MOB Report

Office Of Clinical Site Oversight (OCSO)

National Institute of Allergy and Infectious Diseases (NIAID)

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11th Edition | December 2018

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Delegation of Duties Best Practices

By: Nicholette Stott and Mariette Mare

The clinical trial landscape has evolved a great deal making it more complex for the Principal Investigator (PI) to run cutting-edge research without a qualified and competent study team. Having this qualified and well-trained study team has enabled the PI to conduct more studies however the growing complexity of clinical trials continue to make adequate oversight of a clinical trial increasingly vital.

The PI's responsibility to ensure adequacy of resources (i.e., qualified staff, adequate facilities) to conduct a clinical trial and to ensure oversight of all such persons assisting in conducting a study are quality standards established by International Council for Harmonisation Guidelines for Good Clinical Practice (ICH GCP). These standards are derived from the guiding principles of integrity, transparency, mutual understanding, and accountability in research to ensure clinical trials are effectively conducted. Moreover, these ICH guidelines and principles were adapted by the Food and Drug Administration (FDA) and included in the commitments listed on the signed investigator statement which requires the PI to agree to personally conduct and/or supervise clinical investigations. This includes determining when and to whom it is appropriate to delegate trial activities.

Delegation of duties is basically entrusting someone else to do specific parts of your job. In clinical research, this means the PI can allocate trial-related tasks to his/her staff members to perform on his/her behalf, but the responsibility for those tasks or their outcomes is never relinquished. Even the recent addendum to ICH GCP (ICH E6 R2 Section 4.2.5) further drives this point stating, "the investigator is responsible for supervising any individual or party to whom the investigator delegates trial-related duties and functions conducted at the trial site".

So how is this all documented with ever growing teams and complex trials?

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Delegation of Duties Best Practices Continued

The FDA guidance on Investigator Responsibilities states that "The Investigator should maintain a list of the appropriately qualified persons to whom significant trial-related duties have been delegated." Note the word 'significant.' Due to the diversity of research conducted and how the nuances of each project can affect who is significantly contributing to its conduct, it is challenging to come up with a definite list of site staff members that should be on the Delegation of Duty (DoD) log. The FDA Information Sheet Guidance "Frequently Asked Questions – Statement of Investigator (Form FDA 1572)" does give some clues to this though and indicates that persons who "provide ancillary or intermittent care but who do not make a direct and significant contribution to the clinical data, do not need to be listed individually." A good rule of thumb is if a staff member is making a direct and significant contribution to the clinical data, those persons should be included on the DoD log.

With this in mind, the DoD log(s) must be study-specific and up-to-date with the correct start and finish dates for site staff and any others conducting trial related duties. The log must reflect the actual duties undertaken by the individual listed and be appropriate as per their education, expertise, and training. The investigator and delegated individual(s) must sign, initial, and date each delegated task. The delegation of duties and roles within the study team should be discussed and documented from the initiation of any new clinical trial. Further training and competency may be required by some members of the team which should be completed before commencing work on the study.

It would not be prudent to publish an article about documentation of delegation of duties without addressing that the DoD log is a living document. Investigators are encouraged to carefully scrutinize the list on a frequent basis to ensure that staff members are appropriately listed, delegated, submitted to appropriate regulatory bodies, as applicable, and that all further documentation correctly and appropriately lists the staff members. For the duration of the clinical trial (start-up until close-out), the monitor will also review the DoD log during the Site Monitoring Visit to verify that it remains adequate and current. However, the investigator remains responsible for ensuring adequate supervision of all individuals who have been delegated study specific duties and for the entire conduct of the trial.

Better understanding of delegation, adherence to regulations and requirements and keeping current with the evolving nature and expectations in clinical research with respect to delegation of trial related duties, will help with compliance and avoidance of common inspection findings in the clinical research landscape such as inappropriate delegation of duties, lack of appropriate documentation of delegated duties, and inadequate oversight of site staff and others to whom tasks have been delegated.

When in doubt, always contact your DAIDS Program Officer for assistance….

