Qualité

Non-Compliance Report – Importance of the Study Responsibility Log and Training Log

Aim of reviews to protect the right and safety of trial subjects

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; to safeguard the rights, safety and well-being of trial subjects.

Findings & Implications

At recent study reviews, the RQM team noted that research staff delegated to perform study duties were inadequately trained. In addition, both the study responsibility and training logs were either incomplete or missing. Findings included:

- Start / Stop dates of study team members and PI's signatures to approve and delegate staff responsibilities were missing on the study responsibility log.
- There was no documentation of the study team members involved in significant study duties on the study responsibility log.
- The PI had assigned three study team members as alternate PIs.
- The roles and responsibilities of the lab staff / clinic staff were not indicated on the study responsibility log.
- Clinic nurses who had been collecting study specimens from research subjects had not been trained on the protocol. Their roles and responsibilities had not been delegated by the PI as well.
- No training log was filed at the research site.
- There was no documentation of any protocol-related training, and meeting minutes were also not filed.

Prevention Tips & Recommendation

In relation to the above case, we would like to share with you some information and practical tips to avoid similar mistakes in your research study:

a. Understand the Purpose of the Study Responsibility Log

The purpose of the study responsibility log is to maintain a formal list of the appropriately qualified members to whom the investigator has delegated study-related responsibilities to. The document should capture the study team members' signatures as acknowledgement of their delegated tasks, as well as their date of joining and leaving the study team, to provide a comprehensive account of their involvement in the study. The study responsibility log also serves as a reference for which the signatures of the respective study team members on other essential documents can be verified against.

b. Appropriate Delegation of Study Related-Tasks

It is the PI's responsibility to know what the roles and responsibilities to be delegated are, and ensure that these roles and responsibilities are assigned appropriately. The PI should ensure that any individual to whom a task is delegated is qualified by education, training, and experience to perform the delegated task. Tasks assigned to study staff may include screening for potential study candidates, determining eligibility, obtaining informed consent, performing clinical procedures, maintaining investigational product accountability, dispensing the investigational product, reviewing lab reports, assessing potential adverse events, performing data entry, submitting safety data, conducting patient education, managing specimen collection, data analysis, communicating with the DSRB / regulatory authority, etc.

Study members should only commence study activities after the PI has signed and dated on the study responsibility log.

c. Accountability for Study Responsibilities and Staff Training

While the study is ongoing, the PI has to ensure that there is adequate supervision of the team members involved in study conduct. More importantly, the PI is ultimately accountable for any regulatory violations resulting from inadequate supervision. It is also the PI's responsibility to ensure that there is adequate training for all staff involved in conduct of the study, including appropriate handovers for staff leaving the study team and training of newly-hired staff who have joined the study team after the study has been initiated.

The study responsibility log should be updated throughout the course of the research study. The site should also keep documentation of training modules that have been completed by each staff member. Training logs may include:

- Training(s) that must be completed by new members of the research team.
- Ongoing training(s) that must be maintained by the entire research team.
- Standard operating procedures (SOPs) that address training requirements can also be used to document the process and ensure its sustainability.

Maintaining an adequately-trained research team is essential to the success and quality of a research study. No single individual can expect to fulfill all of these tasks in lone effort. Effective management requires a shared commitment towards excellence, mutual respect for each team member's role, and effective communication within the team. Once staff members are trained and data management systems implemented, this infrastructure has to be maintained and refreshed continually. Ultimately, the PI as a leader of an effective research program must acknowledge the value of each team member, and promote a culture of teamwork and commitment to deliver high-quality research care to patients.

Ms Suzanne Ho
Senior Executive
Research Quality Management
Office of Human Research Protection Programme (OHRPP)
Research & Development Office
National Healthcare Group

WRITE IN TO US!

Confused about what essential documents you need to maintain for your research study? Puzzled about how certain study procedures should be carried out? Clueless about the local regulations and guidelines governing research? Wondering where you can find information and resources to aid your research? Unsure about what proper conduct of research entails?

If you have a research-related question you are unsure about, you are invited to write in to us at researchcoord@nhg.com.sg. Your questions, together with our recommendations, may be selected for feature in subsequent issues of Qualite. In your email, please include your name, job designation, institution and contact information, together with your query.

Remember, other readers facing similar issues may benefit from the questions you ask. We look forward to hearing from you!