MONITOR (CRA) TRAINING CHECKLIST

Monitor / Trainee:
The Date of Training refers to the date the material was introduced to the monitor. This can be done via verbal review, demonstration, didactic lecture, self study module, reference book or regulation review or attendance at a contact hour course. Date Completed refers to the date the monitor/trainee finished the task. N/A = not applicable. ND = not done.

Task	**Date of Training**	**Date Completed**
Introduction to Role of Monitors in GCP Clinical Trials		
CRA Job Description		
History of the Regulations		
Regulations: 21 CFR 812 and 814 21 CFR 50 & 56 21 CFR 312 and 314 ICH Guidelines International Regulations State Laws		
FDA Guidance Documents (list)		
FDA Information Sheets (list)		
FDA Compliance Program Guidance Manuals		
NIH Regulated Research		
HHS Sponsored Research		
The Nuremberg Code		
The Declaration of Helsinki		
The Belmont Report		
Good Clinical Practices		
IRB Role and Functions		
Types of IRBs		
How to Work Effectively With IRBs		
Confidentiality / Privacy		
HIPAA Training (U.S)		
Use of Central and Core Labs in Clinical Studies and Required Monitoring / Documentation		
PI Responsibilities (review of 1572 and Investigator Agreements)		
Legal Issues in Clinical Trials – What is indemnity?		
Budgetary Issues		
Billing in Clinical Trials – brief overview of issues for sites		

Task	Date of Training	Date Completed

Informed Consent and Monitoring
• QA of Templates
    o ICF Checklist
    o Basic and Additional Elements
• Use of Lay Language Glossary for terms
• Review and Approval of Site Modifications
• Review and Approval of IRB Modifications
• IRB Approval and Version Control
• Documentation of ICF and Monitoring
• The Consent Process
• Required Signatures
• Legally Authorized Representatives
• Pediatric Assent
• Short Form
• ICF Deviations / Date Discrepancies		

Protocol Design		
CRF and Data Management		
Monitoring Plans		
Required Monitoring Visits • Pre Study Qualification Visit • Site Initiation • Interim • Study close out		
Required Monitoring Correspondence and Reports		
Required Regulatory Documents		
Meeting with Investigators		
Document Control		
AE, SAE, UADE and required reporting / follow-up		
Protocol Violation / Deviation Documentation, Corrective Action Plans, Reporting and Follow-up		
Recruitment, Retention, Compliance		
Test Article Accountability		
Errors, Misconduct and Fraud		
Common Monitoring Problems		
Resources		
Quality Assurance and GCP		

Task	**Date of Training**	**Date Completed**
FDA / OHRP / IRB Audits		
BioResearch Monitoring of Sponsors, Monitors and CROs		
BioResearch Monitoring of Investigators and IRBs		
BioResearch Monitoring of Sponsors, Monitors and CROs		
BioResearch Monitoring of Investigators and IRBs		
Review of CRF and CRF Manual or directions		
Mock completion of CRF		
Review of Monitoring Plan and assignment of sites		
Monitoring Forms and Checklists		
Training on blank forms:		

• Source Documentation Worksheets
• CRF Transmittal
• Data Clarification Forms
• Monitoring Visit Data Correction Form
• Fax Transmittal Sheets to Sponsor
• Investigator Agreements
• Financial Disclosure Forms
    o FDA 3454
    o FDA 3455 or
    o Sponsor Specific
• Non-Disclosure / Confidentiality Agreements
• Site Signature Page
• Delegation of Duties Form
• Device Accountability Logs
• Shipping Logs / Certifications
• Study Supplies and associated (re) order forms for sites
• Regulatory Binder Template sent to sites
• ICF Checklist and Glossary of Lay Terms
• Telephone logs
• SAE and UADE Reporting		

• Contact Lists		

Task	**Date of Training**	**Date Completed**
Study Specific SOPs – when they are used		
Monitoring SOPs		
Travel Arrangements / Travel Files / Reimbursement Forms / Trip Report		
Maps / Directions to Sites		
Time & Attendance		
Required Investigator Training and Documentation		
GCP Flip Chart or Power Point to use with Investigator Training		
Mentoring Assignments		
FDA Debarment List http://www.fda.gov/ora/compliance_ref/debar/default.htm Disqualified/Restricted/Assurances List For Clinical Investigators http://www.fda.gov/ora/compliance_ref/bimo/dis_res_assur.htm Public Health Service Administrative Actions Listing (Note: This is not an FDA document.) http://silk.nih.gov/public/cbz1bje.@www.orilist.html		
Other:		