

This guide is intended for investigators, clinical teams, and administrators interested in adding research staff members to their team. Dedicated research staff play a vital role in successful implementation and conduct of clinical research projects. The NUCATS Center for Clinical Research can provide assistance to new or experienced investigators as well as administrators and clinical teams involved with research. Email: CCR@northwestern.edu

What are the roles that can help with clinical research operations?

There are two main categories for research professionals:

- **Research Coordinators & Assistants:** Clinical research coordinators (CRC's) are considered the backbone of any research operation. They manage the day-to-day components of a clinical trial and help clinical investigators drive studies to completion. There are two job tiers for CRC's: junior and senior. An additional option is to add a Clinical Research Assistant to your team to assist with data entry and a range of other routine research administrative tasks.
- **Research Nurses:** Clinical Research Nurses (CRN's) can perform both clinical and research related responsibilities in your practice. Some CRN's can also serve as a CRC as described above. Job tiers vary by responsibility and experience. CRN roles can be part-time or full-time.



Learn More

How do you cover staff costs in a research contract?

- **Know how much to negotiate for:** Clinical research staff time devoted to a sponsored trial is most often billed through effort calculations. See our guide so you can factor all the costs of your research operation into the study contract.
- **Start-up & Life of the Study:** In some cases, the industry sponsor (or contract research organization – CRO) may pay per subject encounter. It is important to include the associated costs of the entire lifetime of the study in your calculations (e.g. IRB Submissions, etc.)
- **Negotiations:** The contract approval process involves multiple stakeholders, reviews, and counter-offers. Remember to factor the start-up time in your research project timelines.



Learn More

Why add a clinical research professional to your team?

- **Research Focused:** A clinical research professional helps your department ensure smooth clinical trial operations, subject safety, ethical/regulatory compliance, data collection, and research administrative operations for your department's research program.
- **Financial Viability:** Adding a research professional builds your department's capacity to operate revenue-generating sponsored clinical trials. Industry trial revenue streams may also subsidize investigator initiated research.
- **Patient & Peer Reputation:** A strong research presence builds academic-industry partnerships and may provide publishing opportunities for clinicians. A subject-centered research program can also serve as a patient pipeline – both direct and through word-of-mouth.



Learn More





Important:

While clinical research operations staff are a valuable addition to your team, the principal investigator is ultimately responsible for subject safety and data integrity. Consider both the cost and supervision needed for a given role.

Clinical Research Assistants

Entry Level • Task-Based • Part Time or Full Time

Benefits: Can execute time-consuming administrative tasks, entry-level job tier, and can be good entry-point into research careers.

Limitations: Needs direct supervision and day-to-day support. Can execute tasks but does not have subject-matter expertise in regulatory compliance or research operations. Will need extensive training.

Credentials: Bachelor's or Associate + 2 yr experience

Level of Supervision Needed



Needs hands-on support and clear-cut procedures but can perform routine, time-consuming tasks to free-up capacity for the clinical and/or research team.

Job Tier: Hourly

Cost: \$ - \$\$

Clinical Research Nurses

Experience & Responsibilities Vary • Part Time or Full Time

Benefits: May perform protocol-specified tasks and monitor clinical indicators for research participants. Could also serve coordinator responsibilities (detailed below).

Limitations: May have limited capacity for research administrative tasks (varies between studies & disease groups). May not have regulatory experience.

Credentials: RN. May have research certifications.

Level of Supervision Needed



Protocol-specified clinical tasks can be performed independently. Coordination responsibilities may need supervision – especially with regulatory compliance

Job Tier: Exempt or Hourly

Cost: \$\$\$-\$\$\$\$

Clinical Research Coordinators (Jr)

Semi-Entry Level • Task & Project-Based • Full Time

Benefits: Key driver for moving trials to completion, serves as liaison between your clinical team and the subject population. Can perform both regulatory and subject-facing responsibilities.

Limitations: Some degree of experience but will need training and support. May not have extensive expertise in regulatory compliance.

Credentials: Bachelors (sometimes masters) and/or 2+ years research experience.

Level of Supervision Needed



Some degree of independence but will need direction at times throughout the week

Job Tier: Exempt

Cost: \$\$ - \$\$\$

Clinical Research Coordinators (Sr)

Experienced • Project-Based • Full Time

Benefits: A “take it and run with it” research expert who can manage a research team and consult with your clinical staff. Both regulatory and subject-facing experience.

Limitations: May have limited capacity for routine administrative tasks (varies based on disease group).

Credentials: Bachelors (sometimes masters, or research certifications) and/or 4+ years coordinator experience.

Level of Supervision Needed



High degree of independence, can “manage up” with your team

Job Tier: Exempt

Cost: \$\$\$ - \$\$\$\$

Go back to an overview of adding research staff



Learn more about research contracts



Considerations checklist



What is a clinical research contract?