Monitoring Metrics

Year to Date Monitoring Metrics

February, March	1Q
April, May, June	2Q
July, August, September	3Q
October, November, December, January	4Q
To be determined—4Q2018	TBD

Monitoring Visits

	2017	2018
1Q	119	141
2Q	174	182
3Q	186	165
4Q	208	TBD
Total	**687**	**488**

Monitoring Visits: Any time a monitor travels to a site to conduct monitoring.

Monitoring Trips

	2017	2018
1Q	207	255
2Q	293	317
3Q	321	290
4Q	326	TBD
Total	**1147**	**862**

Monitoring Trips: Includes the total number of monitors traveling to a site to conduct a site monitoring visit.

Records Reviewed

	2017	2018
1Q	1526	1927
2Q	2233	2411
3Q	2636	2367
4Q	2554	TBD
Total	**8949**	**6705**

Regulatory Files Reviewed

	2017	2018
1Q	183	213
2Q	247	265
3Q	320	234
4Q	345	TBD
Total	**1095**	**712**

Pharmacy Assessments

	2017	2018
1Q	400	453
2Q	608	453
3Q	623	438
4Q	712	TBD
Total	**2343**	**1344**

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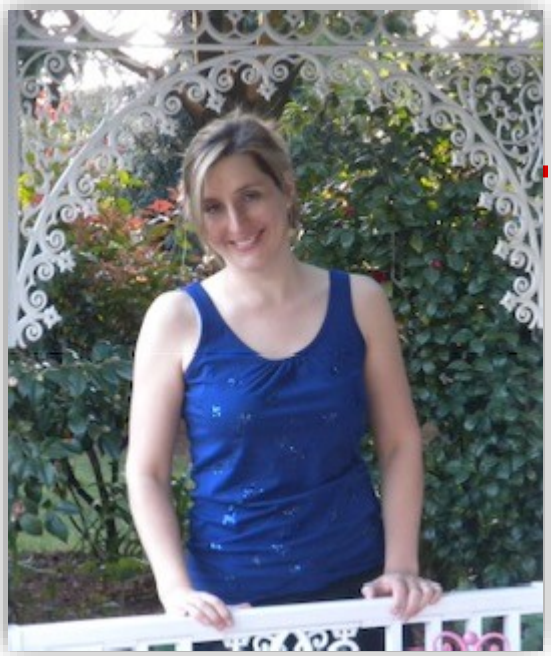
Manager Spotlight

Nicholette Stott



It's always easy to agree to write these articles but when it comes to the request to "find something interesting about yourself to include", it's simpler to revert back to the basics, so I will start there. I have been at PPD now for twelve and a half years. I was certain I was not going to make the tenth-year anniversary but decided earlier this year when visiting the Wilmington office that there is obviously some prestige to reaching twelve years; I would now be entitled to a parking bay in the building itself! Regardless, I should have seen this coming. I come from a long line of folk who only ever have one job: my father recently celebrated his 47th anniversary with his organisation, my grandfather was at his from a child until the day he passed, and my brother recently became Managing Director of his after 14 years. I'm not saying, "PPD, I'm here for the innings", but I am defying modern trends to move when the going gets tough, or in search of a higher salary. It's in these 12 years that I have learned the skills of changing with the tides, of growing to accommodate myself and find meaning as the organisational culture changes. I've also learned new skills in order to experience multiple facets of the same organisation, from trainee CRA to trainer in learning services, and a return to Clinical Management as a CSSM and then NCSM Clinical Team Manager. As a NCSM Clinical Team Manager, I'm also constantly reaching out to become involved in different aspects of the project, as well as local office needs. But when Nicci gets restless, behold everyone, Nicci will create a new place to stimulate herself…..from developing a local Good Clinical Practice training offering for site staff, to be charged according to our local audience's affordability, to becoming involved in the South African Clinical Research Association, which I eventually came to chair, and still do! Trying my hand at motherhood is also an ongoing adventure, with my little psychopath Zoe having just turned 3 to a second on the way. I am already looking forward to next year to see what other adventures awaits me, in order to prevent getting sucked into the perils of the mini-people!

Happy Holidays