 OPEN Oncology Patient Enrollment Network

 CTSU Cancer Trials Support Unit — A SERVICE OF THE NATIONAL CANCER INSTITUTE — Linking practice to progress

CTSU OPEN Rave Request

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 sponsored, 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 (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:** *(As specified by PIO, e.g., E2410)*			
1.2*	**Indicate the Protocol Type** *(Check one)*	Treatment ☐ Cancer Control/Prevention ☐ CCDR ☐		
1.3*	**Protocol Form Public ID(s):** *(Please indicate the associated step # for each public ID)*	**Public Form ID**	**Step #**	**Registration Type**
				Choose an item.
				Choose an item.
				Choose an item.
				Choose an item.
				Choose an item.
1.4*	**Protocol CRF Name:**			
1.5*	**Protocol CRF Version #:**			
1.6*	**LPO Name:**			
1.7*	**Date of Request:**			

1.8*	**Type of Modification:** *(Check all that apply)*	☐ New submission ☐ Addition of questions ☐ Deletion of questions ☐ Question setup changes (such as data type, question order, help text) ☐ Major wording changes (impacts responses) ☐ Minor wording changes to questions (does not impact responses) ☐ Change in valid values (addition, deletion, update) ☐ Updates to the Rave information ☐ Edit check updates
1.9	**If this Request is for a Revision of the EC, Provide the Revised CDE ID #s:**	
1.10*	**Estimated OPEN Release Date:**	

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

SECTION II – OPEN and RSS Setup Information

List the Protocol's RSS Step Information. Select from the drop down list of step descriptions.

2.1*	Reqd?	Step #	Step Description	Specify Rave Transactions that OPEN will Handle:			
				Patient Initialization	**Transfer EC Data**	**Non-Patient Initialization**	**Transfer Non-Patient EC Data**
	e.g. Yes	e.g. 1		e.g. Yes	e.g. Yes	e.g. Yes	e.g. No

2.2*	**Specify Randonode URL (if different from default URL):**	
2.3*	**Is an Embedded Ancillary Protocol Associated with this Protocol?**	☐ Yes ☐ No
2.4	**If Yes, Indicate Whether the Embedded Ancillary Protocol is Optional or Mandatory:**	☐ Optional ☐ Mandatory
2.5*	**Is this a Slot Reservation Protocol?**	☐ Yes ☐ No
2.6	**If Yes, Indicate the step associated with Slot Reservation** *(Slot Reservation can only be applied to one step)*	Step: _____
2.7*	**Is this a Rave Protocol:**	☐ Yes ☐ No (If No, skip to section V, only applies to legacy trials)
2.8*	**Will this protocol use IROC credentialing?**	☐ **Yes** ☐ **No**

For 2.8:

If yes, indicate each type of credentialing that will be collected in OPEN (i.e. IMRT, 3D).

Type of Credentialing	Required
	Choose an item.
	Choose an item.
	Choose an item.

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,* e.g. E2410 or e.g. E2410 (UAT)*)*	**PROD**	
		UAT	
3.4*	**OPEN-Rave ALS Version Used for the Protocol?**	☐4.0 ☐5.1/5.2 ☐6.0 ☐7.0 ☐7.1 (RN should be upgraded to support ALS 7.0 or higher) CTSU-CDISC-CCDR RandoNode Setup	
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 Rave-CTEP-AERS Integration Protocol? (should use the Standard CTSU AE, AER, LAE and LAER forms) (RSS caAERS Load Flag)**	☐ Yes ☐ No (If Yes, LPO should use Rave ALS version 5.1* or above) (This is required for all new CTEP IND trials)
4.2*	**Does this protocol use TSDV based on site auditing? (TSDV Flag)**	☐ Yes ☐ No (If Yes, LPO should use Rave ALS version 5.2* or above) (This is required for all new Rave trials)
4.3*	**Will this trial be available on the Data Quality Portal (DQP Flag)**	☐ Yes ☐ No (If Yes, ☐ check if the study will not use Rave calendaring) Note: if Rave calendaring is not used, the DQP Delinquent Forms and DQP Form Status modules will not be available (This is required for all new Rave trials)
		If yes, will this trial use the standard Phase 2/3 form timeliness windows?* **☐ Yes ☐ No** ***The standard Phase 2/3 form timeliness windows have been defined by the Data Quality Working Group as 15 days for baseline forms, 30 days for treatment forms, and 60 days for follow up forms. A standard for Phase 1 trials has not been established; this form will be updated with the standard Phase 1 form timeliness windows once**

		available. **If the trial will not use the standard Phase 2/3 form timeliness windows, provide the timeliness windows below:** **Baseline forms are delinquent** ☐ **after days.** **Treatment forms are delinquent** ☐ **after days.** **Follow up forms are delinquent after** ☐ **days.**
4.4*	**Does this protocol use the source document portal for Central Monitoring? (CM Flag)** (*NCTN Groups may elect to use the SDP for central monitoring of trials as they see appropriate.*)	☐ Yes ☐ No (If Yes, LPO should use Rave ALS version 6.0* or above) (This is required for select registration trials and trials as determined by CTEP) **If yes, provide:** Step Number: ☐ If this is Not a new activation, enter effective date, otherwise leave blank: Select Effective Date: Click or tap to enter a date. **OR,** use protocol activation date: ☐ Patient Selection Method: Choose an item. Patient 1st X ☐ (Leave blank if 'All' or 'Manual' is selected.) Patient Next Y ☐ (Leave blank if 'All' or 'Manual' is selected.)
4.5*	**What method will be used to assign reviewable data points in Rave?**	☐ **Rave architect** ☐ **Dynamic data points/edit checks** ☐ **Rave architect and Dynamic data points/edit checks**
4.6*	**Does this protocol use the source document portal for Eligibility Review?**	☐ Yes ☐ No (If Yes, LPO should use Rave ALS version 6.0* or above) **If yes, provide:** Step Number: ☐ If this is Not a new activation, enter effective date, otherwise leave blank: Select Effective Date: Click or tap to enter a date. **OR,** use protocol activation date: ☐ Patient Selection Method: Choose an item.

		Patient 1st X [_____] (Leave blank if 'All' or 'Manual' is selected.)
		Patient Next Y [_____] (Leave blank if 'All' or 'Manual' is selected.)
4.7*	**Is this an ePRO protocol?**	☐ Yes ☐ No

SECTION V – LPO Comments		
5.1	**Comments:** *(Optional)*	

SECTION VI – LPO Contact Information		
6.1*	**LPO OPEN Contact:** *(The contact at the LPO for the protocol's OPEN configuration questions)*	Name: Phone: E-Mail:
6.2*	**LPO Rave Contact:** *(The contact at the LPO for the protocol's Rave configuration questions)*	Name: Phone: E-Mail:
6.3*	**LPO Sign Off:** *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*	Name: Date:

SECTION VII – Form Download (To be Completed by CTSU)		
7.1*	**CTSU Reviewer Name:**	
7.2*	**Date of Form Download:**	