Clinical research contracts are agreements between a research sponsor (*often a Pharmaceutical or Contract Research Organization- CRO*) and your department to serve as a site for a given study. There are several considerations as you negotiate this contract to ensure the trial is successful and financially viable. Typically budgets are paid per patient, per protocol-specified visit, or per activity. Since clinical trials are based on performance, it is important to accurately estimate the number of subjects that will be enrolled as a portion of the effort will be allocated to each subject.

What is effort calculation & reporting?

The salaries for Clinical Research Coordinators should be covered by the research studies that they support. The most common models for covering Clinical Research Coordinators are effort and hourly. Effort is most frequently used and is the recommended method for budgeting and charging salaries.

For clinical trials, accurate effort calculations are important in order to cover the necessary staff costs. When determining the total effort there will be effort that is dedicated to **general study maintenance** as well as **subject-specific** effort. You will want to ensure that all of the effort is covered in the budget. Some contracts may require you to calculate the amount per subject or even per subject encounter.

We're Here to Help

Budgeting & contract negotiation is a time-consuming (but critical) process. Contact the NUCATS Center for Clinical Research to arrange a consultation to ensure your research project is set-up for success. Email: CCR@northwestern.edu



Negotiations: A good budget will take some time and thought in order to ensure that the site costs are fully covered. There will be many counter-offers throughout the negotiation process. Providing budget justification to the sponsor will be necessary when negotiating the budget.



Startup Costs: Remember to include all the costs associated with study startup. This includes the site qualification visit, site initiation visit, required training, preparing/submitting to the IRB, regulatory paperwork, prescreening, negotiating the budget, etc.



Life of the Study: Consider the end-to-end steps including subject visits, required documentation, additional training (if needed), processing protocol amendments, adverse event reporting, re-consenting (if needed), administrative processes, resolving data queries, submitting continuing reviews to the IRB, etc.



Study closeout: There are several components of closing a study including the closeout visit, submitting termination to IRB, resolving outstanding data queries, preparing documents for long term storage, etc.

Go back to an overview of adding research staff



Learn more about the value-add of research roles



Considerations checklist



The importance of a research presence

Cutting-Edge Innovation: Involvement in clinical trials enhances your department's reputation as an organization providing top-tier emerging treatments. Effective management of trials may come with added benefits for clinicians including industry collaboration, authoring opportunities, and new equipment.

Patient Ecosystem: Clinical trials are a pipeline for potential patients within your specialty. Providing a positive clinical trial experience for research participants can create a network of patients who value their participation and let others know about their positive experience at Northwestern hospitals.

The value-add of clinical research professionals



Capacity Building Investment: In most cases, salaries for clinical research staff are covered by the research studies they support. The revenue stream and administrative procedures from sponsored studies can also provide support for investigator-initiated research.



Bridge Builder: Research operations staff are the critical link between researchers and the study population. A skilled coordinator or research nurse ensures recruitment and retention goals are met while providing a caring, subject-centered experience. In addition, operations staff connect your clinic with the research infrastructure of Northwestern University, including the IRB and other research departments.



Subject Safety & Compliance: In the rapidly changing world of research compliance, a research operations staff member becomes your go-to point person to identify and implement the relevant ethical and regulatory requirements for your studies. Participant safety always comes first and a research team member allows you to remain focused on subject safety.



Streamlined Operations & Long-Term Vision: A research enterprise has many moving & time-consuming pieces. A coordinator or research nurse allows clinicians to keep asking the questions that drive healthcare innovation forward while creatively addressing patient issues at the nexus of clinical and research medicine.

Contact the NUCATS Center for Clinical Research (CCR) for a consultation to assist with preparing for a research study or adding research staff to your team. Email: CCR@northwestern.edu

Go back to an overview of adding research staff



Considerations checklist



The composition, workloads, and responsibilities of clinical research staff can vary considerably. Larger, more complex, or multi-site collaborative studies might need multiple staff members to ensure smooth operations & regulatory compliance. As a result, one staff member might support three studies while another might manage eight or more and some studies employ clinical research professionals with varying skillsets or roles. The following considerations can help you gauge your unique staffing needs

