## SOP 11: CLO Monitor Qualifications

### Overview:

The Consortium Lead Organization (CLO) Principal Investigator (PI) and Site Coordinator (SC) are responsible for the following tasks:

* 1. Identifying staff to conduct monitoring visits at Participating Organizations (POs); and
  2. Ensuring that CLO monitoring staff are adequately trained and qualified to assure that research sites are in compliance with applicable regulations and Division of Cancer Prevention (DCP) procedures and guidance documents.

### CLO Monitor Qualifications:

Each CLO Monitor must meet the following requirements prior to conducting any monitoring visits:

1. Two or more years of recent work experience in a clinical research environment or in a facility where adult clinical studies are conducted;
2. Monitoring experience or training, to include:
   1. Minimum of six months of monitoring experience as a site monitor for a Contract Research Organization (CRO), pharmaceutical company, or other, and experience that included chart reviews and an assessment of regulatory compliance; or
   2. At least two site monitoring training visits at any institution with a trained and more experienced site monitor or auditor for clinical studies. Training opportunities with a representative from the DCP Monitoring Contractor may be available, with prior approval from DCP; and
3. Review of the following:
   1. DCP Consortia 2012 Standard Operating Procedures (SOPs);
   2. International Conference on Harmonization (ICH) E6, Good Clinical Practice (GCP); and
   3. [SOP 11a: CLO Monitor Qualification Checklist](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP11a-CLO-Monitor-Qualifications-Checklist.docx)*.*

Additionally, it is recommended that CLO monitoring staff attend a professional training course as part of their orientation and maintain documentation of attendance. The training course should include applicable site monitoring topics, such as: 1) ethics regarding the conduct of clinical studies; 2) responsibilities of the sponsor, investigator, and monitor; 2) application of GCP guidelines; 3) informed consent process; 4) regulatory and informed consent documentation; 5) source documentation; 6) protocol compliance; 7) case report forms; 8) pharmacy operations; and 9) adverse event reporting.

The Society of Clinical Research Associates (SoCRA), Association of Clinical Research Professionals (ACRP), and Barnett Educational Services are examples of organizations that offer this type of professional training course, however, staff are not limited to these courses.

### Documentation Requirements:

The CLO is responsible for maintaining the following information for each CLO Monitor:

1. Current CV;
2. Documentation of site monitoring training visits, if applicable;
3. Certificate of completion of a professional training course, and copy of the course syllabus or agenda, if applicable; and
4. Signed and completed [SOP 11a: CLO Monitor Qualification Checklist](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP11a-CLO-Monitor-Qualifications-Checklist.docx)*.*

This documentation should be readily accessible, and may be requested by DCP, the DCP Regulatory Contractor, and/or the DCP Monitoring Contractor.

### Additional information:

Refer to the [DCP Acronym List](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/DCP-Acronym-List.docx) to see the description of commonly used acronyms in this SOP.

**Please send questions and comments to the DCP Help Desk at:**

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