

Task and Duties Assessment

Thank you for completing the Task and Duties Assessment! The responses you provide will guide the determination of the position description appropriate for your posting or reclassification.

Prior to beginning this assessment, you must have departmental and budget approval for the HR action requested.

In this assessment, you will provide information on tasks, duties, and competencies required for the proposed position or reclassification, an organizational chart, and the IRB numbers for studies the position may support (as applicable, up to 5 can be provided). Please ensure you have this information available before you begin the assessment.

If you do not complete the assessment and need to return later to complete it, please make note of the return code provided to you. If you forget or lose your return code, email som-cdi@med.unc.edu. Please do not create a duplicate assessment if you have already started one.

If you have any questions about the assessment or encounter technical difficulties, please email som-cdi@med.unc.edu.

You may review the full assessment by downloading the following file:

[Attachment: "TADA Intake Form 07Nov2023.pdf"]

General Information

Submitter Name

Submitter Email

Please indicate the type of action you intend to take:

- Creation of New Position
- Reclassification of Vacant Existing Position
- Reclassification of Occupied Existing Position

What are the department's business needs to support this request? I.e., what is prompting the change in position duties or need for a new position?

Are you requesting the creation of duplicate positions (i.e., one posting for multiple of the same position?)

- Yes
- No

How many positions are you requesting?

Please enter the position number of the position you would like re-classified:

Clinical Research Accountability Unit

- Anesthesiology
- Cancer
- Dermatology
- Emergency Medicine
- Family Medicine
- Gastroenterology
- Health Sciences
- Infectious Diseases
- Medicine
- Neurology
- Neurosurgery
- OBGYN/Center for Women's Health Research
- Ophthalmology
- Orthopaedics
- Pathology and Laboratory Medicine
- Pediatrics
- Physical Medicine and Rehabilitation
- Psychiatry
- Radiation Oncology
- Radiology
- Surgery
- Urology
- Other

Please Indicate Department/Division:

Will This Position Have Direct Supervisory Responsibilities?

- Yes
- No

Please Indicate the Number of Personnel the Position Will Directly Supervise

Please Indicate the types of positions this position will supervise (check all that apply):

- Full-Time Permanent Employees
- Part-Time Permanent Employees
- Postdocs and/or Postdoc Trainees
- Temporary Employees
- Student Employees (Undergraduate, Graduate, Workstudy)
- Other (Affiliates, Hospital Employees, etc.)

Does This Position Require a Nursing License?

- Yes
- No

Does this position require in-person, hybrid, or remote work?

- In-Person
- Hybrid
- Remote

Is this TADA submission identical to a past TADA submission?

- Yes
- No

Please enter the identical TADA ID:

Please upload the TADA intake form for the identical TADA:

(This form was distributed to you via email when you submitted the intake form)

Please complete the attestation below:

- I attest that this TADA intake form is identical in responsibilities, competencies, and scope to a prior TADA intake form (attached to this submission). I understand that if the TADA intake form has been updated since the prior submission, I may have to provide additional information to the TADA committee for review.

Position Responsibilities and Tasks

Position Responsibilities/Tasks

On this page, please indicate the general task categories for which this position will be responsible.

On the following pages, you will indicate the specific tasks and the required level of competency for each. Only select the position's essential functions (i.e., do not include tasks that the position will rarely do or that would fall under "other work as assigned")

Please note, if you indicate on this page that the position will not include one of the general task categories, you will still see that category on the following pages, but with the determination of "N/A" selected as default. You may change any answers as necessary.

Will this position be responsible for any regulatory tasks? (e.g., regulatory document management, creation/maintenance of regulatory applications) Yes No

Will this position be responsible for any data management or data analysis tasks? (e.g., entering data into EDC, creation of data reports, reviewing data collected for quality) Yes No

Will this position be responsible for any participant-related tasks? (e.g., screening, recruitment, conducting study visits, informed consent, specimen management) Yes No

Will this position be responsible for any study operations management tasks? (e.g., project management, study start-up, budgeting, invoicing, etc.) Yes No

Regulatory Tasks

Answer choices are as follows:

0, N/A, not part of the position

1, This position will have a fundamental knowledge of this task and completes this task under supervision or direction.

2, This position will consistently manage this task independently. They will have a moderate level of expertise regarding this task.

3, This position has advanced skills related to this task. They will assess study needs and employ strategies to improve methodology in this area. They may lead others and coordinate other's activities in relation to this task.

	N/A, Not Part of the Position	Completes Under Direction; Fundamental Level of Expertise	Independently Manage; Moderate Level of Expertise	Advanced Skills; May Improve Methodology and/or Lead Others
Develop and/or submit regulatory applications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Create additional study materials that require regulatory review (e.g., consent forms, recruitment scripts, flyers)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Create, compile, edit, manage, and/or organize regulatory documentation (e.g., delegation of authority logs, training logs, IRB approval letters, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Perform internal quality assurance/quality control on regulatory study files	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Submit safety reports for protocol deviations, adverse events, etc. (e.g., promptly reportable information, DSMB reports)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Serve as study monitor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

You have selected that this position will complete some regulatory tasks under supervision/direction.

