

[First Last Name]

[City, State] | [email@example.com] | [(000) 000-0000] | [LinkedIn URL]

PROFESSIONAL SUMMARY

Detail-oriented **Clinical Research Coordinator** with [X] years of experience supporting Phase I–IV clinical trials in [therapeutic areas, e.g., oncology, cardiology]. Proven track record coordinating study start-up, subject recruitment, regulatory submissions, and data quality to ensure ICH-GCP and FDA compliance. Skilled at collaborating with investigators, sponsors, and cross-functional teams to meet enrollment targets and maintain audit-ready documentation. Adept at using [CTMS/EDC systems] and standardized workflows to streamline study operations and enhance participant safety.

PROFESSIONAL EXPERIENCE

[Clinical Research Coordinator] | [Academic Medical Center / Hospital Name]

[Month Year] – Present | [City, State]

- Coordinated [X+] interventional and observational trials in [primary therapeutic area], managing full study lifecycle from feasibility and start-up through close-out while consistently meeting or exceeding enrollment targets by [X] %.
- Screened and consented [X+] participants using IRB-approved materials, ensuring thorough documentation of eligibility, informed consent, and protocol-specific procedures in [Electronic Medical Record (EMR)] and [EDC] systems.
- Maintained accurate, audit-ready regulatory binders and source documents; prepared and submitted IRB initial applications, amendments, and continuing reviews using [IRB platform name], resulting in zero major findings during sponsor or regulatory audits.

[Assistant Clinical Research Coordinator] | [Research Institute / Private Practice Name]

[Month Year] – [Month Year] | [City, State]

- Supported day-to-day operations for [X] concurrent clinical studies, including scheduling visits, coordinating laboratory work, processing biospecimens per SOPs, and ensuring timely shipment to central labs using [courier/lab systems].
- Performed accurate data entry and query resolution in [EDC/CTMS platform, e.g., REDCap, Medidata Rave], improving data completeness and reducing query turnaround time by [X] % through proactive monitoring and communication with monitors/CRAs.
- Assisted with recruitment initiatives such as chart reviews, outreach calls, and collaboration with clinic staff, contributing to a [X] % increase in eligible participant referrals while maintaining strict HIPAA and confidentiality standards.

EDUCATION

[Bachelor of Science in Biology] | [University Name]

[Month Year] – [Month Year] | [City, State]

- Relevant coursework: [Clinical Research Methods], [Biostatistics], [Epidemiology], [Human Physiology].
- Senior project: [Brief description of research or capstone project related to clinical or biomedical research].

[Clinical Research Certificate / GCP Training] | [Institution / Training Provider]

[Month Year] – [Month Year] | [City, State or Online]

- Completed training in ICH-GCP, FDA regulations, human subjects protection, and clinical trial operations.

SKILLS

Clinical & Regulatory: Informed consent process, ICH-GCP, FDA & IRB regulations, protocol adherence, adverse event/SAE reporting, regulatory binder maintenance, source documentation.

Data & Systems: EDC platforms ([REDCap], [Medidata Rave]), CTMS ([OnCore], [other]), EMR systems ([Epic], [Cerner]), Microsoft Excel/Word/PowerPoint, basic biostatistics and data quality control.

Study Operations: Participant recruitment & screening, visit scheduling, specimen handling & shipping, inventory management, monitoring visit preparation, audit readiness, SOP compliance.

Communication & Collaboration: Interdisciplinary teamwork, sponsor/CRO liaison, patient education, clear written documentation, meeting coordination, stakeholder updates.

Organizational & Soft Skills: Attention to detail, time management, problem-solving, adaptability, ethical decision-making, ability to manage multiple protocols simultaneously.

SELECTED PROJECTS

[Multicenter Phase III Trial Coordination Support] | [Therapeutic Area / Indication]

[Month Year] – [Month Year]

- Coordinated site-level activities for a multicenter Phase III trial, including participant scheduling, visit reminders, and timely completion of case report forms, helping the site achieve [X] % on-time visit completion.
- Implemented a standardized checklist for pre-visit preparation and post-visit documentation, reducing protocol deviations and missing data instances by [X] %.

[Quality Improvement Initiative for Source Documentation] | [Department / Clinic Name]

[Month Year] – [Month Year]

- Reviewed existing source documentation templates across [X] active studies and collaborated with the research team to streamline forms and workflows aligned with sponsor and regulatory expectations.
- Developed a quick-reference guide for coordinators and assistants, improving consistency of documentation and contributing to positive feedback from monitors during routine monitoring visits.