A Clinical Research Coordinator for an International Study

"THE GYMNAST"

Anita Ng
Research Coordinator
The Scarborough Hospital
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1. **What is Research?**
2. **Characteristics of a Clinical Research Coordinator**
3. **The Summary of the Role and Responsibilities of a Clinical Research Coordinator**
    - Managing the study
    - Process of conducting a clinical trial
    - Coordinating three international study sites
4. **Challenges Faced by a Clinical Study Coordinator**
5. **Rewards Gained from the Experience**
6. **Conclusions and Recommendations**

What is Research?

A systematic investigation to establish facts, principals or generalized knowledge (Tri-Council Policy Statement)

What is a Clinical Trial (research study)?

- A method to answer specific questions about new ways of using known treatments
- A way to determine whether new treatments are both safe and effective (National Institutes of Health, NIH)

Characteristics of a Clinical Research Coordinator – 3 “Ps”

Passion

Patience

Preciseness

Role Responsibility Summary

- **Ensures successful implementation, execution and completion of research protocol – study set-up to closeout.**
- **Coordinates and oversees clinical trial to ensure compliance with the study protocol including ethical, sponsorship and regulatory requirements.**
- **Subjects' advocate.**

1. ***Managing the Study***
2. ***Conducting the Study***
3. ***Coordinating Among all Study Sites (International)***

1. Managing the Study:

- Prepare study protocol and Informed Consent Form (ICF)
- Develop Standard Operating Procedures (SOP)
- Submission to Research Ethics Board (REB)
- Budgetary workout
- Storage space
- Shipment arrangement
- Creation of database
- Organize regular progress meeting
- Communicate with REB

2. Conducting the Study Based on Good Clinical Practice:

- Pre-screening and screening.
- Recruitment includes signing of ICF, randomization and enter trial.
- Study activities include educate subjects, training of site personnel, data collection, verification, entry and completion of Case Report Forms (CRF).
- Communicate with REB regarding Serious Adverse Events (SAE), protocol amendment, protocol deviation and annual renewal.

3. Coordinating Among All Centres:

- Orientation and initiation of the trial
- Assessment of skill level
- Training and education of site coordinators
- Collaboration with multidisciplinary and research team
- Conducting regular site visits
- Managing all aspects of the research study

Challenges

- Development of SOPs
- “Blurring of boundaries”
- Understanding the “culture” and logistics of other study sites
- Motivation of staff to link practice with research

Conclusions

- Professional growth and self-actualization
- Disseminate findings to current nephrology practice
- Rewarding career path

Recommendations

- **Role clarity**
- **Mentoring and education for nurse researchers**
- **Sparks interest on a unit level**

References:

1. International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines

2. Tri-Council Policy statement; Ethical Conduct for Research Involving Humans; Medical Research Council of Canada; Natural Sciences and Engineering Council of Canada; Social Sciences and Humanities Research Council of Canada, August 1998

3. Norman M. Goldfarb. (2006, Nov.) Can You Handle the Truth? : Requirements for Study Coordinators. Journal of Clinical Research Best Practice. Volume 2, Number 11

4. Anne M. Kotzer. (2000, July-Sept.) Linking Practice With Research: The Role of the Unit Research Coordinator. JSPN. Volume 5, Number 3 (pp.143-145)

5. Lesley Wilkes. (2005) Role conflict: appropriateness of a nurse researcher's actions in the clinical field. Nurse Researcher. Volume 12, Number 4 (pp. 57-70)

6. (2003, Dec.) Standard Operating Procedure: Responsibilities of Clinical Research Personnel. Ontario Cancer Research Network. (pp. 1-6)

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Questions?