## SOP 11a: CLO Monitor Qualifications Checklist

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| --- | --- |
| CLO Monitor Name: |  |

1. Work Experience

|  | **Initial** |
| --- | --- |
| Two or more years of recent work experience in a clinical research environment or in a facility where adult clinical studies are conducted. |  |

1. Monitoring Experience and/or Training *(Must initial at least one)*

|  | **Initial** |
| --- | --- |
| 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; and/or |  |
| At least two site monitoring training visits at any institution with a trained and more experienced Site Monitor or Auditor for clinical studies.  *(Record date, name of trainer, and site)*  Training Visit #1:  Training Visit #2:  Additional Visits: |  |

1. Review of Procedures and Regulations

|  | **Initial** |
| --- | --- |
| DCP Consortia 2012 Standard Operating Procedures |  |
| ICH E6, Good Clinical Practice |  |

1. Documentation Requirements

|  | **Initial** |
| --- | --- |
| Current CV on file *(required)* |  |
| Documentation of at least two site monitoring training visits *(if applicable)* |  |
| Certificate of completion of a professional training course, and copy of the course syllabus *(if applicable)* |  |

**Comments:**

CLO Monitor Signature: Date: