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Checklist For Study Nurse Conducting Clinical Research Visit In Home

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Pre-Visit Clinical Preparation

- ☐ Review participant's complete medical history
- ☐ Check recent lab results and vital signs trends
- ☐ Verify current medications and allergies
- ☐ Review study protocol inclusion/exclusion criteria
- ☐ Consult with principal investigator on specific concerns
- ☐ Prepare participant-specific care plan
- ☐ Check for any protocol amendments
- ☐ Review adverse event reporting procedures

Medical Equipment & Supplies

- ☐ Blood pressure monitor (calibrated)
- ☐ Thermometer and probe covers
- ☐ Pulse oximeter
- ☐ Glucometer and test strips (if needed)
- ☐ Stethoscope
- ☐ Weight scale (portable if required)
- ☐ Specimen collection supplies (tubes, labels, bags)
- ☐ Sharps container
- ☐ Medical waste disposal bags

Clinical Documentation Preparation

- ☐ Case report forms (CRFs)
- ☐ Adverse event forms
- ☐ Concomitant medication logs
- ☐ Vital signs recording sheets
- ☐ Lab requisition forms
- ☐ Source documentation templates
- ☐ Protocol deviation forms
- ☐ Participant diary/questionnaires

Medication Management

- ☐ Verify study drug accountability
- ☐ Check medication storage requirements
- ☐ Prepare drug dispensing logs
- ☐ Review medication administration schedule
- ☐ Confirm participant's adherence tracking
- ☐ Check for drug interactions
- ☐ Prepare education materials on study medication
- ☐ Plan for medication returns/destruction

Safety & Emergency Preparedness

- ☐ Verify emergency contact numbers
- ☐ Locate nearest hospital/emergency services
- ☐ Pack emergency medical supplies
- ☐ Review participant's emergency action plan
- ☐ Ensure cell phone is fully charged
- ☐ Carry basic first aid kit
- ☐ Review anaphylaxis protocol if applicable
- ☐ Confirm transportation plan for emergencies

Clinical Assessment Procedures

- ☐ Perform comprehensive health assessment
- ☐ Measure and record all vital signs
- ☐ Conduct physical examination per protocol
- ☐ Assess for adverse events or SAEs
- ☐ Review symptom diary with participant
- ☐ Evaluate medication compliance
- ☐ Check injection sites if applicable
- ☐ Perform protocol-specific assessments

Specimen Collection & Handling

- ☐ Verify fasting status if required
- ☐ Label all specimens correctly
- ☐ Follow chain of custody procedures
- ☐ Use appropriate collection techniques
- ☐ Store specimens at correct temperature
- ☐ Complete lab requisition forms
- ☐ Arrange specimen transportation
- ☐ Document collection time and conditions

Participant Education & Support

- ☐ Review study procedures and timeline
- ☐ Educate on medication administration
- ☐ Discuss adverse event reporting
- ☐ Provide symptom management strategies
- ☐ Review diary completion instructions
- ☐ Answer clinical questions
- ☐ Assess participant understanding
- ☐ Provide 24/7 contact information

Regulatory Compliance

- ☐ Ensure GCP compliance throughout visit
- ☐ Maintain participant confidentiality
- ☐ Complete source documentation in real-time
- ☐ Report protocol deviations immediately
- ☐ Document all clinical decisions
- ☐ Ensure informed consent is current
- ☐ Follow institutional review board guidelines
- ☐ Maintain regulatory binder updates

Quality Assurance

- ☐ Double-check all data entries
- ☐ Verify CRF completion
- ☐ Cross-reference source documents
- ☐ Confirm specimen labeling accuracy
- ☐ Review medication accountability
- ☐ Check equipment calibration logs
- ☐ Validate data against protocol requirements
- ☐ Prepare for potential monitoring visits

Post-Visit Clinical Tasks

- ☐ Enter data into EDC system within 24 hours
- ☐ Report any SAEs immediately
- ☐ Update participant's medical record
- ☐ Coordinate with study team on findings
- ☐ Schedule follow-up as needed
- ☐ Process and ship specimens
- ☐ Complete visit payment documentation
- ☐ File all source documents appropriately

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