Are the skills needed for these tasks:

- Clerical/administrative in nature (little to no knowledge of clinical research regulatory processes required to assist with these tasks)
- Technical in nature (knowledge of clinical research regulatory processes required to assist with these tasks)

As necessary, please provide any further information needed to explain the skills required for these clinical research operations tasks:

Number of Regulatory Tasks

Data Management and Data Analysis Tasks

Answer choices are as follows:

0, N/A, not part of the position

1, This position will have a fundamental knowledge of this task and completes this task under supervision or direction.

2, This position will consistently manage this task independently. They will have a moderate level of expertise regarding this task.

3, This position has advanced skills related to this task. They will assess study needs and employ strategies to improve methodology in this area. They may lead others and coordinate other's activities in relation to this task.

	N/A, Not Part of the Position	Completes Under Direction; Fundamental Level of Expertise	Independently Manage; Moderate Level of Expertise	Advanced Skills; May Improve Methodology and/or Lead Others
Perform internal quality assurance/quality control on study data files	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Enter data into electronic data capture systems	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Create databases for research studies (e.g., REDCap)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Compile, review, organize, or prepare study data for analysis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Conduct statistical analyses	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Create reports of study data	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Review incoming or outgoing data for integrity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Create source documents, checklists, and/or case report forms	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Number of Data Tasks

Participant-Related Tasks

Answer choices are as follows:

0, N/A, not part of the position

1, This position will have a fundamental knowledge of this task and completes this task under supervision or direction.

2, This position will consistently manage this task independently. They will have a moderate level of expertise regarding this task.

3, This position has advanced skills related to this task. They will assess study needs and employ strategies to improve methodology in this area. They may lead others and coordinate other's activities in relation to this task.

	N/A, Not Part of the Position	Completes Under Direction; Fundamental Level of Expertise	Independently Manage; Moderate Level of Expertise	Advanced Skills; May Improve Methodology and/or Lead Others
Conduct in-services for clinical staff	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Screen/recruit participants per protocols and standard operating procedures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Serve as participant liason and advocate during study participation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Present study-related information directly to participants and/or their families	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Manage and report participant complaints	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Obtain informed consent from participants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Facilitate integration of research into participants clinical care environment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Conduct study visits to gather participant study data per research protocol	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Perform clinical tests and procedures that do not require licensure (e.g., biospecimen collection, ECGs, vital signs, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Perform clinical tests and procedures that do require licensure (e.g., IV insertion, study drug administration)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Record and organize study data, complete CRFs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Document and track protocol deviations and/or discrepancies in data recorded	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Use Epic/Oncore to complete study documentation, place orders, etc.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Create templates in Epic/Oncore	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Maintain study supplies (e.g., lab kits, phlebotomy supplies, other materials)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Process study biospecimens	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Track and/or ship biospecimens	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Document adverse events	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Schedule study visits with participants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Number of Participant Tasks

Study Operations Management Tasks

Answer choices are as follows:

0, N/A, not part of the position

1, This position will have a fundamental knowledge of this task and completes this task under supervision or direction.

2, This position will consistently manage this task independently. They will have a moderate level of expertise regarding this task.

3, This position has advanced skills related to this task. They will assess study needs and employ strategies to improve methodology in this area. They may lead others and coordinate other's activities in relation to this task.

	N/A, Not Part of the Position	Completes Under Direction; Fundamental Level of Expertise	Independently Manage; Moderate Level of Expertise	Advanced Skills; May Improve Methodology and/or Lead Others
Complete start-up activities for research studies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Allocate resources for research studies and create and maintain timelines	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Develop standard operating procedures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Provide training for junior staff	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Track and report study expenditures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Create study budgets	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Invoice study sponsors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Grant writing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Write and/or contribute to study manuscripts, publications, and other presentations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Develop study protocols, manuals of procedures, and/or other related documents	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Manage required reporting to funders per award agreements, ensure timely submissions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Identify technical, external, organizational, and project management risks and develop proactive solutions to mitigate risk

Number of Study Operations/Advanced Tasks

You indicated that this position will complete start-up activities for research studies. Please elaborate on what specific elements of study start-up the position is responsible for (IRB applications, creation of data systems, assistance with the establishment of study sites, etc.)

You have selected that this position will complete some study operations management tasks under supervision/direction.

Are the skills needed for these tasks:

- Clerical/administrative in nature (little to no knowledge of clinical research operations management required to assist with these tasks)
- Technical in nature (knowledge of clinical research operations management required to assist with these tasks)

As necessary, please provide any further information needed to explain the skills required for these clinical research operations tasks:

Other Tasks

Answer choices are as follows:

0, N/A, not part of the position

1, This position will have a fundamental knowledge of this task and completes this task under supervision or direction.

2, This position will consistently manage this task independently. They will have a moderate level of expertise regarding this task.

3, This position has advanced skills related to this task. They will assess study needs and employ strategies to improve methodology in this area. They may lead others and coordinate other's activities in relation to this task.

