

Mila Allison

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SUMMARY

Supervisory **oncology clinical research** professional with 10 years managing cancer trials, **human subjects research**, regulatory operations, and **distributed study teams**. Holds a **Master of Science in Clinical Research** and has activated and overseen NCI sponsored and pharmaceutical sponsored oncology studies across multisite health care environments. Leads trial activation, IRB submissions, protocol implementation, participant screening, trial navigation, research education, audit readiness, data quality oversight, SOP development, privacy compliance, information security, and study documentation. Supervises coordinators and regulatory staff through assignments, priorities, training, performance standards, evaluations, and operational problem solving. Builds practical workflows from protocol requirements, monitors study records and metrics, and develops remediation plans that protect participants and support reliable research delivery. This background supports effective partnership with investigators, providers, sponsors, participating sites, research teams, and participants across competing clinical research deadlines.

EXPERIENCE

Clinical Research Program Manager, Oncology Trials

January 2023 - Present

Piedmont Oncology Research Collaborative

Durham, NC

Leads a six site oncology trial portfolio across NCI sponsored and industry sponsored studies, supervising coordinators and regulatory staff while directing activation, IRB readiness, participant navigation, monitoring preparation, quality oversight, and remediation planning.

- Led six site oncology trials through activation, staffing, screening, and ongoing study operations.
- Supervised coordinators through **assignments**, leave decisions, coaching, training plans, and performance **evaluations**.
- Translated sponsor documents into activation plans with milestones, owners, dependencies, and site requirements.
- Directed IRB workflows while protecting privacy, information security, and **human subjects research** standards.
- Used referral and enrollment metrics to improve provider outreach and **trial navigation** workflows.
- Prepared monitoring reviews and **remediation plans**, keeping records, training, and **certifications** inspection ready.

Senior Oncology Clinical Research Coordinator, Trial Operations

May 2020 - December 2022

Carolina Cancer Trials Institute

Chapel Hill, NC

Coordinated concurrent interventional oncology studies across investigators, nursing, pharmacy, laboratories, regulatory staff, and sponsors, connecting study start up, participant education, **data quality**, documentation, and audit preparation.

- Coordinated concurrent oncology studies across investigators, nursing, pharmacy, laboratories, and sponsors.
- Managed study startup from document review through IRB approval and site readiness milestones.
- Evaluated source records and case report data, then created issue logs and **remediation plans**.
- Educated prospective participants about research requirements and coordinated investigator follow up for eligibility.
- Prepared regulatory files, training records, delegation documents, and data issues for **sponsor audits**.
- Authored procedures that standardized screening, documentation, escalation, and participant follow up practices.

Oncology Clinical Research Coordinator, Protocol Delivery

July 2018 - April 2020

Triangle Academic Medical Center

Raleigh, NC

Managed daily oncology protocol coordination across participant visits, regulatory deadlines, data queries, investigator requests, **IRB documentation**, screening referrals, training credentials, monitoring visits, and workflow communication.

- Managed oncology protocol coordination across participant visits, data queries, and regulatory deadlines.
- Prepared **IRB submissions**, amendments, continuing reviews, and supporting human subjects documents.
- Screened clinical records against protocol criteria and coordinated referrals with oncology **providers**.
- Tracked training and study credentials, escalating expirations before research activities were disrupted.
- Supported **monitoring visits** by assembling essential documents and coordinating finding resolution.
- Communicated protocol updates through meeting materials, written guidance, and workflow updates.

Clinical Research Specialist, Research Documentation

October 2016 - June 2018

Blue Ridge Clinical Research Center

Winston Salem, NC

Supported regulated cancer and therapeutic research through document control, participant materials, source verification, deadline coordination, quality checks, corrective action tracking, and sponsor visit preparation within established study procedures.

- Supported cancer studies through human subjects protection and regulated research documentation.
- Maintained regulatory binders and electronic files with approvals, delegations, training, and protocols.
- Coordinated calendars and deadlines for multiple protocols, resolving conflicts before participant activities.
- Reviewed research data against source records and routed discrepancies through study processes.
- Prepared participant materials and explained routine research logistics within assigned responsibilities.

- Supported sponsor visits by organizing records and tracking corrective actions through completion.

PROJECTS

Distributed Oncology Trial Navigation Program 📅 2025

Partnered with providers, coordinators, and participating sites to clarify referral pathways, improve participant education, and connect eligible patients with decentralized oncology trial opportunities.

Multisite Study Readiness Framework 📅 2024

Worked with regulatory staff and investigators to create shared activation milestones, document owners, training checks, and escalation paths for coordinated site readiness.

Research Quality Remediation Initiative 📅 2023

Collaborated with study teams to review records, identify recurring data issues, and build practical remediation plans that supported reliable monitoring outcomes.

LEADERSHIP & AWARDS

- Clinical Research Staff Mentor, Piedmont Oncology Research Collaborative
- Oncology Research Quality Workgroup Lead, Piedmont Oncology Research Collaborative
- Recognized by research colleagues for practical guidance during complex oncology study readiness work

EDUCATION

Master of Science in Clinical Research

2016

Duke University GPA: 4.0

Durham, NC

Coursework: Clinical trial management, human subjects research, biostatistics, regulatory science

Bachelor of Science in Health Sciences

2014

University of North Carolina at Chapel Hill GPA: 4.0

Chapel Hill, NC

Coursework: Oncology, health research methods, health care systems, human biology

CERTIFICATIONS

- Certified Clinical Research Professional 📅 2018
- Good Clinical Practice Training 📅 2026
- Human Subjects Research Protection Training 📅 2026

TECHNICAL SKILLS

- **Clinical Trial Management:** Trial activation, trial monitoring, trial navigation
- **Oncology Research:** Cancer trials, oncology programs, oncology protocols
- **Regulatory Submissions:** IRB submissions, continuing reviews, amendments
- **Human Research Protection:** Human subjects protection, informed consent, participant safety
- **Quality Management:** Data quality, issue logs, remediation plans
- **Study Documentation:** Source records, case report data, regulatory files
- **Compliance Standards:** Privacy, information security, Good Clinical Practice
- **Study Operations:** Screening, recruitment, enrollment
- **Research Procedures:** SOP development, protocol implementation, workflow design
- **Audit Preparation:** Sponsor audits, NCI audits, monitoring visits
- **People Management:** Staff supervision, performance evaluations, staff training
- **Planning Methods:** Milestones, resource planning, competing priorities

SKILLS

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|---------------------------------|-----------------------------------|-------------------------|----------------------|
| • Oncology Clinical Research | • Pharmaceutical Sponsored Trials | • Information Security | • Data Quality |
| • Decentralized Clinical Trials | • IRB Documentation | • SOP Development | • Audit Readiness |
| • Human Subjects Research | • Regulatory Compliance | • Participant Screening | • Sponsor Monitoring |
| • NCI Sponsored Trials | • Privacy | • Trial Navigation | |

PROFESSIONAL AFFILIATIONS

- Clinical Research Staff Mentor, Piedmont Oncology Research Collaborative

- Oncology Research Quality Workgroup, Piedmont Oncology Research Collaborative
- Professional participant in oncology clinical research collaboration and quality review activities

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST