

Standard Operating Procedures

The WVCTSI Clinical Trial Center of Excellence (COE) has issued Standard Operating Procedures that provide harmonized guidance to help define standard practices and ensure execution of human subject research is in accordance with institutional, state and federal regulations. Research personnel responsible for human subject research are encouraged to read and understand the SOPs.

These SOPs will become effective on May 17, 2021 and can be accessed here:

<https://www.wvctsi.org/clinicaltrialscoe/clinicaltrials SOP/>

Information/training sessions have been planned as follows:

| | SOP Number | SOP Title | Date | Time |
|-----------|------------|--|-----------|------------------|
| Session 1 | COE-101.00 | Mission, Goals and Governance | 3-May-21 | 11:00 to 12:00 |
| | COE-121.00 | Remote monitoring/access | | |
| | COE-102.00 | External Audit Management | | |
| Session 2 | COE-106.00 | Utilization of OnCore™ for Clinical Research | 5-May-21 | 2:00 to 3:00pm |
| | COE-107.00 | OnCore: Access | | |
| | COE-122.00 | Advarra eReg System Administration | | |
| | COE-123.00 | eReg Training and Access | | |
| Session 3 | COE-108.00 | ClinicalTrials.gov Disclosure | 7-May-21 | 12:00 to 1:00pm |
| | COE-110.00 | Informed Consent Process | | |
| | COE-109.00 | Safety Reporting: Adverse Events, Unanticipated Adverse Device Effect, Protocol Deviations and UPIRISO | | |
| | COE-120.00 | Electronic Signatures | | |
| | COE-111.00 | External Safety Reports | | |
| Session 4 | COE-105.00 | Clinical Research Personnel Responsibilities and Training Program | 10-May-21 | 11:00 to 12:00pm |
| | COE-112.00 | Medicare Coverage Analysis | | |
| | COE-115.00 | Investigational Product Management | | |
| | COE-113.00 | Data Management: Security, Privacy, Sharing, Transmission, and Archiving | | |
| Session 5 | COE-117.00 | Sponsor Communication | 12-May-21 | 1:00 to 2:00pm |
| | COE-118.00 | IRB Communication | | |
| | COE-119.00 | Risk Management | | |
| | COE-104.00 | Registration of Clinical Trials with the Center of Excellence | | |

Please indicate which sessions you plan on attending to obtain the zoom information: [RSVP](#)

The sessions have associated assessments and certificates can be provided for completed assessments as needed.

The sessions will be recorded and posted on the WVCTSI YouTube channel [here](#) for any team members that are not able to attend the live sessions and wish to view them at a later time.

If you have questions, please do not hesitate to contact Shelley Welch or Tanya Moran, Co-Directors, Clinical Trials Center of Excellence.

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