

Carol Lee

Clinical Research Assistant

Biology graduate with 2 years of clinical research experience spanning specimen processing, EDC data entry, and regulatory document management across multiple IRB-approved studies. Achieved a 99.32% GCP compliance score by verifying each element against protocol requirements before sponsor monitoring visits. Skilled in REDCap, ICH-GCP Guidelines, and source document verification.

CONTACT INFORMATION

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KEY SKILLS

- ICH-GCP Guidelines
- Electronic Data Capture (EDC)
- REDCap
- IRB Regulatory Documentation
- Specimen Processing and Handling
- HIPAA Compliance
- FDA Regulations
- OnCore CTMS
- MS Office Suite
- Source Document Verification

PROFESSIONAL EXPERIENCE

2025 - Present

Clinical Research Assistant, Penobscot Valley Clinical Sciences Group, Bangor, ME

- Maintained a 99.32% GCP compliance score across 443 audited source documents, consent forms, and regulatory binder items by verifying each element against protocol requirements before sponsor monitoring visits.
- Processed 287 biological specimens across 3 studies, labeling, centrifuging, and shipping kits to central labs within 45 minutes of each collection.
- Recorded protocol deviations for the research team, keeping the count to 1 deviation per study per quarter by cross-referencing visit procedures against protocol manuals.
- Entered participant visit data into EDC within 36 hours of each appointment, resolving an average of 7 queries per cycle during data cleaning.

2024 - 2025

Research Intern, Androscoggin Basin Health Research LLC, Lewiston, ME

- Prepared and organized 23 regulatory documents per trial for 3 IRB-approved studies, keeping each binder audit-ready within 18 hours of document receipt.
- Processed 114 specimens for a gastrointestinal study over 6 months, packaging and logging each sample in REDCap with zero mislabeling incidents.
- Assisted the coordinator with HIPAA-compliant chart reviews using EMR, abstracting data for an average of 9 participant visits per week.

EDUCATION

BS, Biology

University of Maine, Orono, ME | 2020 - 2024