Frequently Asked Questions Regarding Clinical Research Positions

1. What kind of duties will be considered under clinical research, study or trials positions?

A. Those tasks required of a staff member in the conduct or assisting in the conduct of a systematic investigation of the effects of materials, drugs, or other interventions, according to a formal study plan for human population. While this systematic evaluation frequently refers to interventions involving surgery, drugs, gene therapy, or radiation techniques, investigation of detection, prevention, diagnosis, outcomes, supportive care, survey, or quality of life may also be included.

2. What are the titles generally used for positions for clinical research/study/trials?

A. There are two groups of clinical research/study position titles: Biweekly and Monthly:

**Biweekly:**
- Clinical Study Assistant: TE05
- Senior Clinical Study Assistant: TE06
- Clinical Study Technician: TE07

**Monthly:**
- Clinical Research Specialist: PAO2RS
- Clinical Research Coordinator: PAE3RS
- Clinical Research Nurse Specialist: PAE-HE
- Clinical Research Nurse: PAEHE
- Clinical Research Manager: PAE4RS
- Clinical Research Administrator: PAE4RS

3. What if we wish to hire a nurse for clinical research who does not meet the qualifications for a Clinical Research Nurse?

A. You can hire the candidate as a Clinical Research Nurse Specialist or Clinical Research Specialist.

4. What are the qualification requirements of each position?

A. In order to provide flexibility and wider latitude for the hiring supervisors, various combinations of education and experience are provided for each position. A table of minimum qualification requirements is included in this section for easy reference.

5. Why is the CRC/CCRP not required in the lower rank positions?

A. It is not required for the lower levels because, the nature of those positions do not generally require that level of competence in order to enter the position and in order to qualify to take the certification examination, one must have at least two years of clinical research experience. A person entering the lower positions may not have the experience to qualify to take the exam.
6. What happens if an employee passes the certification examination after being hired?

A. At the discretion of the department, staff employees who subsequently pass the certification exam will be eligible for a 5% salary increase regardless of position classification. The effective date of the salary increase must be no earlier than the date of the notification letter that the employee has passed the exam or, in the absence of a date in the notification, the effective date of the salary increase must be no earlier than 30 days after the date the examination was taken. Obtaining the certification will qualify the employee to the higher rank positions in clinical research where a certification is required. However, a promotion or an upgrade of position is not automatic and not based solely on meeting the minimum qualifications of the higher rank.

7. How are the ranks determined?

A. Ranks are determined and differentiated by the complexity of the duties and responsibilities and required qualifications at each level. A generic job description for each position is provided as guide to departments when they need to establish a new position or reclassify an existing position. At least 50% of the duties of the planned position must come from the generic job description established for a specific position and must include core clinical research tasks in order to consider the position a clinical research position. Unit specific duties may be added.

8. Will these different ranks of clinical research positions represent a career ladder with an automatic upgrade when the minimum qualifications for the higher rank is achieved by the employee?

A. The different ranks do provide a career path for the clinical research staff but there will be no automatic upgrade from a lower level to a higher level position solely based on meeting the minimum qualification requirements. The ranks are determined by the job content (duties and responsibilities) and competency, not by the qualifications alone of the incumbent or by a prospective candidate. There are two ways a staff member may move up the career ladder:

1. If and when a higher level position is available and the staff meets the minimum qualification of that position, he or she may apply for the position; or

2. The position may be reclassified and upgraded provided the following conditions are met:
   a. the duties and responsibilities of the position have significantly changed and are considered to be the functions of a higher rank position
   b. the change is permanent, not ad hoc or short term
   c. the incumbent has been performing the higher level responsibilities for at least six months prior to the request for the upgrade, and
   d. the incumbent meets the minimum qualification requirements of the higher rank.
There may be other factors that a Principal Investigator or administrator may consider before an upgrade is requested, such as performance of the incumbent or whether there are more than one staff member performing at a higher level in their particular unit.

9. What is the difference between the Clinical Research Manager and the Clinical Research Administrator?

A. The duties and responsibilities are similar but the size of the unit and scope of responsibilities and qualification requirements are different. A Clinical Research Manager position is generally established for units to oversee two or more studies under one or more Principal Investigators (PI), while a Clinical Research Administrator is generally established for larger units, whole department or center with several studies under two or more PIs and sub-investigators. When requesting for these types of positions, a list of employees to be supervised must be submitted.

10. Is there a streamlined procedure to request creation of positions under this group?

A. Yes. If you need to create a new position, send an Essential Job Functions Form (EJFF) to the compensation team with a note to create a new position. If the position is for a Clinical Research Manager or Clinical Research Administrator, you will need to include a list of position numbers of employees the position will supervise. If there is a discrepancy between your requested rank and the duties and responsibilities in the EJFF, you will be contacted before the position is created. If the position is established, you will receive a Notification Letter.

11. Are the generic jobs description readily available for reference whenever a department wishes to establish a new position?

A. Yes. Generic job descriptions for all the clinical research/study positions listed herein are available in this section. A particular position for a unit does not necessarily have to perform all the tasks listed therein, but each job description serves as a guide to supervisors as to what type and level of complexity of duties or tasks and qualifications are considered appropriate for each level. However, there are specific tasks that are considered core function or key words in clinical research. Some of them are: recruitment and screening of subject patients, IRB and Informed Consent Forms, patient safety, protocol, Case Report Forms (CRF), source documents, site evaluation and preparation, study coordination, test articles accountability, adverse events, monitoring visits or audits, study close out.

12. Is there a generic Essential Job Functions Form (EJFF)?

A. No. The unit must prepare the EJFF based on the duties and responsibilities of the particular position and rank being requested, but only the ESSENTIAL or MAJOR tasks must be included, not the whole job description. Marginal functions should not be included in the EJFF. The summary in the EJFF must be consistent with the summary in the generic job description but must include unit-specific information (Ex. nature of study, program or specific group of patients, etc). Additional duties that are unit-specific
may be added in the EJFF, provided, that at the PA levels, they do not consist primarily of non-exempt duties.

13. **What is the difference between the research technician and the clinical study technician?**

**A.** The main difference between the research (RS) technician and clinical study technician (CST) is that the RS group conducts basic or bench research primarily in a laboratory setting while the clinical study technician group conducts applied research primarily in a clinical setting and/or with interaction with human subjects.