Study Start Up Training Checklist For Research Staff

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Protocol Training Module

- ☐ Read entire protocol thoroughly
- ☐ Attend protocol training session
- ☐ Review protocol synopsis
- ☐ Understand inclusion/exclusion criteria
- ☐ Learn visit schedule and procedures
- ☐ Review primary and secondary endpoints
- ☐ Understand safety monitoring plan
- ☐ Complete protocol knowledge assessment
- ☐ Training Date: _____
- ☐ Trainer: _____
- ☐ Score: _____

Good Clinical Practice (GCP)

- ☐ Complete GCP certification course
- ☐ Review ICH-GCP guidelines
- ☐ Understand FDA regulations (21 CFR)
- ☐ Learn about research ethics
- ☐ Review informed consent process
- ☐ Understand participant rights
- ☐ Learn documentation standards
- ☐ Pass GCP examination
- ☐ Certificate Date: _____
- ☐ Expiration: _____

Regulatory Training

- ☐ Review IRB/EC requirements
- ☐ Understand consent form process
- ☐ Learn about protocol deviations
- ☐ Review adverse event reporting
- ☐ Understand privacy regulations (HIPAA)
- ☐ Learn document retention requirements
- ☐ Review audit preparation
- ☐ Complete regulatory quiz
- ☐ Completion Date: _____

Safety Training

- ☐ Review safety monitoring plan
- ☐ Learn SAE identification and reporting
- ☐ Understand AE grading scales
- ☐ Practice safety event documentation
- ☐ Review emergency procedures
- ☐ Learn unblinding procedures (if applicable)
- ☐ Understand SUSAR reporting
- ☐ Complete safety assessment
- ☐ Training Hours: _____

System Training

- ☐ Complete EDC system training
- ☐ Practice data entry scenarios
- ☐ Learn query resolution process
- ☐ Understand CTMS navigation
- ☐ Review document management system
- ☐ Learn randomization system (IWRS/IXRS)
- ☐ Practice drug accountability system
- ☐ Obtain system access credentials
- ☐ Systems Trained: _____

Laboratory Training

- ☐ Review lab manual
- ☐ Learn specimen collection procedures
- ☐ Understand processing requirements
- ☐ Review shipping procedures
- ☐ Practice labeling requirements
- ☐ Learn centrifuge operation
- ☐ Understand temperature requirements
- ☐ Complete lab competency assessment
- ☐ Lab Certification: _____

Study Procedures Training

- ☐ Practice informed consent discussion
- ☐ Learn screening procedures
- ☐ Review enrollment process
- ☐ Practice visit procedures
- ☐ Learn physical exam requirements
- ☐ Review questionnaire administration
- ☐ Practice device operation
- ☐ Demonstrate procedure competency
- ☐ Procedures Mastered: _____

Documentation Training

- ☐ Learn source documentation standards
- ☐ Practice ALCOA-C principles
- ☐ Review note-to-file procedures
- ☐ Understand correction procedures
- ☐ Learn filing system
- ☐ Practice CRF completion
- ☐ Review query response process
- ☐ Complete documentation exercise
- ☐ Exercise Score: ـــــــــــــــــ

Drug/Device Training

- ☐ Review investigational product handling
- ☐ Learn storage requirements
- ☐ Understand dispensing procedures
- ☐ Practice accountability documentation
- ☐ Review administration techniques
- ☐ Learn about side effects
- ☐ Understand return/destruction process
- ☐ Complete IP handling assessment
- ☐ Assessment Date: ـــــــــــــــــ

Site-Specific Training

- ☐ Review site SOPs
- ☐ Tour facility and locate supplies
- ☐ Meet team members
- ☐ Learn emergency procedures
- ☐ Review site-specific forms
- ☐ Understand workflow processes
- ☐ Learn equipment location
- ☐ Complete site orientation checklist
- ☐ Orientation Date: ـــــــــــــــــ

Communication Training

- ☐ Review communication plan
- ☐ Learn escalation procedures
- ☐ Understand meeting schedules
- ☐ Review email/phone etiquette
- ☐ Learn report timelines
- ☐ Practice participant communication
- ☐ Review team communication tools
- ☐ Complete communication exercise

Financial Training

- [ ] Understand study budget
- [ ] Learn about participant payments
- [ ] Review expense reporting
- [ ] Understand invoicing process
- [ ] Learn about financial compliance
- [ ] Review cost tracking procedures
- [ ] Understand budget limitations
- [ ] Complete financial overview

Monitoring Preparation

- [ ] Understand monitoring visit process
- [ ] Learn about source data verification
- [ ] Review document availability
- [ ] Practice monitor interaction
- [ ] Understand CAPA process
- [ ] Learn follow-up letter response
- [ ] Review metrics and KPIs
- [ ] Complete monitoring readiness check

Competency Assessment

- [ ] Complete written examination
- [ ] Demonstrate practical skills
- [ ] Pass role-specific assessment
- [ ] Receive supervisor sign-off
- [ ] Document training completion
- [ ] File training records
- [ ] Schedule refresher training
- [ ] Receive study delegation
- [ ] Final Score: _____
- [ ] Delegation Date: _____