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 25Sep2023.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 ◯ Opthalmology ◯ 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	◯	◯	◯	◯
Create additional study materials that require regulatory review (e.g., consent forms, recruitment scripts, flyers)	◯	◯	◯	◯
Create, compile, edit, manage, and/or organize regulatory documentation (e.g., delegation of authority logs, training logs, IRB approval letters, etc.)	◯	◯	◯	◯
Perform internal quality assurance/quality control on regulatory study files	◯	◯	◯	◯
Submit safety reports for protocol deviations, adverse events, etc. (e.g., promptly reportable information, DSMB reports)	◯	◯	◯	◯
Serve as study monitor	◯	◯	◯	◯

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	◯	◯	◯	◯
Enter data into electronic data capture systems	◯	◯	◯	◯
Create databases for research studies (e.g., REDCap)	◯	◯	◯	◯
Compile, review, organize, or prepare study data for analysis	◯	◯	◯	◯
Conduct statistical analyses	◯	◯	◯	◯
Create reports of study data	◯	◯	◯	◯
Review incoming or outgoing data for integrity	◯	◯	◯	◯
Create source documents, checklists, and/or case report forms	◯	◯	◯	◯

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	○	○	○	○
Screen/recruit participants per protocols and standard operating procedures	○	○	○	○
Serve as participant liason and advocate during study participation	○	○	○	○
Present study-related information directly to participants and/or their families	○	○	○	○
Manage and report participant complaints	○	○	○	○
Obtain informed consent from participants	○	○	○	○
Facilitiate integration of research into participants clinical care environment	○	○	○	○
Conduct study visits to gather participant study data per research protocol	○	○	○	○

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

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	○	○	○	○
Allocate resources for research studies and create and maintain timelines	○	○	○	○
Develop standard operating procedures	○	○	○	○
Provide training for junior staff	○	○	○	○
Track and report study expenditures	○	○	○	○
Create study budgets	○	○	○	○
Invoice study sponsors	○	○	○	○
Grant writing	○	○	○	○
Write and/or contribute to study manuscripts, publications, and other presentations	○	○	○	○
Develop study protocols, manuals of procedures, and/or other related documents	○	○	○	○
Manage required reporting to funders per award agreements, ensure timely submissions	○	○	○	○

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.)

_____

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	◯	◯	◯	◯
Prepare for study monitoring visits	◯	◯	◯	◯
Coordinate study monitoring visits	◯	◯	◯	◯
Resolve data and/or regulatory queries found during monitoring visits	◯	◯	◯	◯
Determine corrective action to be taken as a result of monitoring visits	◯	◯	◯	◯
Prepare and disseminate updates to other members of study team and external parties as appropriate (regulatory updates, enrollment updates, data updates, etc.)	◯	◯	◯	◯

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.). 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.	◯ Yes ◯ No
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.