JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 6, No. 7, July 2010 "Can You Handle the Truth?"

Transitioning to a New Research Coordinator

By Ashrafunissa Janmohammad

Transitioning from one clinical research coordinator (CRC) to another is like changing jugglers in mid-act. The process of transition should be smooth and thorough, otherwise rubber balls are going to be bouncing all over the place. The transition process will be faster and smoother if the following steps are taken as part of a standard operating procedure:

1. Create the transition team. The transition team should consist of the departing CRC, the new CRC (if not available, then a transition CRC), the Principal Investigator, other site personnel like the regulatory specialist, and the site monitor. Inform the sponsor and/or contract research organization (CRO) as soon as possible of the pending transition. Update team membership as appropriate. Meet regularly during the transition period, which will probably last one to three months.

2. Develop and update the transition plan. Identify tasks, assign them to personnel, and establish a schedule. Review progress and update the plan periodically.

3. Evaluate the workload and identify replacement CRC(s). Based on the status of the studies and the condition of the paperwork, determine how much work there will be for the new CRC(s), who may be current or new employees. Adjust the transition team accordingly. If the departing study coordinator will leave before the new CRC(s) are available, it is especially important to complete as much of the process as possible before that happens. When allocating studies, assume the learning curve and bumps in the process will consume extra time. Think twice before enrolling one last subject.

4. Hire or assign new study coordinator(s). It may be possible to assign some or all of the studies to current CRCs with excess capacity. If not, update or write the position description and requirements. Hiring a new employee or even transferring someone from another department will probably take longer than expected, so there is no time to lose.

5. Identify and assign a mentor. If the person does not have previous CRC experience, the mentor's role will be especially important. A mentor can explain the organization's culture (i.e., eccentricities) and lead a new coordinator through his or her training program.

7. Introduce the new CRC to other personnel. Create a brief written summary of who's who, where they are, what they do, who they report to, and how to contact them. Photos are helpful. Include both internal and external (e.g., site monitor, IRB administrator, study subjects, community contacts) personnel.

8. Inform the human resources department. If the arriving CRC is already an employee, the process will be relatively simple.

6. Identify and address facility and equipment requirements. Update staff directories and voicemail messages. Obtain new user names and passwords for eCRF (EDC), IVRS and other computer systems; update systems. The computer will probably need a lot of work, starting with secure retention of all computer files and email messages. Make sure the departing CRC does not delete any files or email messages without approval. If the CRC wants to delete personal files or email messages, it is probably wise to supervise this activity. Reorganizing and purging paper and computer files will probably take months, so complete this project in stages.

9. Debrief the departing CRC. Interview the departing CRC in detail. Review all the study documentation with the departing CRC. Take detailed notes. The departing CRC should write

a summary and status report on each study and each active subject. For open studies, include topics like number and status of subjects, status of study drug and equipment, and open protocol deviations. For pending subjects, include topics like recruiting, consenting and screening status. For current subjects, include topics like near-term visits, open adverse events and data queries, and any documents that need to be transmitted to the sponsor, CRO or IRB in the near term. Obtain full explanations of any current problems and what needs to be done, as well as any past problems that may reoccur.

10. Ensure that the study records are complete, up-to-date and in order. Study records include the following:

- Source documents
- Case report forms
- Regulatory binder
    - IRB documents
    - 1572 form (optional, if study coordinator is listed)
    - Correspondence
    - Meeting notes
    - Shipping documents
    - Data queries
    - Delegation of authority log (updated)
    - Monitoring visit reports and any audit reports
    - Sponsor, CRO, lab and IRB contact information
    - Financial disclosure form (at next update, if study coordinator is listed; if unable to contact CRC, write a note to file)
    - Other documents
- Signed consent forms
- Unused forms and form masters (digital and paper versions)
- Subject contact information
- Study protocol, investigator's brochure, handbook, investigator meeting documents, newsletters, instructions for equipment, laboratory and shipping, etc.

Some documents may be in places like the PI's office, waiting for signature, so gather them up. Inventory, organize and, if necessary, reorder study drug, materials and shipping supplies.

11. Orient and train the new CRC. Employ your existing orientation and training program if available. If no training program exists, develop one for this transition; the site monitor can help. The arriving CRC should obtain an in-person briefing from each member of the transition team and other relevant personnel, e.g., subinvestigators, lab director, radiologist and pharmacist. Explain to the arriving CRC the current status of the study or studies, how the site "really" functions (including how to work with the Principal Investigator), laboratory, billing department, etc. If possible, have the arriving CRC shadow the departing CRC during at least one subject visit.

12. Conduct exit meetings. Meet with the departing CRC one last time. The Principal Investigator and arriving CRC should meet separately and together with the departing CRC. Thank the departing CRC for his or her contributions, ask for any last advice, and ask if you can contact him or her if any new questions arise. The departing CRC may be willing to visit every week or so for couple of months on a consulting basis.

13. Meet with the new CRC(s) and audit his or her work periodically. Review progress, address issues, and update the plan.

The checklist in Figure 1 can be adapted for a specific research site:

Figure 1. Study Coordinator Transition Checklist

Task	Comments
❑ Create the transition team.	
❑ Develop and update the transition plan.	
❑ Evaluate the workload and identify replacement CRC(s).	
❑ Hire or assign new study coordinator(s).	
❑ Identify and assign a mentor.	
❑ Introduce the new CRC to other personnel.	
❑ Inform the human resources department.	
❑ Identify and address facility and equipment requirements.	
❑ Debrief the departing CRC.	
❑ Ensure study records are complete, up-to-date and in order.	
❑ Orient and train the new CRC.	
❑ Conduct exit meetings.	
❑ Meet with the new CRC(s) and audit his or her work periodically.	

Author

Ashrafunissa (Ashrafu) Janmohammad is a Research Coordinator at London Health Sciences Centre. Contact her at 1.519.685.8207 or Ashrafu.Nissa@lhsc.on.ca.

