A Collective Effort by the Study Team

Completion of the CAPA should never be a lone effort. Conversely, it is recommended that the principal investigator and his / her study team collaborate closely to address study findings following a study review visit. In instances where the protocol non-compliances are significant, the study team may approach the auditor(s) / inspector(s) for advice or additional guidance on proposed actions that can sufficiently address the problem.

Resources for More Information

A CAPA template has been developed by NHG's Research Quality Management (RQM) unit for investigators' use and reference. The CAPA template is available for download from the NHG research website, at: http://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/research+sops

References

1. Resources, NHG Research Website. Accessed on 26 Jun 2013. http://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/research+sops
2. Here are quick tips on corrective action plans. (2011).Clinical Trials Administrator. Retrieved from http://search.proquest.com/docview/908312855?accountid=12763; http://sirious.library.unsw.edu.au:9003/sfx_local?url_ver=Z39.88-2004&rft_val_fmt=info:ofi/fmt:kev:mtx:journal&genre=article&sid=ProQ:ProQ%3Ahealthcompleteshell&atitle=Here+are+quick+tips+on+corrective+action+plans&title=Clinical+Trials+Administrator&issn=15448460&date=2011-12-018&volume=&issue=&spage=&au=&isbn=&jtitle=Clinical+Trials+Administrator&btitle=
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4. Writing an Effective Corrective Action Plan. Northwestern University Institutional Review Board. Website accessed on 26 Jun 2013. http://irb.northwestern.edu/policies/compliance/corrective-action-plan
5. ISO 9000, 9001 and 9004 Plain English Definitions. Praxiom Research Group Limited. Website accessed on 26 Jun 2013. http://www.praxiom.com/iso-definition.htm#Corrective action

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Non-Compliance Report: Major Deviations in Study Conduct from the DSRB-Approved Protocol

Background

The National Healthcare Group (NHG) Research Quality Management (RQM) team conducts regular and random study reviews on ongoing clinical research studies carried out in NHG and its partner institutions, under the oversight of the NHG Domain Specific Review Board (DSRB).

The purpose of these study reviews is to increase awareness among investigators and their study staff on proper research practices and documentation techniques; and ultimately, to safeguard the rights, safety and well-being of trial subjects.

Study Review Findings

A recent study review visit by the RQM team revealed that a study team had conducted study procedures differently from how they had been described in the DSRB-approved protocol.

Pertinent findings identified had included:

The number of times that blood had to be taken from each subject had not been clearly stated in the informed consent form.

The quantity of blood collected from each subject was different from that specified in the approved protocol, constituting a protocol deviation.

Useful Tips & Recommendations

Here are some practical tips that investigators can take note of to avoid similar lapses in their research studies:

1. **Start with a well-written protocol:**
   Before initiating a trial, the Principal Investigator (PI) should ensure that the protocol clearly describes the procedures to be performed on subjects, and that the procedures described are practically feasible to carry out. Information included in the informed consent form should correspond with that in the study protocol and DSRB application form.

2. **Have a process in place for identifying, tracking, reporting and correcting protocol deviations/violations:**
   It is the PI's responsibility to document and explain any deviation(s) from the DSRB-approved protocol. Processes should also be established to evaluate and determine if any corrective action is required to rectify the deviation, or whether a protocol amendment is needed. Protocol non-compliances should be reported by completing the ROAM Online DSRB Non-Compliance / Protocol Deviation Form, which should be submitted within a week of first knowledge of the deviation. To reduce the incidence of study deviations, it is recommended that routine meetings be held with study staff to discuss study-related issues, review trial progress and update study team members on any changes to the protocol study procedures.

3. **Ensure that research staff are appropriately trained and qualified:**
   It is the PI's responsibility to ensure that all study team members involved in the research are appropriately qualified and trained on the study protocol. All investigators and study staff are also required to meet the minimum training requirements set by DSRB [e.g. Good Clinical Practice (GCP) training, Collaborative Institutional Training Initiative (CITI) programme].

4. **Acquaint oneself with the guidelines and regulations governing the conduct of research:**
   Besides having good knowledge of the protocol details, PIs and study team members are strongly encouraged to familiarise themselves with institutional guidelines, standard operating procedures and regulatory requirements governing research. It is the PI's responsibility to ensure that research is conducted in compliance with all applicable guidelines and regulations.

5. **Keep the DSRB informed of any study amendments:**
   Only the approved protocol and research documents should be implemented. Where the need for a protocol amendment arises, the PI is responsible for informing the DSRB via the Study Amendment Cover Note. The amended documents should also be submitted for approval. The PI may only implement the protocol amendments after written approval from DSRB has been obtained.

References

1. Singapore Guideline for Good Clinical Practice (SG GCP)
2. NHG Proper Conduct of Research Standard Operating Procedures (PCR SOP) 501-A02 – Responsibilities of the Research Team
3. NHG Proper Conduct of Research Standard Operating Procedures (PCR SOP) 501-A03 – Training and Education
4. NHG Proper Conduct of Research Standard Operating Procedures (PCR SOP) 501-B04 – Interactions with Domain Specific Review Board

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