- Blinding

2. Real and potential sources of error in critical data collection and reporting
   - Conduct & documentation of procedures & assessments related to
     - Critical study endpoints
     - Protocol-required safety
     - Evaluating, documenting & reporting SAEs and UPIRSOs, subject deaths, & withdrawals
   - Adherence to protocol eligibility criteria
   - Conduct & document procedure for ensuring study blind is maintained (if appropriate)
   -

National Institute of Child Health and Human Development (NICHD)
(http://www.nichd.nih.gov/funding/policies/upload/Final_NICHD_Clinical_Research_Monitoring_Policy.pdf (Link Checked in March 1, 2017)

FDA: Guidance for Industry Oversight of Clinical Investigations- A Risk-Based Approach to Monitoring Draft Guidance
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