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# Clinical Research Project Manager Checklists

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## Project Initiation Checklist

- [ ] Review and understand protocol completely
- [ ] Develop project charter and scope document
- [ ] Create comprehensive project plan
- [ ] Establish project timeline and milestones
- [ ] Define team roles and responsibilities
- [ ] Set up project communication plan
- [ ] Identify and document project risks
- [ ] Establish budget and resource allocation

## Site Selection & Activation

- [ ] Identify potential research sites
- [ ] Conduct site feasibility assessments
- [ ] Review site capabilities and resources
- [ ] Evaluate investigator qualifications
- [ ] Conduct site selection visits
- [ ] Complete site contracts and budgets
- [ ] Coordinate site initiation visits
- [ ] Ensure regulatory document collection

## Regulatory Management

- [ ] Prepare regulatory submission packages
- [ ] Track IRB/EC submissions and approvals
- [ ] Maintain regulatory binders (TMF)
- [ ] Ensure protocol compliance
- [ ] Manage protocol amendments
- [ ] Coordinate safety reporting
- [ ] Maintain investigator site files
- [ ] Prepare for regulatory inspections

## Budget & Financial Management

- [ ] Develop detailed project budget
- [ ] Track study costs and expenses
- [ ] Process site payments
- [ ] Monitor budget variance
- [ ] Manage vendor contracts
- [ ] Review and approve invoices

- [ ] Conduct financial reconciliation
- [ ] Prepare financial reports

## Team Management

- [ ] Recruit and onboard team members
- [ ] Conduct team training sessions
- [ ] Define clear roles and expectations
- [ ] Hold regular team meetings
- [ ] Monitor team performance
- [ ] Address conflicts and issues
- [ ] Provide feedback and coaching
- [ ] Manage resource allocation

## Vendor Management

- [ ] Identify required vendors (CRO, labs, etc.)
- [ ] Develop vendor selection criteria
- [ ] Conduct vendor assessments
- [ ] Negotiate contracts and budgets
- [ ] Monitor vendor performance
- [ ] Manage vendor relationships
- [ ] Review vendor deliverables
- [ ] Conduct vendor audits

## Patient Recruitment & Retention

- [ ] Develop recruitment strategy
- [ ] Create recruitment materials
- [ ] Monitor enrollment progress
- [ ] Implement retention strategies
- [ ] Track screen failures
- [ ] Address recruitment challenges
- [ ] Coordinate with sites on recruitment
- [ ] Report recruitment metrics

## Data Management

- [ ] Develop data management plan
- [ ] Design case report forms (CRFs)
- [ ] Set up EDC system
- [ ] Create data validation checks
- [ ] Monitor data quality
- [ ] Manage database lock process
- [ ] Coordinate data cleaning
- [ ] Prepare for database audit

## Monitoring & Quality Assurance

- [ ] Develop monitoring plan
- [ ] Schedule monitoring visits
- [ ] Review monitoring reports
- [ ] Track and close action items
- [ ] Manage protocol deviations
- [ ] Oversee CAPA implementation
- [ ] Coordinate quality audits
- [ ] Prepare for inspections

## Safety Management

- [ ] Establish safety monitoring plan
- [ ] Set up SAE reporting process
- [ ] Coordinate DSMB meetings
- [ ] Review safety signals
- [ ] Manage safety database
- [ ] Ensure timely safety reporting
- [ ] Communicate safety updates
- [ ] Maintain safety documentation

## Communication Management

- [ ] Develop communication matrix
- [ ] Schedule regular status meetings
- [ ] Prepare progress reports
- [ ] Manage stakeholder expectations
- [ ] Coordinate team communications
- [ ] Distribute important updates
- [ ] Maintain communication logs
- [ ] Facilitate issue resolution

## Risk Management

- [ ] Conduct risk assessments
- [ ] Develop risk mitigation plans
- [ ] Monitor risk indicators
- [ ] Update risk register regularly
- [ ] Implement contingency plans
- [ ] Report critical risks
- [ ] Review lessons learned
- [ ] Adjust strategies as needed

## Study Closure

- [ ] Develop closure plan
- [ ] Coordinate final monitoring visits
- [ ] Ensure data completeness
- [ ] Manage database lock
- [ ] Archive study documents
- [ ] Close out vendor contracts
- [ ] Complete financial reconciliation
- [ ] Prepare final study report

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