

CTSUS 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 review 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.

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* | Indicate the Protocol Type <i>(Check one)</i> | Treatment <input type="checkbox"/> Cancer Control/Prevention <input type="checkbox"/> CCDR <input type="checkbox"/> | | |
| 1.3* | Protocol Form Public ID(s): <i>(Please indicate the associated step # for each public ID)</i> | Public Form ID | Step # | Registration Type |
| | | | | Choose an item. |
| | | | | Choose an item. |
| | | | | Choose an item. |
| | | | | Choose an item. |
| 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: | |

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.

| | Reqd? | Step # | Step Description | Specify Rave Transactions that OPEN will Handle: | | | |
|------|--|--------|---|--|------------------|----------------------------|------------------------------|
| | | | | Patient Initialization | Transfer EC Data | Non-Patient Initialization | Transfer Non-Patient EC Data |
| 2.1* | e.g. Yes | e.g. 1 | | e.g. Yes | e.g. Yes | e.g. Yes | e.g. No |
| | | | Select or type. | | | | |
| | | | Select or type. | | | | |
| | | | Select or type. | | | | |
| | | | Select or type. | | | | |
| 2.2* | Specify Randonode URL (if different from default URL): | | | | | | |
| 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 | If Yes, Indicate the step associated with Slot Reservation <i>(Slot Reservation can only be applied to one step)</i> | | Step: _____ | | | | |
| 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) | | | | |
| 2.8 | Will this protocol use IROC credentialing? | | <input type="checkbox"/> Yes <input type="checkbox"/> No | | | | |

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: <i>(Must match the protocol # in RSS)</i> | 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 <input type="checkbox"/> 7.0 <input type="checkbox"/> 7.1 *RN should be upgraded to support ALS 7.0 CTSUS-CDISC-CCDR RandoNode Setup |
| 3.5 | Use the OPEN-Rave Supplemental Checklist to ensure the Rave configurations and study setup are completed correctly. <i>(Not for submission to the CTSUS)</i> | CTSUS-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 CTSUS 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 |
| 4.2* | 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 |
| 4.3* | Will this trial be available on the Data Quality Portal (DQP Flag) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Check if legacy study/Rave calendaring is not used *This is required for all new Rave trials |
| 4.4* | Does this protocol use the source document portal for Central Monitoring? (CM Flag) | <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 If yes, provide: Step Number: <input type="text"/> 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: <input type="checkbox"/> Patient Selection Method: Choose an item. Patient 1 st X <input type="text"/> (Leave blank if 'All' or 'Manual' is selected.) Patient Next Y <input type="text"/> (Leave blank if 'All' or 'Manual' is selected.) |

| | | |
|------|---|---|
| 4.5* | Does this protocol use the source document portal for Eligibility Review? | <input type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, LPO should use Rave ALS version 6.0* or above) |
| | | <p>If yes, provide: Step Number: <input type="text"/></p> <p>If this is Not 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 type="checkbox"/></p> <p>Patient Selection Method: Choose an item.</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> |

SECTION V – LPO Comments

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

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| 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* | CTSUS Reviewer Name: | |
| 7.2* | Date of Form Download: | |