CTSU OPEN Rave Request Form

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

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 **Cl**earance Branch, 6705 Rockledge Drive, MSC 7074, Bethesda, MD 20892-7974, ATTN: PRA (OMB#0925-0753). Do not return the completed form to this address.

OMB# 0925-0753

Expiration Date: 07/31/2021

*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]](#footnote-1) must notify CTSU of the Rave production release date to configure the Rave production settings.

| 1. SECTION I – Protocol and Request Information
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| --- |
| 1.1\* | 1. Protocol Name/Number:

*(As specified by PIO)* |  |
| 1.2\* | 1. Protocol Form Public ID(s):

*(Please indicate the associated step # for each public ID)* |  |
| 1.3\* | 1. Protocol CRF Name:
 |  |
| 1.4\* | 1. Protocol CRF Version #:
 |  |
| 1.5\* | 1. LPO Name:
 |  |
| 1.6\* | 1. Date of Request:
 |   |
| 1.7\* | **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 |
| 1.8 | 1. If this Request is for a Revision of the EC, Provide the Revised CDE ID #s:
 |  |
| 1.9\* | 1. Estimated OPEN Release Date:
 |   |

| 1. SECTION II – OPEN and RSS Setup Information
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| 2.1 | Specify RandoNode URL: | e.g https://webapps.ecog.org/RandoNode/services /RandoNodeRemove Question |
| 2.1\* | Indicate the Protocol Type: *(Check one)* | [ ]  Treatment [ ]  Prevention |
| 2.2\* | 1. List the Protocol’s RSS Step Information.
2. Select from the drop down list of step descriptions.
 | Reqd?e.g.Yes | Count Accrual Step | Step # | Step Description | Specify Rave Transactions that OPEN will Handle: |
|  |  | Patient Initialization | Transfer EC Data |
|  |  | e.g. 1 | Select or type. | e.g. Yes | e.g. Yes |
| **Remove this column** |  |  |   |  |  |
|  |  |  |   |  |  |
|  |  |  | . |  |  |
|  |  |  | . |  |  |
| 2.3\* | 1. 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\* | 1. Is this a Slot Reservation Protocol?
 | [ ]  Yes [ ]  No |
| 2.6\* | 1. Is this a Rave Protocol:
 | [ ]  Yes [ ]  No (If No, skip to section V, only applies to legacy trials) |

**Remove question**

| 1. SECTION III – Rave Information
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| 3.1\* | 1. Name of the Rave Instance that will Host this Protocol:
 |  |
| 3.2\* | 1. URL of the Rave Instance that will Host this Protocol:
 |  |
| 3.3\* | 1. Rave Study Names:

*(Must match the protocol # in RSS)* | 1. PROD
 |  |
| UAT |  |
| 3.4\* | 1. OPEN-Rave ALS Version Used for the Protocol?
 | [ ]  4.0 [ ]  5.1/5.2 [ ]  6.0 [ ]  7.0 |
| 3.5 | 1. 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](https://www.ctsu.org/open/Group_Resources/Forms/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\* | 1. Is this a Balance protocol?
 | ☐ Yes ☐ No (If Yes, LPO should use Rave ALS version 6.0\* or above) |
| 4.2\* | 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 |
| 4.3\* | **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 |
| 4.4\* | **Does this protocol use ~~central monitoring~~ the source document portal for central monitoring? (CM Flag)****Add section below line on right****Rephrased question 4.4 when the CM portal was renamed Source Document Portal.**  | ☐ Yes ☐ 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: 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: [x] 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\* | **Will this trial be available on the Data Quality Portal (DQP Flag)** | ☐ Yes ☐ No\*This is required for all new Rave trials |
| 4.6\* | **Is this an ePRO protocol?** | ☐ Yes ☐ No**Remove question** |
| 4.7\* | **Will this protocol use the CTSU Imaging Portal**  | ☐ Yes ☐ No |

| 1. SECTION V – LPO Comments
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| 5.1 | 1. Comments:

*(Optional)* |  |

| 1. SECTION VI – LPO Contact Information
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| 6.1\* | 1. LPO OPEN Contact:

*(The contact at the LPO for the protocol’s OPEN configuration questions)* | Name: Phone: E-Mail:  |
| 6.2\* | 1. LPO Rave Contact:

*(The contact at the LPO for the protocol’s Rave configuration questions)* | Name: Phone: E-Mail:  |
| 6.3\* | 1. LPO Sign Off:
2. *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:  |

| 1. SECTION VII – Form Download (To be Completed by CTSU)
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| 7.1\* | 1. CTSU Reviewer Name:
 |  |
| 7.2\* | 1. Date of Form Download:
 |   |

1. LPO is used in this document to represent the lead organization for the protocol. [↑](#footnote-ref-1)