- ❑ **Recruitment & Screening:** How much time will it take to recruit participants for your trial? Some factors that result in increased staff time include a high number of inclusion/exclusion criteria, larger advertising campaigns, and recruiting subjects who aren't existing patients at your practice (particularly from underrepresented populations).
- ❑ **Study Population:** The extent of participant engagement varies. A population with chronic conditions or a project testing a novel intervention (e.g. drug, device) may require more involved interactions with participants or yield a greater number of adverse events that require attention.
- ❑ **Research Phase & Oversight:** Industry and FDA studies are far more time-consuming due to documentation, monitoring, and data management. An industry trial with only 10 participants may be just as time consuming as a large-scale NIH or DoD study with more than 50 participants.
- ❑ **Protocol Complexity & Standard-of-Care Workflow Alignment:** How complex are the protocol-specified activities? Are they standard-of-care or research specific? Will visits take place in just your clinic or will the subject need to be escorted to several locations for imaging, blood draws, or other study activities?
- ❑ **Visit Preparation & Follow-Up:** In addition to the visit itself, your staff will need time both before and after the visit to prepare equipment, enter data, and complete administrative tasks related to subject visits.
- ❑ **Study Lifespan & Retention:** In general, trials earlier in their lifespan are more labor intensive. However, studies with longer follow-up windows (2+ years) may require more staff time to ensure participant retention.
- ❑ **Regulatory Demands:** The upkeep of regulatory documentation is often independent of trial data and needs to be considered as part of the budget & project plans. Some teams may consider adding a regulatory study coordinator to manage the compliance aspects of an entire study portfolio.
- ❑ **Start-Up & Closure Time:** In addition to the subject-specific aspects of the trial, your study staff also has to perform time-consuming tasks related to study start-up and closure. These include things like budget negotiations, site qualification/initiation visits, protocol development, consent form approval, annual IRB review filings, routine regulatory tasks, staff onboarding, and data closure/transfer, etc.

How do I get started?

We are here to help. The NUCATS Center for Clinical Research can connect you with the right people and resources to navigate the process.

Contact us at CCR@northwestern.edu to arrange a consultation

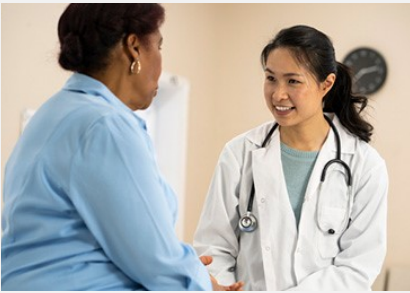
What does this look like in action?

Review some sample scenarios of three different research staff member workloads to help you determine what role is best to address the needs of your team.



Although these scenarios are fictitious, they embody three sample workloads for clinical research operations staff.

Adding Capacity with a Research Assistant



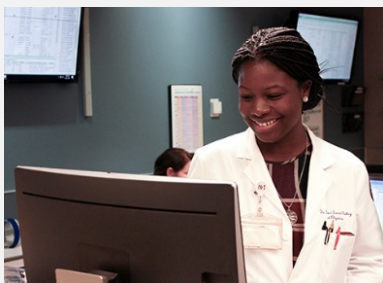
Dr. Scott has four industry funded trials managed by her research coordinator, Ashley. She was recently approached by a pharmaceutical company and wants her clinic to serve as a site for one of their Phase III drug studies. **Unfortunately, Ashley is at capacity and cannot coordinate another trial.** In a research meeting, Ashley noted that a significant amount of her time is consumed by **essential routine administrative tasks** like expense reimbursements, data entry, and regulatory paperwork. Dr. Scott proposed the idea of **hiring a research assistant** to manage routine tasks for all of Ashley's studies and free up enough time for her to start-up and coordinate the new trial. **Ashley would need to train and supervise the new research assistant** but it would be a worthwhile investment and would allow her to focus on the more advanced coordination aspects of Dr. Scott's trials while **the new research assistant can take care of the routine, but time-consuming, tasks.**

Michael – Junior Coordinator

Michael is an internal medicine research coordinator with a **portfolio of seven trials**. Most of his studies are **standard-of-care or long-term follow-up** so he spends much of his day scheduling subject visits, performing screening calls, and entering data from the EMR into the research data platform. One of Michael's studies focuses on diabetes in lower socioeconomic status neighborhoods so **recruitment**, subject communication, and **adverse event monitoring** are particularly time consuming. He didn't realize that transportation to the clinic was such a big issue for some subjects and has had to spend several hours each week on the phone arranging transportation and **working with his finance administrator** to get them ride-share vouchers so they can make it to their visit.



Tanisha - Research Nurse



Tanisha is a full-time research nurse working in orthopedic surgery. **She manages three industry-funded trials of 10-15 subjects each** for pre-approval medical devices. In addition to considerable administrative work, she has 2-3 monthly calls with a central data monitoring team as well as **several on-site monitoring visits** per quarter. One trial is in the follow-up stage so that one isn't as time consuming but the other two just started and **each subject has a half-day encounter every 3-4 weeks**. She spends most of her day preparing for subject visits, monitoring subject symptoms, performing protocol-specified assessments, and ensuring the sub-investigators have everything they need to perform trial procedures.

Go to an overview of
adding research staff



Considerations
checklist