	N/A, Not Part of the Position	Completes Under Direction; Fundamental Level of Expertise	Independently Manage; Moderate Level of Expertise	Advanced Skills; May Improve Methodology and/or Lead Others
Develop root cause analyses and corrective and preventative action plans	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Prepare for study monitoring visits	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Coordinate study monitoring visits	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Resolve data and/or regulatory queries found during monitoring visits	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Determine corrective action to be taken as a result of monitoring visits	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Prepare and disseminate updates to other members of study team and external parties as appropriate (regulatory updates, enrollment updates, data updates, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Number of General Tasks _____

For the below section, please indicate the estimated percent effort required for the various tasks. If the position does not work in a particular task category, please enter 0. The total percentage must equal 100.

Regulatory Tasks (e.g., regulatory document management, creation/maintenance of regulatory applications) _____

Data Management or Data Analysis Tasks (e.g., entering data into EDC, creation of data reports, reviewing data collected for quality) _____

Participant-related tasks (e.g., screening, recruitment, conducting study visits, informed consent, specimen management) _____

Finance Tasks (e.g., creation of budgets, tracking expenditures and revenue, invoicing study sponsors) _____

Project Management Tasks _____

Supervision of Permanent Personnel _____

Clinical Research Education (e.g., training junior personnel, onboarding) _____

Other Tasks (i.e., tasks that do not fall into a category above- not "other duties as assigned") _____

Total Percentage: _____

You indicated above that this position will complete tasks in categories other than the ones listed. Please elaborate on the other tasks that this position will complete. _____

The percentages entered above do not equal 100. Please adjust the percentages accordingly.

How would you describe this position?

- Assistant Clinical Research Coordinator
- Associate Clinical Research Coordinator
- Clinical Research Coordinator
- Senior Clinical Research Coordinator
- Clinical Research Regulatory Coordinator
- Senior Clinical Research Regulatory Coordinator
- Clinical Research Regulatory Coordinator Manager
- Clinical Research Data Coordinator
- Senior Clinical Research Data Coordinator
- Clinical Research Data Coordinator Manager
- Clinical Research Participant Coordinator
- Senior Clinical Research Participant Coordinator
- Clinical Research Participant Coordinator Manager
- Clinical Research Nurse Coordinator
- Senior Clinical Research Nurse Coordinator
- Other

(You can find links to all listed position descriptions here:

<https://www.med.unc.edu/crso/career-development-initiative/career-development-initiative-position-descriptions/>)

Please describe the title of the position:

Study Information

For how many studies will this position provide routine support (i.e., spending 10% effort or more completing study tasks and/or making impactful decisions about study conduct and/or operations)?

Do any of those studies have IRB applications currently open or in draft?

Yes
 No

Provide the IRB numbers below.

If there are fewer than 5 studies, fill out the appropriate fields and leave all extra fields blank.

If there are more than 5 studies, please choose the 5 studies that the position will focus the most on.

Study 1 IRB number

(Please Use Formatting XX-XXXX)

Study 2 IRB number

(Please Use Formatting XX-XXXX)

Study 3 IRB number

(Please Use Formatting XX-XXXX)

Study 4 IRB number

(Please Use Formatting XX-XXXX)

Study 5 IRB number

(Please Use Formatting XX-XXXX)

Please upload the current organizational chart for your unit. Follow the "standards for organizational charts" document that is linked below when creating the chart.

All vacant positions should be included in the organizational chart, including the proposed position that you are submitting this survey for.

Please refer to the following resource on standards for organizational charts:

[Attachment: "Standards for Organizational Charts.docx"]

An example of an organizational chart is below:

[Attachment: "Org Chart Sample.pdf"]

By clicking "yes", you attest that you have reviewed the attached organizational chart to ensure all required elements are included (e.g., position numbers, incumbent names, position titles, position classifications, position levels, etc.).

- Yes
 No

If requesting a new position, please ensure that the new position is also included on your organizational chart.

Incomplete organizational charts will cause delays in TADA processing.

Will this position be identical in roles and responsibilities to another position that is currently in your work unit?

- Yes
 No

Please indicate the position number of the position with identical roles and responsibilities:

Will this position enter facilities where patient care is provided, whether in a patient care area or in an administration wing?

- Yes
 No
(From UNC-CH EHS Manual Chapter 06.01- Occupational Health Requirements for University Employees Located in Healthcare Facilities)

Are you planning to submit multiple TADA intake forms for your unit at this time?

- Yes
 No

Do you have any other information about the position that you would like to submit as part of this assessment?

- Yes
 No

Please write any additional information here:

Do you have any comments or suggestions about this assessment or process that you would like to add?

- Yes
 No

Please write your comments here:

Date of Submission

Thank you for completing the TADA! This survey will be submitted to the Tasks and Duties Assessment Committee for review. An outcome letter will be provided to you after the committee review to submit (along with the appropriate position description form) to your HR representative. If you have any questions about this survey or the Career Development Initiative, please email som-cdi@med.unc.edu.