Clinical Research Home Visit Checklist

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Visit Authorization & Compliance

- [ ] Verify IRB approval for home visits
- [ ] Confirm protocol allows home visits
- [ ] Check participant eligibility for home visit
- [ ] Ensure informed consent covers home procedures
- [ ] Verify insurance coverage for off-site visits
- [ ] Document medical necessity if required
- [ ] Obtain supervisor approval
- [ ] Review institutional home visit policy

Pre-Visit Risk Assessment

- [ ] Review participant's home environment history
- [ ] Assess neighborhood safety factors
- [ ] Check for environmental hazards
- [ ] Evaluate accessibility requirements
- [ ] Consider participant's medical stability
- [ ] Review emergency response capabilities
- [ ] Assess need for second team member
- [ ] Document risk mitigation strategies

Essential Contact Information

- [ ] Participant's primary phone number
- [ ] Alternative contact number
- [ ] Emergency contact person and number
- [ ] Principal investigator contact
- [ ] Study coordinator contact
- [ ] Medical monitor number (if applicable)
- [ ] Local emergency services number
- [ ] Nearest hospital information

Core Documentation Package

- [ ] Study protocol (abbreviated version)
- [ ] Informed consent forms
- [ ] Visit-specific CRFs
- [ ] Source document worksheets
- [ ] Adverse event forms
- [ ] Protocol deviation forms

- [ ] Visit completion checklist
- [ ] Reimbursement forms

Standard Operating Procedures

- [ ] Review home visit SOPs
- [ ] Follow specimen collection SOPs
- [ ] Implement safety SOPs
- [ ] Apply infection control procedures
- [ ] Follow equipment maintenance SOPs
- [ ] Implement data security protocols
- [ ] Apply emergency response procedures
- [ ] Follow communication protocols

Medical Supplies Inventory

- [ ] Vital signs equipment
- [ ] Phlebotomy supplies
- [ ] Specimen containers
- [ ] PPE (masks, gloves, gowns)
- [ ] Sanitization supplies
- [ ] Bandages and gauze
- [ ] Alcohol swabs
- [ ] Sharps container

Technology Requirements

- [ ] Laptop/tablet with study database access
- [ ] Mobile phone with full battery
- [ ] Portable scanner/camera for documents
- [ ] GPS device or smartphone navigation
- [ ] Backup paper forms
- [ ] Portable printer (if needed)
- [ ] Secure file storage device
- [ ] Hotspot for internet access

Visit Execution Protocol

- [ ] Arrive within scheduled window
- [ ] Verify participant identity
- [ ] Confirm consent and willingness
- [ ] Set up clean workspace
- [ ] Follow visit procedure sequence
- [ ] Maintain professional boundaries
- [ ] Document start and stop times
- [ ] Complete all required assessments

Data Quality Measures

- [ ] Complete forms in real-time
- [ ] Review for missing data
- [ ] Verify accuracy of entries
- [ ] Cross-check source documents
- [ ] Ensure legible handwriting
- [ ] Use only approved corrections
- [ ] Initial and date all entries
- [ ] Obtain required signatures

Specimen Management

- [ ] Verify specimen requirements
- [ ] Label before collection
- [ ] Follow collection procedures
- [ ] Document collection times
- [ ] Store at proper temperature
- [ ] Arrange timely transport
- [ ] Complete chain of custody
- [ ] Track specimen status

Participant Engagement

- [ ] Maintain professional demeanor
- [ ] Respect participant's home
- [ ] Address concerns promptly
- [ ] Provide clear instructions
- [ ] Ensure understanding of procedures
- [ ] Thank participant for participation
- [ ] Schedule next visit if applicable
- [ ] Provide study team contact information

Post-Visit Requirements

- [ ] Complete data entry within timeline
- [ ] Submit specimens to lab
- [ ] Report any incidents/AEs
- [ ] File documentation appropriately
- [ ] Clean and restock supplies
- [ ] Update visit tracking log
- [ ] Communicate with study team
- [ ] Prepare for next visit