

Protocol Eligibility Criteria (EC) Checklist Submission Process for OPEN

1. The Lead Protocol Organization (LPO) creates the Eligibility Criteria/Enrollment/Registration Form (EC Checklist) for their protocol.
2. The LPO reviews the form for Common Data Elements (CDE) compliance and creates an eCRF in Form Builder. (Form Builder is the metadata repository that is part of the NCI's Cancer Data Standards Repository (caDSR)).
3. Once the form is compliant, the LPO will complete and submit the OPEN Rave Request Form to the CTSU OPEN Team at CTSUOPENForms@westat.com. The submitting LPO should complete sections I through VI on the request form.
4. CTSU OPEN Team will download the EC form into the User Acceptance Testing (UAT) environment of OPEN.
5. Once the form is loaded into OPEN, the CTSU OPEN Team will notify the submitting LPO.
6. The LPO will review the EC Checklist Form in OPEN. If there are any required changes, the LPO will make the required changes in Form Builder and will re-submit the OPEN Rave Request Form to the CTSU OPEN Team. The CTSU OPEN Team will re-download the form in OPEN.
7. The LPO will set up the form, apply the validation checks and test the form in OPEN. Once the LPO completes their testing, they will notify the OPEN Team. The OPEN Team will test the EC Form and notify the LPO of any findings.
8. When the EC Checklist is finalized and the protocol is ready for activation, the LPO will contact the CTSU OPEN Team to migrate the EC Form from UAT to the Production environment of OPEN.
9. The OPEN Team will notify the LPO and other CTSU staff that the form was released to production.
10. Any updates to the EC forms require resubmission of the OPEN Rave Request Form to the CTSUOPENForms@westat.com for re-downloading to OPEN.