ECP Registry - Site Regulatory Binder Table of Contents Guide

1. ECP Registry Directory	▸ Key Operational Contacts for the ECP Registry ▸ All Contact Information from your site including the Principal investigator, all Co-Investigators, Research Coordinator(s), and all site staff involved in the ECP Registry
2. Screening and Enrollment	▸ Screening Log
3. CMS Approval Letters	▸ ECP Registry CMS Approval Letter Dated 1/7/14 ▸ CMS Approval letter for ECP Registry Amendment 10/14/14
4. IND Waiver Letter	▸ Letter Dated 3/20/13
5. CDRH email on ECP Registry	▸ Email Dated 7-30-13
6. IRB Initial Approval Letter	▸ Initial Notification of Approval
7. IRB Approved Current Protocol	▸ Protocol ▸ Investigator Signature Page
8. Informed Consent	▸ IRB Approved Versions of ICF ▸ HIPAA Authorization (If a separate document from the ICF) ▸ Partial Waiver of HIPPA Authorization

9. IRB Approved Advertising Materials	▸ IRB Approval letters for any materials
10. Protocol Amendments/IRB Approval Letters	▸ IRB approval letter for all protocol amendments ▸ PI Signature page for all amendments
11. All Significant IRB Communication	▸ IRB Submission Forms /Contingency letters ▸ SOP for reporting AEs and SAEs at your Center ▸ IRB notification and responses to SAE reports ▸ Close out/final report notice
12. Annual IRB Renewal	▸ Progress Reports ▸ Annual IRB renewal
13. IRB Roster/FWA	▸ IRB membership information ▸ Federal Wide Assurance
14. Certification/Human Subject Protection	▸ Education and training documentation on human subject protection for all investigators and research team members
15. Curriculum Vitae (CV) / Licenses	▸ Signed and dated CVs from the PI, Co-Investigators, research coordinators, and site staff (updated every two years) ▸ Current medical license, medical specialty, and board certification number (if applicable) for all Principal and Co-investigators

16. ECP Delegation of Authority Log	▸ This is the study personnel responsibility list. This log includes: name, signature, initials and delegated study related tasks of all individuals involved in the trial.
17. Laboratory	▸ Laboratory Accreditation/Certification CAP/ CLIA Certifications ▸ Lab normal ranges for labs performed in this study ▸ Lab Director's CV and Medical License
18. Credentialing	▸ Completion of Electronic Training ▸ ECP Standard of Operating Procedures ▸ ECP Credentialing letter from CCC
19. Site Monitoring	▸ Site Initiation Visit Log ▸ Site Monitoring Visit Log ▸ CCC Site Initiation and Activation Letter ▸ CCC Site Monitoring Reports ▸ Site Close Out Visit Report
20. Protocol Violations/Deviations	▸ Correspondence related to protocol violations and/or deviations
21. DSMB Correspondence	▸ DSMB Correspondence
22. JCAHO	▸ Joint Commission: Accreditation, Certification

23. Site Correspondence	▸ Other Study related communication (letters, memos, written documentation of telephone conversations, facsimiles, newsletters, copies of electronic correspondence with the CCC and DCC)