

Standard Operating Procedures

**WVCTSI Clinical Trials Center of Excellence**

The WVCTSI Clinical Trials Center of Excellence Standard Operating Procedures will provide harmonized guidance to help define standard practices and ensure execution of human subject research is in accordance with institutional, state and federal regulations.

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| **SOP Number** | **Title**  | **Version** | **Date of Issuance** | **Date Effective** |
| COE-101.00 | Mission, Goals and Governance | 1.0 | 16Apr2021 | 17May2021 |
| COE-102.00 | External Audit Management | 1.0 | 16Apr2021 | 17May2021 |
| COE-103.00 | Quality Management System and Standards | 1.0 | 15Oct2021 | 15Nov2021 |
| COE-104.00 | Registration of Clinical Trials  | 1.0 | 16Apr2021 | 17May2021 |
| COE-105.00 | Clinical Research Personnel Responsibilities and Training Program | 1.0 | 16Apr2021 | 17May2021 |
| COE-106.00 | Utilization of OnCoreTM for Clinical Research  | 1.0 | 16Apr2021 | 17May2021 |
| COE-107.00 | OnCoreTM: Access | 1.0 | 16Apr2021 | 17May2021 |
| COE-108.00 | ClincialTrials.gov Disclosure | 1.0 | 16Apr2021 | 17May2021 |
| COE-109.00 | Safety Reporting: Adverse Events, Unanticipated Adverse Device Effect, Protocol Deviations and UPIRTSO | 1.0 | 16Apr2021 | 17May2021 |
| COE-110.00 | Informed Consent Process: Development and Implementation | 1.0 | 16Apr2021 | 17May2021 |
| COE-111.00 | External Safety Reports | 1.0 | 16Apr2021 | 17May2021 |
| COE-112.00 | Medicare Coverage Analysis | 1.0 | 16Apr2021 | 17May2021 |
| COE-113.00 | Data Management: Security, Confidentiality, Sharing, Transmission, and Archiving | 1.0 | 16Apr2021 | 17May2021 |
| COE-114.00 | Use of EPIC for Clinical Trials: Research Order Sets | 1.0 | TBD |  |
| COE-115.00 | Investigational Product Management | 1.0 | 16Apr2021 | 17May2021 |
| COE-116.00 | Biospecimen Management | 1.0 | 13Jan2022 | 14Feb2022 |
| COE-117.00 | Sponsor/CRO Communication | 1.0 | 16Apr2021 | 17May2021 |
| COE-118.00 | Institutional Review Board (IRB) Communication | 1.0 | 16Apr2021 | 17May2021 |
| COE-119.00 | Clinical Trials Risk Assessment and Appeals Process | 1.0 | 16Apr2021 | 17May2021 |
| COE-120.00 | Electronic Signatures | 1.0 | 16Apr2021 | 17May2021 |
| COE-121.00 | External Monitoring/Access | 1.0 | 16Apr2021 | 17May2021 |
| COE-122.00 | Advarra eReg System Administration | 1.0 | 16Apr2021 | 17May2021 |
| COE-123.00 | eReg Training and Access | 1.0 | 16Apr2021 | 17May2021 |
| COE-124.00 | Clinical Research Participant Recruitment | 1.0 | 13Jan2022 | 14Feb2022 |