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Does One Size Training Fit All or Should It?

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Disclaimer

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Does One Size Training Fit All or Should It?

One Size Has Never Fit All & We're Excited We're Addressing It!

The Path of "Least" Resistance

- **Conformity**
  - Anyone involved in the study has documented GCP training
- **Why**
  - Investigator turnover
    - 35% US, 41% Canada, 47% Africa, 55% Europe, 53% SA, 53% Asia Pacific
  - FDA Guidance for Industry Investigator Responsibilities Protecting the Rights, Safety, and Welfare of Study Subjects – October 2009

2. What Is Adequate Training?

The investigator should ensure that there is adequate training for all staff participating in the conduct of the study, including any new staff hired after the study has begun to meet unanticipated workload or to replace staff who have left. The investigator should ensure that staff:

- Are familiar with the purpose of the study and the protocol
- Have an adequate understanding of the specific details of the protocol and attributes of the investigational product needed to perform their assigned tasks
- **Are aware of regulatory requirements and acceptable standards for the conduct of clinical trials and the protection of human subjects**
- Are competent to perform or have been trained to perform the tasks they are delegated
- Are informed of any pertinent changes during the conduct of the trial and receive additional training as appropriate

Source: FDA Guidance for Industry Investigator Responsibilities Protecting the Rights, Safety, and Welfare of Study Subjects – October 2009

The Clinical Research Site Team

- **Principal Investigator**
- **Sub-Investigator**
- **Coordinator**
- **Support Research Staff**
  - Assistant Coordinators
  - Data Entry
  - Regulatory Officer
  - Compliance Officer
  - Pharmacy
  - Laboratory
  - Readers
- **Site Management**
  - Clinical oversight
  - No clinical oversight
- **Outside Vendors/Support Staff**
  - Radiology, ophthalmology, cardiology, dietician, and physical therapist – *you get the idea*

Lack of standardized job descriptions & responsibilities

Goal - *Human Subject Protection, Protocol Compliance & Data Integrity*

- **Site personal supporting the site, but not directly the patient**
  - Data entry, regulatory & budget/contract staff, etc.
  - Research assistance (depending upon their responsibilities)
- **Outside vendors performing technical study related task**
  - Endoscopy, Echocardiogram, etc.

Distinction of Involvement

- Degree of patient interaction
- Autonomy of protocol implementation

How Many Times Do I Have to Pass?

- **Who should demonstrate knowledge?**

AND

- **How often should it be tested?**

Conclusion

- **Lack of standardized job descriptions & industry standards make it difficult to create unique training requirements for site staff.**

Consideration

- Those involved in technical support of the protocol should have documented protocol training pertinent to their responsibilities and to the extent the Investigator requires, documented GCP training.
- Others should have documented GCP and protocol training.
- Industry criteria on the frequency of GCP testing.

Don’t think you’re on the right path, just because it’s a well-worn path.

- Author Unknown

THANK YOU

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