**Documentation Checklist**

| **Document** | **Completed** |
| --- | --- |
| **Study-related** | |
| Protocol |  |
| Staffing plan, including multisite organization chart |  |
| Recruitment plan |  |
| Statistical analysis plan |  |
| Budget |  |
| Contractual documents (e.g., memorandum of understanding [MOU], reliance agreement) |  |
| Electronic health record use plan and IT-facilitated updates as needed |  |
| Study plan and timeline |  |
| Communication plan |  |
| Committee membership and meeting plan, including advisory and steering committees |  |
| Manual of procedures |  |
| Data coordinating activities |  |
| Patient recruitment and intervention materials |  |
| Clinical staff training and intervention materials |  |
| Interviewer/research staff training |  |
| Vendor contracts |  |
| Specimen management plan |  |
| Site initiation plan |  |
| Dissemination and sustainability plan |  |
| **Regulatory** | |
| Data sharing plan including data use agreements between parties |  |
| IRB review and approval |  |
| Registry in ClinicalTrials.gov |  |
| Informed consent process and form, if applicable |  |
| **Oversight** | |
| Data and safety monitoring plan/committee |  |
| Data management plan |  |
| Quality management plan |  |