration questions)</i>	Name: Phone: E-Mail:
6.2*	LPO Rave Contact: <i>(The contact at the LPO for the protocol's Rave configuration questions)</i>	Name: Phone: E-Mail:
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: Date:

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

7.1*	CTSU Reviewer Name:	
7.2*	Date of Form Download:	